IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF PHYSICIANS, INC., AMERICAN PUBLIC HEALTH ASSOCIATION, INFECTIOUS DISEASES SOCIETY OF AMERICA, MASSACHUSETTS PUBLIC HEALTH ASSOCIATION D/B/A MASSACHUSETTS PUBLIC HEALTH ALLIANCE, SOCIETY FOR MATERNAL-FETAL MEDICINE, THE MASSACHUSETTS CHAPTER OF THE AMERICAN ACADEMY OF PEDIATRICS, JANE DOE 1, JANE DOE 2, and JANE DOE 3, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; JIM O'NEILL, in his official capacity as Acting Director of Centers for Disease Control and Prevention; CENTERS FOR DISEASE CONTROL AND PREVENTION; and DOES 1–50, inclusive, *Defendants.*	Case No. 1:25-cv-11916-BEM **PLAINTIFFS'APPENDIX OF EVIDENCE IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION** **REQUEST FOR ORAL ARGUMENT**

Plaintiffs, by and through their attorneys, hereby submit their Appendix of Evidence in Support of their Motion for Preliminary Injunction as follows:

Exhibit	Description:
1.	Robert F. Kennedy, Jr., *Secretarial Directive on the Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women* (May 19, 2025)
2.	Robert F. Kennedy, Jr., May 27, 2025 Directive Published via X.

3.	*Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States,* CDC (May 28, 2025)
4.	*Adult Immunization Schedule for Ages 19 Years or Older, United States*, CDC (May 28, 2025)
5.	*Advisory Committee on Immunization Practices, Final Agenda (June 25–26, 2025), CDC* (June 24, 2025),
6.	CDC, *Meeting of the Advisory Committee on Immunization Practices* (ACIP), June 25–26, 2025 Meeting Summary (June 25–26, 2025)
7.	HHS, *Thimerosal (Mercury) Removed from U.S. Flu Vaccines Following ACIP Recommendation* (July 23, 2025)
8.	CDC*, Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger*, *United States* (July 2, 2025)
9.	CDC, *Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States* (July 2, 2025)
10.	*Advisory Committee on Immunization Practices, Final Agenda (Sept. 18–19, 2025), CDC* (Sept. 19, 2025)
11.	CDC, *Summary of Meeting Minutes of the Advisory Committee on Immunization Practices (ACIP), September 18–19, 2025* (Sept. 18–19, 2025)
12.	CDC, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers* (Oct. 6, 2025)
13.	CDC, *Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States* (Oct. 7, 2025)
14.	CDC, *Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States* (Oct. 7, 2025)
15.	*Advisory Committee on Immunization Practices, Final Agenda (Dec. 4–5, 2025), CDC* (Dec. 4, 2025)
16.	HHS, *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine Birth Dose for Infants Born to Women Who Test Negative for the Virus* (Dec. 5, 2025)
17.	CDC, *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus* (Dec. 16, 2025)
18.	HHS, *Decision Memorandum Adopting Revised Childhood and Adolescent Immunization Schedule* (Jan. 5, 2026)
19.	HHS, *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries* (Jan. 5, 2026)

20.	CDC, *Childhood Immunization Schedule by Recommendation Group* (Jan. 5 2026)
21.	Amendment to the Charter of the Advisory Committee on Immunization Practices, signed by the Secretary on December 3, 2025
22.	Plaintiffs' Federal Rule of Evidence 1006 Summary Chart for Prevnar-13
23.	Plaintiffs' Federal Rule of Evidence 1006 Summary Chart for Hepatitis B
24.	Plaintiffs' Federal Rule of Evidence 1006 Summary Chart for RSV
25.	Declaration of Georges C. Benjamin, M.D., dated January 25, 2026
26.	Declaration of James Lewis, M.D., MPH, dated January 22, 2026
27.	Declaration of Susan J. Kressly, M.D., FAAP, dated January 19, 2026
28.	Declaration of Molly O'Shea, M.D., dated January 23, 2026
29.	Declaration of Shannon Scott-Vernaglia, M.D., dated January 23, 2026
30.	Declaration of Thomas Boyce, M.D., dated January 22, 2026
31.	Declaration of Suzanne Berman, M.D., dated January 23, 2026
32.	Declaration of Margie Andreae, M.D., dated January 22, 2026
33.	Declaration of Mary-Cassie Shaw, M.D., FAAP, dated January 23, 2026
34.	Declaration of Andrew Racine, M.D. Ph.D., FAAP, dated January 24, 2026
35.	Declaration of Jason M. Goldman, M.D., MACP, dated January 25, 2026
36.	Declaration of Andrew T. Pavia, M.D., FAAP, FACP, FIDSA, dated January 22, 2026
37.	Declaration of Ravi Jhaveri, M.D., dated January 22, 2026
38.	Declaration of David Wheeler, M.D., dated January 23, 2026
39.	Declaration of Richard Martinello, M.D., dated January 24, 2026
40.	Declaration of Ronald Nahass, M.D., M.S., FIDSA, dated January 20, 2026
41.	Declaration of Wilbur Chen, M.D., dated January 21, 2026
42.	Declaration of Brenda Anders Pring, M.D., dated January 18, 2026
43.	Declaration of Aaron Bornstein, M.D., dated January 18, 2026
44.	Declaration of Carlene Pavlos, dated January 23, 2026
45.	Declaration of Dr. Jenifer Leaf Jaeger, M.D., MPH, FAAP, dated January 22, 2026
46.	Declaration of Sindhu K. Srinivas, M.D., MSCE, dated January 23, 2026
47.	Declaration of Jamie Loehr, M.D., FAAFP, dated January 21, 2026
48.	Declaration of Charlotte Moser, M.S., dated January 23, 2026

49.	Declaration of Jane Doe 3, dated January 25, 2026
50.	Declaration of Jane Doe, M.D., dated January 25, 2026
51.	Declaration of Robert H. Hopkins, Jr., M.D., MACP, FAAP [ACP Member], dated January 25, 2026
52.	Declaration of Patrick S. Ramsey, M.D., MSPH, dated January 25, 2026
53.	Declaration of Jane Doe 2, dated January 25, 2026

Dated: January 26, 2026

Respectfully submitted,

By: */s/ James J. Oh*

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 26th day of January 2026:

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EXHIBIT 1

SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN

May 19, 2025

The Department of Health and Human Services (HHS) continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available Food and Drug Administration (FDA) approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

By Secretarial Directive on June 18, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of Pfizer- BioNTech and the Moderna COVID-19 vaccines in the U.S. population for children ages six months through five years, consistent with the parameters of the Emergency Use Authorizations (EUAs) issued by FDA, for the Pfizer- BioNTech and the Moderna COVID-19 vaccines.[1]

By Secretarial Directive on June 24, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of COVID-19 vaccines in the U.S. population for children ages six through 17 years, consistent with the parameters of EUAs issued by FDA.

The CDC also currently recommends the COVID-19 vaccine during pregnancy.[2]

Based on a review of the recommendation of the FDA and National Institutes of Health (NIH), I have determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine. Accordingly, the HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years and are rescinded.

Based on a review of the recommendation of the FDA, I have similarly determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby. Therefore, the CDC recommendation that pregnant women receive the COVID-19 vaccine is rescinded.

Accordingly, the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above.

Robert F. Kennedy, Jr.
Secretary

[1] The Pfizer and Moderna vaccines are currently approved by the FDA for children 12 years of age and older.
[2] https://www.cdc.gov/vaccines-pregnancy/recommended-vaccines/index.html.

EXHIBIT 2

← Post

Secretary Kennedy
@SecKennedy

Today, the COVID vaccine for healthy children and healthy pregnant women has been removed from @CDCgov recommended immunization schedule. Bottom line: it's common sense and it's good science. We are now one step closer to realizing @POTUS's promise to Make America Healthy Again.



10:16 AM · May 27, 2025 · **7.4M** Views

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EXHIBIT 3

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger

UNITED STATES 2025

Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody (Nirsevimab)	RSV-mAb	Beyfortus
Vaccine	**Abbreviation(s)**	**Trade name(s)**
COVID-19 vaccine	1vCOV-mRNA	Comirnaty/Pfizer-BioNTech COVID-19 Vaccine
		Spikevax/Moderna COVID-19 Vaccine
	1vCOV-aPS	Novavax COVID-19 Vaccine
Dengue vaccine	DEN4CYD	Dengvaxia
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel Infanrix
Haemophilus influenzae type b vaccine	Hib (PRP-T)	ActHIB Hiberix
	Hib (PRP-OMP)	PedvaxHIB
Hepatitis A vaccine	HepA	Havrix Vaqta
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated: egg-based)	IIV3	Multiple
Influenza vaccine (inactivated: cell-culture)	ccIIV3	Flucelvax
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M-M-R II Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB-4C	Bexsero
	MenB-FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/ MenB-FHbp	Penbraya
Mpox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15 PCV20	Vaxneuvance Prevnar 20
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo
Rotavirus vaccine	RV1 RV5	Rotarix RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac Tdvax
Varicella vaccine	VAR	Varivax
Combination vaccines *(use combination vaccines instead of separate injections when appropriate)*		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	DTaP-IPV/Hib	Pentacel
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix Quadracel
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Revised 05/28/2025

How to use the child and adolescent immunization schedule

1. Determine recommended vaccine by age **(Table 1)**
2. Determine recommended interval for catch-up vaccination **(Table 2)**
3. Assess need for additional recommended vaccines by medical condition or other indication **(Table 3)**
4. Review vaccine types, frequencies, intervals, and considerations for special situations **(Notes)**
5. Review contraindications and precautions for vaccine types **(Appendix)**

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/hcp/imz-schedules/app.html

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html
- ACIP Shared Clinical Decision-Making Recommendations: www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/surv-manual/php/

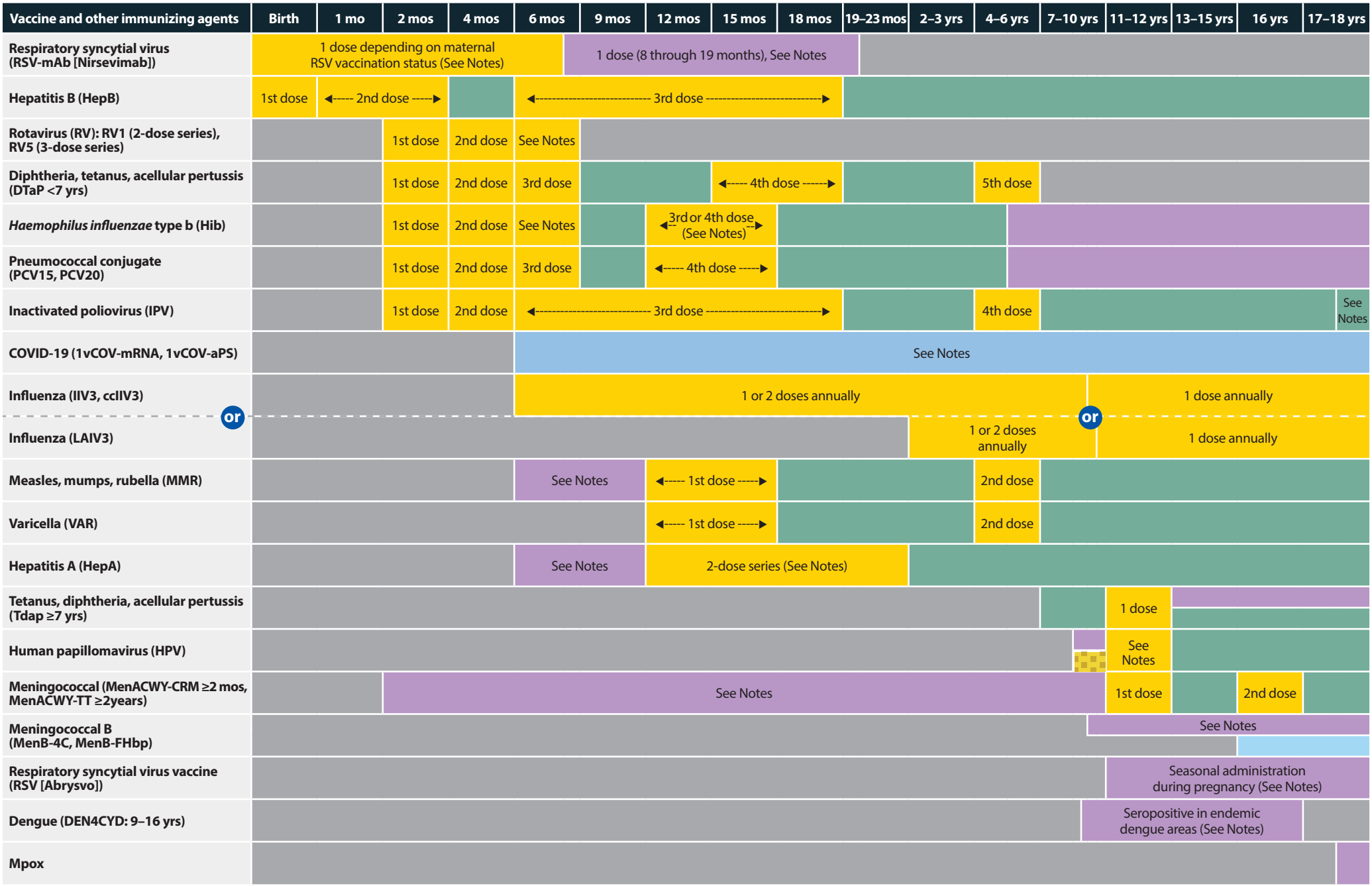
U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Scan QR code for access to online schedule

CS310020-E

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).



Range of recommended ages for all children
Range of recommended ages for catch-up vaccination
Range of recommended ages for certain high-risk groups or populations
Recommended vaccination can begin in this age group
Recommended vaccination based on shared clinical decision-making
No Guidance/ Not Applicable

Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2025

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the Notes that follow.**

Children age 4 months through 6 years					
Vaccine	**Minimum Age for Dose 1**	**Minimum Interval Between Doses**			
		Dose 1 to Dose 2	**Dose 2 to Dose 3**	**Dose 3 to Dose 4**	**Dose 4 to Dose 5**
Hepatitis B	Birth	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose** minimum age for the final dose is 24 weeks		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days.	**4 weeks**	**4 weeks** maximum age for final dose is 8 months, 0 days		
Diphtheria, tetanus, and acellular pertussis	6 weeks	**4 weeks**	**4 weeks**	**6 months**	**6 months** A fifth dose is not necessary if the fourth dose was administered at age 4 years or older ***and*** at least 6 months after dose 3
Haemophilus influenzae type b	6 weeks	**No further doses needed** if first dose was administered at age 15 months or older. **4 weeks** if first dose was administered before the 1st birthday. **8 weeks (as final dose)** if first dose was administered at age 12 through 14 months.	**No further doses needed** if previous dose was administered at age 15 months or older **4 weeks** if current age is younger than 12 months ***and*** first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib, Pentacel, Hiberix), Vaxelis or unknown **8 weeks *and* age 12 through 59 months (as final dose)** if current age is younger than 12 months ***and*** first dose was administered at age 7 through 11 months; **OR** if current age is 12 through 59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose was administered at younger than 15 months; **OR** if both doses were PedvaxHIB and were administered before the 1st birthday	**8 weeks (as final dose)** This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	**No further doses needed** for healthy children if first dose was administered at age 24 months or older **4 weeks** if first dose was administered before the 1st birthday **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after	**No further doses needed** for healthy children if previous dose was administered at age 24 months or older **4 weeks** if current age is younger than 12 months ***and*** previous dose was administered at <7 months old **8 weeks (as final dose for healthy children)** if previous dose was administered between 7–11 months (wait until at least 12 months old); **OR** if current age is 12 months or older ***and*** at least 1 dose was administered before age 12 months	**8 weeks (as final dose)** This dose is only necessary for children age 12 through 59 months regardless of risk, or age 60 through 71 months with any risk, who received 3 doses before age 12 months.	
Inactivated poliovirus	6 weeks	**4 weeks**	**4 weeks** if current age is <4 years **6 months (as final dose)** if current age is 4 years or older	**6 months (minimum age 4 years for final dose)**	
Measles, mumps, rubella	12 months	**4 weeks**			
Varicella	12 months	**3 months**			
Hepatitis A	12 months	**6 months**			
Meningococcal ACWY	2 months MenACWY-CRM 2 years MenACWY-TT	**8 weeks**	See Notes	See Notes	
Children and adolescents age 7 through 18 years					
Meningococcal ACWY	Not applicable (N/A)	**8 weeks**			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	**4 weeks**	**4 weeks** if first dose of DTaP/DT was administered before the 1st birthday **6 months (as final dose)** if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday	**6 months** if first dose of DTaP/DT was administered before the 1st birthday	
Human papillomavirus	9 years	**Routine dosing intervals are recommended.**			
Hepatitis A	N/A	**6 months**			
Hepatitis B	N/A	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose**		
Inactivated poliovirus	N/A	**4 weeks**	**6 months** A fourth dose is not necessary if the third dose was administered at age 4 years or older ***and*** at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years **OR** if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	**4 weeks**			
Varicella	N/A	**3 months** if younger than age 13 years. **4 weeks** if age 13 years or older			
Dengue	9 years	**6 months**	6 months		

Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2025

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions are often not mutually exclusive. If multiple conditions are present, refer to guidance in all relevant columns. See Notes for medical conditions not listed.

Vaccine and other immunizing agents	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count[a]		CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Heart disease or chronic lung disease	Kidney failure, End-stage renal disease or on dialysis	Chronic liver disease	Diabetes
			<15% or <200/mm³	≥15% and ≥200/mm³						
RSV-mAb (nirsevimab)		2nd RSV season		1 dose depending on maternal RSV vaccination status (See Notes)			2nd RSV season for chronic lung disease (See Notes)	1 dose depending on maternal RSV vaccination status (See Notes)		
Hepatitis B										
Rotavirus		SCID[b]								
DTaP/Tdap	DTaP Tdap: 1 dose each pregnancy									
Hib		HSCT: 3 doses	See Notes			See Notes				
Pneumococcal										
IPV										
COVID-19		See Notes		See Notes						
Influenza inactivated		Solid organ transplant: 18yrs (See Notes)								
LAIV3							Asthma, wheezing: 2–4 years[c]			
MMR	*									
VAR	*									
Hepatitis A										
HPV	*	3-dose series (See Notes)								
MenACWY										
MenB										
RSV (Abrysvo)	Seasonal administration (See Notes)									
Dengue										
Mpox	See Notes									

Recommended for all age-eligible children who lack documentation of a complete vaccination series

Not recommended for all children, but recommended for some children based on increased risk for or severe outcomes from disease

Recommended vaccination based on shared clinical decision-making

Recommended for all age-eligible children, and additional doses may be necessary based on medical condition or other indications. See Notes.

Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction

Contraindicated or not recommended
*Vaccinate after pregnancy, if indicated

No Guidance/ Not Applicable

a. For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

b. Severe Combined Immunodeficiency

c. LAIV3 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

Notes

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule, 2025.

Additional information

- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3-2, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Barnett ED, Lynfield Ruth, Sawyer MH, eds. *Red Book: 2021–2024 Report of the Committee on Infectious Diseases*. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021:72–86).
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the child and adolescent vaccine schedule are covered by VICP except dengue, PPSV23, RSV, Mpox and COVID-19 vaccines. Mpox and COVID-19 vaccines are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID-19 vaccination

(minimum age: 6 months [Moderna and Pfizer-BioNTech COVID-19 vaccines], 12 years [Novavax COVID-19 Vaccine])

Routine vaccination

Age 18 years and older who are NOT moderately or severely immunocompromised

- **Unvaccinated:**
  - 1 dose 2024–25 Moderna or Pfizer-BioNTech
  - 2 doses 2024–25 Novavax at 0, 3–8 weeks
  - Previously vaccinated before 2024–25 vaccine with:
  - **1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
  - **1 dose Novavax:** 1 dose 2024–25 Novavax 3–8 weeks after most recent dose. If more than 8 weeks after most recent dose, administer 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.
  - **2 or more doses Novavax:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.

Shared clinical decision-making

Ages 6 month –17 years who are NOT moderately or severely immunocompromised. Shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian. Where the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

Age 6 months–4 years

All vaccine doses should be from the same manufacturer.

- **Unvaccinated:**
  - 2 doses 2024–25 Moderna at 0, 4–8 weeks
  - 3 doses 2024–25 Pfizer-BioNTech at 0, 3–8, and at least 8 weeks after dose 2
- **Incomplete initial vaccination series before 2024–25 vaccine with:**
  - **1 dose Moderna:** complete initial series with 1 dose 2024–25 Moderna 4–8 weeks after most recent dose
  - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech 8 weeks apart (administer dose 1 3–8 weeks after most recent dose).
  - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 8 weeks after the most recent dose.
- **Completed initial vaccination series before 2024–25 vaccine with:**
  - **2 or more doses Moderna:** 1 dose 2024–25 Moderna at least 8 weeks after the most recent dose.
  - **3 or more doses Pfizer-BioNTech:** 1 dose 2024–25 Pfizer-BioNTech at least 8 weeks after the most recent dose.

Age 5–11 years

- **Unvaccinated:** 1 dose 2024–25 Moderna or Pfizer-BioNTech
- **Previously vaccinated before 2024–25 vaccine with 1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Pfizer-BioNTech at least 8 weeks after the most recent dose.

Age 12–17 years

- **Unvaccinated:**
  - 1 dose 2024–25 Moderna or Pfizer-BioNTech
  - 2 doses 2024–25 Novavax at 0, 3–8 weeks
- **Previously vaccinated before 2024–25 vaccine with:**
  - **1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
  - **1 dose Novavax:** 1 dose 2024–25 Novavax 3–8 weeks after most recent dose. If more than 8 weeks after most recent dose, administer 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.
  - **2 or more doses Novavax:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.

Shared clinical decision-making

Shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian. This provision would allow for COVID-19 vaccination in children aged 6 months and older based on shared clinical decision-making, allowing for vaccination of immunocompromised children. www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

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COVID-19 vaccination - *continued*

Persons who ARE moderately or severely immunocompromised.

Age 6 months–4 years

Use vaccine from the same manufacturer for all doses (initial vaccination series and additional doses*).

- **Unvaccinated:**
  - 4 doses (**3-dose initial series 2024–25 Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna 6 months later [minimum interval 2 months]).May administer additional doses.*
  - 4 doses (**3-dose initial series 2024–25 Pfizer-BioNTech** at 0, 3 weeks, and at least 8 weeks after dose 2, followed by 1 dose 2024–25 Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
- **Incomplete initial 3-dose vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna 6 months later (minimum interval 2 months). May administer additional doses of Moderna.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna 6 months later (minimum interval 2 months). May administer additional doses of Moderna.*
  - **Previous vaccination with Pfizer-BioNTech**
    - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 8 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Pfizer-BioNTech.*
    - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 8 weeks after most recent dose, followed by 1 dose 2024–25 Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Pfizer-BioNTech.*
- **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**
  - **3 or more doses Moderna:** 2 doses 2024–25 Moderna 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna.*
  - **3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Pfizer-BioNTech.*

Age 5–11 years

Use vaccine from the same manufacturer for all doses in the initial vaccination series.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series 2024–25 Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
  - 4 doses (**3-dose initial series 2024–25 Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
- **Incomplete initial 3-dose vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
  - **Previous vaccination with Pfizer-BioNTech**
    - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
    - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
- **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**
  - **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Pfizer-BioNTech.*

Age 12–17 years

Use vaccine from the same manufacturer for all doses in the initial vaccination series.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - 4 doses (**3-dose initial series Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - 3 doses (**2-dose initial series Novavax** at 0, 3 weeks, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **Incomplete initial vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

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COVID-19 vaccination - *continued*

- **Previous vaccination with Pfizer-BioNTech**
  - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **Previous vaccination with Novavax**
  - **1 dose Novavax:** complete initial series with 1 dose 2024–25 Novavax at least 3 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

• **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**
- **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **2 or more doses Novavax:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

Special situations

Age 18 years and older who ARE moderately or severely immunocompromised

Use vaccine from the same manufacturer for all doses in the initial vaccination series.

• **Unvaccinated:**
- 4 doses (**3-dose initial series Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- 4 doses (**3-dose initial series Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- 3 doses (**2-dose initial series Novavax** at 0, 3 weeks, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

• **Incomplete initial vaccination series before 2024–25 vaccine:**
- **Previous vaccination with Moderna**
  - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **Previous vaccination with Pfizer-BioNTech**
  - 1 dose Pfizer-BioNTech: complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - 2 doses Pfizer-BioNTech: complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **Previous vaccination with Novavax**
  - **1 dose Novavax:** complete initial series with 1 dose 2024–25 Novavax at least 3 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

• **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**
- **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **2 or more doses Novavax:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

***Additional doses of 2024–25 COVID-19 vaccine for moderately or severely immunocompromised:** based on shared clinical decision-making and administered at least 2 months after the most recent dose. For description of moderate and severe immunocompromising conditions and treatment, see www.cdc.gov/covid/hcp/vaccine-considerations/immunocompromised.html#cdc_cg_special_populations_section_3-description-of-moderate-and-severe-immunocompromising-conditions-and-treatment

Unvaccinated persons have never received any COVID-19 vaccine doses. There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available. Administer an age-appropriate COVID-19 vaccine product for each dose.

For information about transition from age 4 years to age 5 years or age 11 years to age 12 years during COVID-19 vaccination series, see Tables 1 and 2 at www.cdc.gov/covid/hcp/vaccine-considerations/index.html

For information about interchangeability of COVID-19 vaccines, see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability.

Current COVID-19 schedule and dosage formulation available at www.cdc.gov/covidschedule. For more information on Emergency Use Authorization (EUA) indications for COVID-19 vaccines, see www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas

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Dengue vaccination (minimum age: 9 years)

Routine vaccination

- Age 9–16 years living in areas with endemic dengue **AND** have laboratory confirmation of previous dengue infection
  - 3-dose series administered at 0, 6, and 12 months
- Endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau. For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm?s_cid=rr7006a1_w and www.cdc.gov/dengue/index.html
- Dengue vaccine should not be administered to children traveling to or visiting endemic dengue areas.

Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

Routine vaccination

- 5-dose series (3-dose primary series at age 2, 4, and 6 months, followed by booster doses at ages 15–18 months and 4–6 years)
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

Special situations

- **Children younger than age 7 years with a contraindication specific to the pertussis component of DTaP:** May administer Td for all recommended remaining doses in place of DTaP. Encephalopathy within 7 days of vaccination when not attributable to another identifiable cause is the only contraindication specific to the pertussis component of DTaP. For additional information, see www.cdc.gov/pertussis/hcp/vaccine-recommendations/td-offlabel.html.
- **Wound management in children younger than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine:** For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm.

Haemophilus influenzae type b vaccination (minimum age: 6 weeks)

Routine vaccination

- **ActHIB, Hiberix, Pentacel, or Vaxelis:** 4-dose series (3-dose primary series at age 2, 4, and 6 months, followed by a booster dose* at age 12–15 months)
  - *Vaxelis is not recommended for use as a booster dose. A different Hib-containing vaccine should be used for the booster dose.
- **PedvaxHIB:** 3-dose series (2-dose primary series at age 2 and 4 months, followed by a booster dose at age 12–15 months)
- **American Indian and Alaska Native infants:** Vaxelis and PedvaxHIB preferred over other Hib vaccines for the primary series.

Catch-up vaccination

- **Dose 1 at age 7–11 months:** Administer dose 2 at least 4 weeks later and dose 3 (final dose) at age12–15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at age 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- **Dose 1 before age 12 months and dose 2 before age 15 months:** Administer dose 3 (final dose) at least 8 weeks after dose 2.
- **2 doses of PedvaxHIB before age 12 months:** Administer dose 3 (final dose) at age12–59 months and at least 8 weeks after dose 2.
- **1 dose administered at age 15 months or older:** No further doses needed
- **Unvaccinated at age 15–59 months:** Administer 1 dose.
- **Previously unvaccinated children age 60 months or older who are not considered high risk:** Catch-up vaccination not required.

For other catch-up guidance, see Table 2. Vaxelis can be used for catch-up vaccination in children younger than age 5 years. Follow the catch-up schedule even if Vaxelis is used for one or more doses. For detailed information on use of Vaxelis see www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm.

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Special situations

- **Chemotherapy or radiation treatment:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.
- **Hematopoietic stem cell transplant (HSCT):**
  - 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant, regardless of Hib vaccination history
- **Anatomic or functional asplenia (including sickle cell disease):**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated* persons age 5 years or older
  - 1 dose
- **Elective splenectomy:**
  Unvaccinated* persons age 15 months or older
  - 1 dose (preferably at least 14 days before procedure)
- **HIV infection:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated* persons age 5–18 years
  - 1 dose
- **Immunoglobulin deficiency, early component complement deficiency, or early component complement inhibitor use:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

Unvaccinated* = Less than routine series (through age 14 months) **or no doses (age 15 months or older)*

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Hepatitis A vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination
- **2-dose series** (minimum interval: 6 months) at age 12–23 months

Catch-up vaccination
- **Unvaccinated persons through age 18 years should complete a 2-dose series** (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents age 18 years or older may receive HepA-HepB (Twinrix) as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

International travel
- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (www.cdc.gov/travel/):
  - **Infants age 6–11 months**: 1 dose before departure; revaccinate with 2 doses (separated by at least 6 months) between age 12–23 months.
  - **Unvaccinated age 12 months or older**: Administer dose 1 as soon as travel is considered.

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Hepatitis B vaccination
(minimum age: birth)

Routine vaccination
- **Mother is HBsAg-negative**
  - 3-dose series at age 0, 1–2, 6–18 months **(use monovalent HepB vaccine for doses administered before age 6 weeks)**
    - Birth weight ≥2,000 grams: 1 dose within 24 hours of birth if medically stable
    - Birth weight <2,000 grams: 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2,000 grams)
  - Infants who did not receive a birth dose should begin the series as soon as possible (see Table 2 for minimum intervals).
  - Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the birth dose.
  - **Minimum intervals (see Table 2):** when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations.
  - **Final (3rd or 4th) dose:** age 6–18 months **(minimum age 24 weeks)**
- **Mother is HBsAg-positive**
  - **Birth dose (monovalent HepB vaccine only):** administer **HepB vaccine** and **hepatitis B immune globulin (HBIG)** in separate limbs within 12 hours of birth, regardless of birth weight.
  - **Birth weight <2000 grams:** administer 3 additional doses of HepB vaccine beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**.
  - Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.
- **Mother is HBsAg-unknown**

  If other evidence suggestive of maternal hepatitis B infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to have chronic hepatitis B infection), manage infant as if mother is HBsAg-positive.
  - **Birth dose (monovalent HepB vaccine only):**
    - Birth weight ≥2,000 grams: administer **HepB vaccine** within 12 hours of birth. Determine mother's HBsAg status as soon as possible. If mother is determined to be HBsAg-positive, administer **HBIG** as soon as possible (in separate limb), but no later than 7 days of age.
    - Birth weight <2,000 grams: administer **HepB vaccine** and **HBIG** (in separate limbs) within 12 hours of birth. Administer 3 additional doses of **HepB vaccine** beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**.
  - If mother is determined to be HBsAg-positive or if status remains unknown, test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.

Catch-up vaccination
- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months. See Table 2 for minimum intervals.
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation **Recombivax HB** only).
- Adolescents age 18 years may receive:
  - **Heplisav-B:** 2-dose series at least 4 weeks apart
  - **PreHevbrio*:** 3-dose series at 0, 1, and 6 months
  - **HepA-HepB (Twinrix):** 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

Special situations
- Revaccination is generally not recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- **Post-vaccination serology testing and revaccination** (if anti-HBs <10mIU/mL) is recommended for certain populations, including:
  - Infants born to HBsAg-positive mothers
  - Persons who are predialysis or on maintenance dialysis
  - Other immunocompromised persons
  - For detailed revaccination recommendations, see www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm.

***Note:** PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant women.

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Human papillomavirus vaccination
(minimum age: 9 years)

Routine and catch-up vaccination

- HPV vaccination routinely recommended at **age 11–12 years (can start at age 9 years)** and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated.
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9–14 years at initial vaccination**: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - **Age 15 years or older at initial vaccination**: 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 12 weeks; dose 1 to dose 3 = 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series **of any valency** has been completed using recommended dosing intervals.

Special situations

- **Immunocompromising conditions, including HIV infection:** 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
- **History of sexual abuse or assault:** Start at age 9 years
- **Pregnancy:** Pregnancy testing not needed before vaccination; HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant

Influenza vaccination
(minimum age: 6 months [IIV3], 2 years [LAIV3],18 years [recombinant influenza vaccine, RIV3])

Routine vaccination

- Use any influenza vaccine appropriate for age and health status annually:
  - **Age 6 months–8 years** who have received fewer than 2 influenza vaccine doses before July 1, 2024, or whose influenza vaccination history is unknown: 2 doses, separated by at least 4 weeks. Administer dose 2 even if the child turns 9 years between receipt of dose 1 and dose 2.
  - **Age 6 months–8 years** who have received at least 2 influenza vaccine doses before July 1, 2024: 1 dose.
  - **Age 9 years or older:** 1 dose
  - **Age 18 years solid organ transplant recipients receiving immunosuppressive medications:** high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines are acceptable options. No preference over other age-appropriate IIV3 or RIV3.
- For the 2024–25 season, see www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm.
- For the 2025–26 season, see the 2025–26 ACIP influenza vaccine recommendations.

Special situations

- **Close contacts (e.g., household contacts) of severely immunosuppressed persons who require a protected environment:** should not receive LAIV3. If LAIV3 is given, they should avoid contact with, or caring for such immunosuppressed persons for 7 days after vaccination.

Note: Persons with an egg allergy can receive any influenza vaccine (egg-based or non-egg based) appropriate for age and health status.

Measles, mumps, and rubella vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination

- 2-dose series at age 12–15 months, age 4–6 years
- MMR or MMRV* may be administered

Note: For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV* may be used if parents or caregivers express a preference.

Catch-up vaccination

- **Unvaccinated children and adolescents:** 2-dose series at least 4 weeks apart*
- The maximum age for use of MMRV* is 12 years.

Special situations

- **International travel**
  - **Infants age 6–11 months:** 1 dose before departure; revaccinate with 2-dose series at age 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.*
  - **Children age 12 months or older:**
    - Unvaccinated: 2-dose series (separated by at least 4 weeks*) before departure
    - Previously received 1 dose: administer dose 2 at least 4 weeks after dose 1*
- In mumps outbreak settings, for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm

***Note:** If MMRV is used, the minimum interval between MMRV doses is 3 months.

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Meningococcal serogroup A,C,W,Y vaccination
(minimum age: 2 months [MenACWY-CRM, Menveo], 2 years [MenACWY-TT, MenQuadfi]), 10 years [MenACWY-TT/MenB-FHbp, Penbraya])

Routine vaccination
- 2-dose series at age 11–12 years; 16 years

Catch-up vaccination
- **Age 13–15 years:** 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- **Age 16–18 years:** 1 dose

Special situations
Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

- **Menveo***
  - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
  - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
  - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- **MenQuadfi**
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

Travel to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj (www.cdc.gov/travel/)**:**

- **Children younger than age 24 months:**
  - **Menveo* (age 2–23 months)**
    - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
    - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
    - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
- **Children age 2 years or older:** 1 dose Menveo* or MenQuadfi

First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits: 1 dose Menveo* or MenQuadfi

Adolescent vaccination of children who received MenACWY prior to age 10 years:

- **Children for whom boosters are recommended because of an ongoing increased risk of meningococcal disease** (e.g., those with complement component deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk.
- **Children for whom boosters are not recommended** (e.g., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

**Menveo has two formulations: lyophilized and liquid. The liquid formulation should not be used before age 10 years. See www.cdc.gov/vaccines/vpd/mening/downloads/menveo-single-vial-presentation.pdf.*

Note: For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Children age 10 years or older may receive a single dose of Penbraya as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day (see "Meningococcal serogroup B vaccination" section below for more information).

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Meningococcal serogroup B vaccination
(minimum age: 10 years [MenB-4C, Bexsero; MenB-FHbp, Trumenba; MenACWY-TT/MenB-FHbp, Penbraya])

Shared clinical decision-making
- **Adolescents not at increased risk age 16–23 years (preferred age 16–18 years)* based on shared clinical decision-making.**
  - **Bexsero or Trumenba (use same brand for all doses):** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

*To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision-making for MenB, see www.cdc.gov/vaccines/hcp/admin/downloads/isd-job-aid-scdm-mening-b-shared-clinical-decision-making.pdf

Special situations
Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use.

- **Bexsero or Trumenba (use same brand for all doses including booster doses)** 3-dose series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3)

For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Children age 10 years or older may receive a dose of Penbraya (MenACWY–TT/MenB–FHbp) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. For age-eligible children not at increased risk, if Penbraya is used for dose 1 MenB, MenB-FHbp (Trumenba) should be administered for dose 2 MenB. For age-eligible children at increased risk of meningococcal disease, Penbraya may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day **and** at least 6 months have elapsed since most recent Penbraya dose.

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Mpox vaccination
(minimum age: 18 years [Jynneos])

Special situations

- **Age 18 years and at risk for mpox infection:** complete 2-dose series, 28 days apart.

  Risk factors for mpox infection include:
  - Gay, bisexual, or other MSM, or a person who has sex with gay, bisexual, or other MSM who in the past 6 months have had one of the following:
    - A new diagnosis of at least 1 sexually transmitted disease
    - More than 1 sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
  - Persons who are sexual partners of the persons described above
  - Persons who anticipate experiencing any of the situations described above
- **Pregnancy:** There is currently no ACIP recommendation for Jynneos use in pregnancy due to lack of safety data in pregnant women. Pregnant women with any risk factor described above may receive Jynneos.

For detailed information, see www.cdc.gov/mpox/hcp/vaccine-considerations/vaccination-overview.html

Pneumococcal vaccination
(minimum age: 6 weeks [PCV15], [PCV 20]; 2 years [PPSV23])

Routine vaccination with PCV

- 4-dose series at 2, 4, 6, 12–15 months

Catch-up vaccination with PCV

- Healthy children ages 2–4 years with any incomplete* PCV series: 1 dose PCV
- For other catch-up guidance, see Table 2.

Note: For children **without** risk conditions, PCV20 is not indicated if they have received 4 doses of PCV13 or PCV15 or another age appropriate complete PCV series.

Special situations

Children and adolescents with cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; or diabetes mellitus:

Age 2–5 years

- Any incomplete* PCV series with:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23.
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 administer at least 8 weeks after the most recent PCV dose.

Age 6–18 years

- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.**
- Received PCV before age 6 years but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: 1 dose PCV20 or 1 dose PPSV23 administer at least 8 weeks after the most recent PCV dose.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: no further doses of any PCV or PPSV23 indicated.

Children and adolescents on maintenance dialysis, or with immunocompromising conditions such as nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; or sickle cell disease or other hemoglobinopathies:

Age 2–5 years

- Any incomplete* PCV series:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.

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Pneumococcal vaccination - *continued*

Age 6–18 years

- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or 1 dose of PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.**
- Received PCV before age 6 years but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no additional dose of PCV or PPSV23
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer either PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose and at least 5 years after dose 1 PPSV23.

Pregnancy: no recommendation for PCV or PPSV23 due to limited data. Summary of existing data on pneumococcal vaccination during pregnancy can be found at www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm

For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app, which can be downloaded here: wcms-wp.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html

**Incomplete series* = Not having received all doses in either the recommended series or an age-appropriate catch-up series. See Table 2 in ACIP pneumococcal recommendations at stacks.cdc.gov/view/cdc/133252

***When both PCV15 and PPSV23 are indicated, administer all doses of PCV15 first. PCV15 and PPSV23 should not be administered during the same visit.*

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Poliovirus vaccination (minimum age: 6 weeks)

Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended on or after age 4 years and at least 6 months after the previous dose.

Catch-up vaccination

- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- **Adolescents age 18 years known or suspected to be unvaccinated or incompletely vaccinated:** administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.* Unless there are specific reasons to believe they were not vaccinated, most persons aged 18 years or older born and raised in the United States can assume they were vaccinated against polio as children.

Series containing oral poliovirus vaccine (OPV), either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s_%20cid=mm6601a6_w.
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements.
  - Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
  - Doses of OPV administered on or after April 1, 2016, should not be counted.
  - For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w.
- For other catch-up guidance, see Table 2.

Special situations

- **Adolescents aged 18 years at increased risk of exposure to poliovirus and completed primary series*:** may administer one lifetime IPV booster

***Note:** Complete primary series consist of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

For detailed information, see: www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

Respiratory syncytial virus immunization (minimum age: birth [Nirsevimab, RSV-mAb, Beyfortus])

Routine immunization

- **Infants born October – March in most of the continental United States***
  - Mother did not receive RSV vaccine or mother's RSV vaccination status is unknown or mother received RSV vaccine in previous pregnancy: administer 1 dose nirsevimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **less than 14 days** prior to delivery: administer 1 dose nirsevimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **at least 14 days** prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html)
- **Infants born April–September in most of the continental United States***
  - Mother did not receive RSV vaccine or mother's RSV vaccination status is unknown or mother received RSV vaccine in previous pregnancy: administer 1 dose nirsevimab shortly before start of RSV season.*
  - Mother received RSV vaccine **less than 14 days** prior to delivery: administer 1 dose nirsevimab shortly before start of RSV season.*
  - Mother received RSV vaccine **at least 14 days** prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html)

Infants with prolonged birth hospitalization** (e.g., for prematurity) discharged October through March should be immunized shortly before or promptly after discharge.

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Special situations

- **Ages 8–19 months with chronic lung disease of prematurity requiring medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season; severe immunocompromise; cystic fibrosis with either weight for length <10th percentile or manifestation of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable)**:**
  - 1 dose nirsevimab shortly before start of second RSV season*
- **Ages 8–19 months who are American Indian or Alaska Native:** 1 dose nirsevimab shortly before start of second RSV season*
- **Age-eligible and undergoing cardiac surgery with cardiopulmonary bypass**:** 1 additional dose of nirsevimab after surgery. See www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

***Note:** While the timing of the onset and duration of RSV season may vary, administration of nirsevimab is recommended October through March in most of the continental United States (optimally October through November or within 1 week of birth). Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdiction with tropical climate) should follow guidance from public health authorities (e.g., CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

****Note:** Nirsevimab can be administered to children who are eligible to receive palivizumab. Children who have received nirsevimab should not receive palivizumab for the same RSV season.

For further guidance, see www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm and www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html

Respiratory syncytial virus vaccination (RSV [Abrysvo])

Routine vaccination

- **Pregnant at 32 weeks 0 days through 36 weeks and 6 days gestation from September through January in most of the continental United States*:** 1 dose Abrysvo. Administer RSV vaccine regardless of previous RSV infection.
  - Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab (RSV monoclonal antibody) is recommended to prevent severe respiratory syncytial virus disease in infants.
- **All other pregnant women:** RSV vaccine not recommended
- **Subsequent pregnancies:** additional doses not recommended. No data are available to inform whether additional doses are needed in subsequent pregnancies. Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab.

***Note:** Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climate) should follow guidance from public health authorities (e.g., CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

Rotavirus vaccination (minimum age: 6 weeks)

Routine vaccination

- **Rotarix:** 2-dose series at age 2 and 4 months
- **RotaTeq:** 3-dose series at age 2, 4, and 6 months
- If any dose in the series is either **RotaTeq** or unknown, default to 3-dose series.

Catch-up vaccination

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

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Tetanus, diphtheria, and pertussis (Tdap) vaccination (minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

Routine vaccination

- **Age 11–12 years:** 1 dose Tdap (adolescent booster)
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36

Note: Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

Catch-up vaccination

- **Age 13–18 years who have not received Tdap:** 1 dose Tdap (adolescent booster)
- **Age 7–18 years not fully vaccinated* with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- **Tdap administered at age 7–10 years:**
  - **Age 7–9 years** who receive Tdap should receive the adolescent Tdap booster dose at age 11–12 years
  - **Age 10 years** who receive Tdap do not need the adolescent Tdap booster dose at age 11–12 years
- **DTaP inadvertently administered on or after age 7 years**:
  - **Age 7–9 years**: DTaP may count as part of catch-up series. Administer adolescent Tdap booster dose at age 11–12 years.
  - **Age 10–18 years**: Count dose of DTaP as the adolescent Tdap booster dose.
- For other catch-up guidance, see Table 2.

Special situations

- **Wound management** in persons age 7 years or older with history of 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons age 11 years or older who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant adolescent, use Tdap.
- For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm.

**Fully vaccinated* = 5 valid doses of DTaP or 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

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Varicella vaccination
(minimum age: 12 months)

Routine vaccination

- 2-dose series at age 12–15 months, 4–6 years
- VAR or MMRV may be administered*
- Dose 2 may be administered as early as 3 months after dose 1 (a dose inadvertently administered after at least 4 weeks may be counted as valid).

*__Note__: For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

Catch-up vaccination

- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have a 2-dose series:
  - **Age 7–12 years**: Routine interval: 3 months (a dose inadvertently administered after at least 4 weeks may be counted as valid)
  - **Age 13 years and older**: Routine interval: 4–8 weeks (minimum interval: 4 weeks)
  - The maximum age for use of *MMRV* is 12 years.

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Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

Guide to Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4-1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024–25 Influenza Season | MMWR (cdc.gov), *and* Contraindications and Precautions for COVID-19 Vaccination

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
COVID-19 mRNA vaccines [Pfizer-BioNTech, Moderna]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine[3]	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID-19 vaccine[3]; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
COVID-19 protein subunit vaccine [Novavax]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a Novavax COVID-19 vaccine[3]	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of Novavax COVID-19 vaccine[3]; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of a Novavax COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg)	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable (ccIIV3) [Flucelvax]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[4] of ccIIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV3) [Flublok]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[4] of RIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV3) [Flumist]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg) • Children age 2–4 years with a history of asthma or wheezing • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear or any other cranial CSF leak • Children and adolescents receiving aspirin or salicylate-containing medications • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons age 5 years old or older • Persons with underlying medical conditions other than those listed under contraindications that might predispose to complications after wild-type influenza virus infection, e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus) • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should **NOT** be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
3. See package inserts and FDA EUA fact sheets for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG).
4. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. See Package inserts for U.S.-licensed vaccines.

Appendix

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
Dengue (DEN4CYD)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Lack of laboratory confirmation of a previous dengue infection	• Pregnancy • HIV infection without evidence of severe immunosuppression • Moderate or severe acute illness with or without fever
Diphtheria, tetanus, pertussis (DTaP)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP	• Guillain-Barré syndrome (GBS) within 6 weeks after previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid-containing vaccine • For DTaP only: Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized • Moderate or severe acute illness with or without fever
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Younger than age 6 weeks	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • Pregnancy: PreHevbrio is not recommended due to lack of safety data in pregnant women. Use other hepatitis B vaccines if HepB is indicated[4]	• Moderate or severe acute illness with or without fever
Hepatitis A-Hepatitis B vaccine (HepA-HepB) [Twinrix]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended.*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever • For MMRV only: Personal or family (i.e., sibling or parent) history of seizures of any etiology • If using MMRV, see Varicella/MMRV for additional precautions
Meningococcal ACWY (MenACWY) MenACWY-CRM [Menveo] MenACWY-TT [MenQuadfi]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Men ACWY-CRM only: severe allergic reaction to any diphtheria toxoid— or CRM197—containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	• For MenACWY-CRM only: Preterm birth if younger than age 9 months • Moderate or severe acute illness with or without fever
Meningococcal B (MenB) MenB-4C [Bexsero] MenB-FHbp [Trumenba]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY-TT/MenB-FHbp) [Penbraya]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction to a tetanus toxoid-containing vaccine	• Moderate or severe acute illness, with or without fever
Mpox [Jynneos]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness, with or without fever
Pneumococcal conjugate (PCV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria-toxoid-containing vaccine or its component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
RSV monoclonal antibody (RSV-mAb)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[5]	• Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Rotavirus (RV) RV1 [Rotarix] RV5 [RotaTeq]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe combined immunodeficiency (SCID) • History of intussusception	• Altered immunocompetence other than SCID • Chronic gastrointestinal disease • RV1 only: Spina bifida or bladder exstrophy • Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid–containing vaccine • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized • Moderate or severe acute illness with or without fever
Varicella (VAR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever • If using MMRV, see MMR/MMRV for additional precautions

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.
4. For information on the pregnancy exposure registry for persons who were inadvertently vaccinated with PreHevbrio while pregnant, please visit www.prehevbrio.com/#safety.
5. Full prescribing information for BEYFORTUS (nirsevimab-alip) www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf.

EXHIBIT 4

Recommended Adult Immunization Schedule
for ages 19 years or older

UNITED STATES
2025

Vaccines in the Adult Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
COVID–19 vaccine	1vCOV–mRNA	Comirnaty/Pfizer–BioNTech COVID–19 Vaccine Spikevax/Moderna COVID–19 Vaccine
	1vCOV–aPS	Novavax COVID–19 Vaccine
Haemophilus influenzae type b vaccine	Hib	ActHIB, Hiberix, PedvaxHIB
Hepatitis A vaccine	HepA	Havrix, Vaqta
Hepatitis A and hepatitis B vaccine	HepA–HepB	Twinrix
Hepatitis B vaccine	HepB	Engerix–B, Heplisav–B, PreHevbrio, Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated, egg-based)	IIV3	Multiple
	aIIV3	Fluad
	HD–IIV3	Fluzone High–Dose
Influenza vaccine (inactivated, cell–culture)	ccIIV3	Flucelvax
Influenza vaccine (recombinant)	RIV3	Flublok
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M–M–R II, Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY–CRM	Menveo
	MenACWY–TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB–4C	Bexsero
	MenB–FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY–TT/ MenB–FHbp	Penbraya
Mpox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance
	PCV20	Prevnar 20
	PCV21	Capvaxive
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo, Arexvy, mResvia
Tetanus and diphtheria vaccine	Td	Tenivac
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel, Boostrix
Varicella vaccine	VAR	Varivax
Zoster vaccine, recombinant	RZV	Shingrix

*Administer recommended vaccines if vaccination history is incomplete or unknown.
Do not restart or add doses to vaccine series if there are extended intervals between doses.
The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Revised 05/28/2025

How to use the adult immunization schedule

1. Determine recommended vaccinations by age **(Table 1)**
2. Assess need for additional recommended vaccinations by medical condition or other indication **(Table 2)**
3. Review vaccine types, dosing frequencies and intervals, and considerations for special situations **(Notes)**
4. Review contraindications and precautions for vaccine types **(Appendix)**

Report

- Suspected cases of reportable vaccine–preventable diseases or outbreaks to the local or state health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc–info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/hcp/imz-schedules/app.html.

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/acip-recs/hcp/vaccine-specific/
- ACIP Shared Clinical Decision–Making Recommendations: www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
- *General Best Practice Guidelines for Immunization* www.cdc.gov/vaccines/hcp/acip–recs/general–recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine–Preventable Diseases (including case identification and outbreak response): www.cdc.gov/surv-manual/php/index.html

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Scan QR code for access to online schedule

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2025

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID–19	1 or more doses of 2024–2025 vaccine (See Notes)			2 or more doses of 2024-2025 vaccine (See Notes)
Influenza inactivated (IIV3, ccIIV3) **Influenza recombinant** (RIV3)	1 dose annually			1 dose annually (HD–IIV3, RIV3, or aIIV3 preferred)
Influenza inactivated (aIIV3; HD–IIV3) **Influenza recombinant** (RIV3)	Solid organ transplant (See Notes)			
Influenza live, attenuated (LAIV3)	1 dose annually			
Respiratory syncytial virus (RSV)	Seasonal administration during pregnancy (See Notes)		60 through 74 years (See Notes)	≥75 years
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (See Notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For health care personnel (See Notes)
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (See Notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PCV21, PPSV23)			See Notes	See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication (See Notes for booster recommendations)			
Meningococcal B (MenB)	19 through 23 years	2 or 3 doses depending on vaccine and indication (See Notes for booster recommendations)		
***Haemophilus influenzae* type b** (Hib)	1 or 3 doses depending on indication			
Mpox	2 doses			
Inactivated poliovirus (IPV)	Complete 3-dose series if incompletely vaccinated. Self–report of previous doses acceptable (See Notes)			

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination based on shared clinical decision–making

No Guidance/ Not Applicable

Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2025

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions or indications are often not mutually exclusive. If multiple medical conditions or indications are present, refer to guidance in all relevant columns. See Notes for medical conditions or indications not listed.

VACCINE	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count		Men who have sex with men	Asplenia, complement deficiency	Heart or lung disease	Kidney failure, End–stage renal disease or on dialysis	Chronic liver disease; alcoholism[a]	Diabetes	Health care Personnel[b]
			<15% or <200/mm³	≥15% and ≥200/mm³							
COVID–19		See Notes									
Influenza inactivated Influenza recombinant		Solid organ transplant (See Notes)	1 dose annually								
LAIV3					1 dose annually if age 19–49 years		1 dose annually if age 19–49 years				
RSV	Seasonal administration (See Notes)	See Notes				See Notes			Liver disease (See Notes)	See Notes	
Tdap or Td	Tdap: 1 dose each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	*										
VAR	*			See Notes							
RZV		See Notes									
HPV	*	3-dose series if indicated									
Pneumococcal											
HepA											
Hep B	See Notes									Age ≥ 60 years	
MenACWY											
MenB											
Hib		HSCT: 3 doses[c]				Asplenia: 1 dose					
Mpox	See Notes				See Notes						See Notes
IPV		Complete 3-dose series if incompletely vaccinated. Self–report of previous doses acceptable (See Notes)									

- Recommended for all adults who lack documentation of vaccination, **OR** lack evidence of immunity
- Not recommended for all adults, but recommended for some adults based on either age **OR** increased risk for or severe outcomes from disease
- Recommended vaccination based on shared clinical decision–making
- Recommended for all adults, and additional doses may be necessary based on medical condition or other indications. See Notes.
- Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended *Vaccinate after pregnancy, if indicated
- No Guidance/ Not Applicable

a. Precaution for LAIV3 does not apply to alcoholism.

b. See Notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations.

c. Hematopoietic stem cell transplant.

Notes

Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

For vaccination recommendations for persons ages 18 years or younger, see the Recommended Child and Adolescent Immunization Schedule, 2025: www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

Additional Information

- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3–2, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip–recs/general–recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8–1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip–recs/general–recs/immunocompetence.html
- For information about vaccination in the setting of a vaccine–preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no–fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the adult immunization schedule except PPSV23, RSV, RZV, Mpox, and COVID–19 vaccines are covered by the National Vaccine Injury Compensation Program (VICP). Mpox and COVID–19 vaccines are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID–19 vaccination

Routine vaccination

Age 19–64 years (not pregnant)

- **Unvaccinated:**
  - 1 dose 2024–25 Moderna or Pfizer-BioNTech
  - 2 doses 2024–25 Novavax at 0, 3–8 weeks
- **Previously vaccinated before 2024–25 vaccine with:**
  - **1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
  - **1 dose Novavax:** 1 dose 2024–25 Novavax 3–8 weeks after most recent dose. If more than 8 weeks after most recent dose, administer 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.
  - **2 or more doses Novavax:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
  - **1 or more doses Janssen:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.

Age 65 years and older

- **Unvaccinated:** follow recommendations above for unvaccinated persons ages 19–64 years **and** administer dose 2 of 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).
- **Previously vaccinated before 2024–25 vaccine:** follow recommendations above for previously vaccinated persons ages 19–64 years **and** administer dose 2 of 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).

Special situations

Persons who are moderately or severely immunocompromised. Use vaccine from the same manufacturer for all doses in the initial vaccination series.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series 2024–25 Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
  - 4 doses (**3-dose initial series 2024–25 Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
  - 3 doses (**2-dose initial series 2024–25 Novavax** at 0, 3 weeks, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
- **Incomplete initial vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*

Notes

COVID-19 vaccination - *continued*

- **Previous vaccination with Pfizer-BioNTech**
  - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*
  - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*
- **Previous vaccination with Novavax**
  - **1 dose Novavax:** complete initial series with 1 dose 2024–25 Novavax at least 3 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*

- **Completed the initial vaccination series before 2024–25 vaccine with:**
  - **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses.*
  - **2 or more doses Novavax:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses.*

***Additional doses of 2024–25 COVID-19 vaccine for moderately or severely immunocompromised:** based on shared clinical decision-making and administered at least 2 months after the most recent dose (see Table 2 at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02.). For description of moderate and severe immunocompromising conditions and treatment, see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromising-conditions-treatment.

Unvaccinated persons have never received any COVID-19 vaccine doses. There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available. Administer an age-appropriate COVID-19 vaccine product for each dose.

For information about interchangeability of COVID-19 vaccines, see wcms-wp.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability.

Current COVID-19 schedule and dosage formulation available at www.cdc.gov/covidschedule. For more information on Emergency Use Authorization (EUA) indications for COVID-19 vaccines, see www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

Haemophilus influenzae type b vaccination

Special situations

- **Anatomical or functional asplenia (including sickle cell disease):** 1 dose if previously did not receive Hib vaccine
  - **Elective splenectomy:** 1 dose preferably at least 14 days before splenectomy
- **Hematopoietic stem cell transplant (HSCT):** 3-dose series 4 weeks apart starting 6–12 months after successful transplant, regardless of Hib vaccination history

Hepatitis A vaccination

Routine vaccination

- **Any person who is not fully vaccinated and requests vaccination** (identification of risk factor not required): complete 2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA–HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 5 months])

Special situations

- **Any person who is not fully vaccinated and who is at risk for hepatitis A virus infection or severe disease from hepatitis A virus infection:** complete 2-dose series HepA or 3-dose series HepA–HepB as above. Risk factors include:
  - **Chronic liver disease** including persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.
  - **HIV infection**
  - **Men who have sex with men**
  - **Injection or noninjection drug use**
  - **Persons experiencing homelessness**
  - **Work with hepatitis A virus** in research laboratory or with nonhuman primates with hepatitis A virus infection
  - **Travel in countries with high or intermediate endemic hepatitis A:** HepA–HepB (Twinrix) may be administered on an accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months.
  - **Close, personal contact with international adoptee** (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A: dose 1 as soon as adoption is planned; preferably at least 2 weeks before adoptee's arrival.

Notes

Hepatitis A vaccination - *continued*

- **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy
- **Settings for exposure,** including health care setting serving persons who use injection or noninjection drugs, or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

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Hepatitis B vaccination

Routine vaccination

- **Age 19 through 59 years:** complete a 2- or 3- or 4-dose series
  - 2-dose series only applies when 2 doses of Heplisav–B are used at least 4 weeks apart
  - 3-dose series Engerix–B, PreHevbrio*, or Recombivax HB at 0, 1, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 8 weeks; dose 1 to dose 3 = 16 weeks)
  - 3-dose series HepA–HepB (Twinrix) at 0, 1, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 5 months)
  - 4-dose series HepA–HepB (Twinrix) accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months

***Note:** PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant women.

- **Age 60 years or older without** known risk factors for hepatitis B virus infection **may** receive a HepB vaccine series.
- **Age 60 years or older with** known risk factors for hepatitis B virus infection **should** receive a HepB vaccine series.
- **Any adult age 60 years of age or older** who requests HepB vaccination **should** receive a HepB vaccine series.
  - **Risk factors for hepatitis B virus infection include:**
    - **Chronic liver disease** including persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.
    - **HIV infection**
    - **Sexual exposure risk** e.g., sex partners of hepatitis B surface antigen (HBsAg)–positive persons, sexually active persons not in mutually monogamous relationships, persons seeking evaluation or treatment for a sexually transmitted infection, men who have sex with men
    - **Current or recent injection drug use**
    - **Percutaneous or mucosal risk for exposure to blood** e.g., household contacts of HBsAg–positive persons, residents and staff of facilities for developmentally disabled persons, health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood–contaminated body fluids, persons on maintenance dialysis (including in–center or home hemodialysis and peritoneal dialysis), persons who are predialysis, and patients with diabetes**
    - **Incarceration**
    - **Travel in countries with high or intermediate endemic hepatitis B**

****Age 60 years or older with diabetes:** Based on shared clinical decision making, 2-, 3-, or 4-dose series as above.

Special situations

- **Patients on dialysis:** complete a 3- or 4-dose series
  - 3-dose series Recombivax HB at 0, 1, 6 months (Note: Use Dialysis Formulation 1 mL = 40 mcg)
  - 4-dose series Engerix–B at 0, 1, 2, and 6 months (Note: Use 2 mL dose instead of the normal adult dose of 1 mL)
- **Age 20 years or older with an immunocompromising condition:** complete a 2- or 3- or 4-dose series.
  - 3-dose series Recombivax HB at 0,1, 6 months (Note: Use Dialysis Formulation 1ml = 40 mcg)
  - 4-dose series Engerix–B at 0,1,2, and 6 months (Note: Use 2mL dose instead of the normal adult dose of 1mL)
  - 2-doses series Heplisav–B at 0, 1 months
  - 3-dose series PreHevbrio* at 0,1, 6 months

Notes

Human papillomavirus vaccination

Routine vaccination

- **All persons through age 26 years:** complete 2– or 3-dose series depending on age at initial vaccination or condition.
  - **Age 9–14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart:** 1 additional dose
  - **Age 9–14 years at initial vaccination and received 2 doses at least 5 months apart:** HPV vaccination series complete, no additional dose needed
  - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 12 weeks; dose 1 to dose 3 = 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series of any valency has been completed using the recommended dosing intervals.

Shared clinical decision–making

- **Adults age 27–45 years:** Based on shared clinical decision–making, complete a 2-dose series (if initiated age 9–14 years) or 3-dose series (if initiated ≥15 years).

For additional information on shared clinical decision–making for HPV; see www.cdc.gov/vaccines/hcp/admin/downloads/isd–job–aid–scdm–hpv–shared–clinical–decision–making–hpv.pdf

Special situations

- **Age ranges recommended above for routine and catch–up vaccination or shared clinical decision–making also apply in special situations**
  - **Immunocompromising conditions, including HIV infection**: complete 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
  - **Pregnancy**: Pregnancy testing is not needed before vaccination. HPV vaccination is not recommended until after pregnancy. No intervention needed if inadvertently vaccinated while pregnant.

Influenza vaccination

Routine vaccination

- **Age 19 years or older:** 1 dose any influenza vaccine appropriate for age and health status annually
  - **Solid organ transplant recipients aged 19 through 64 years receiving immunosuppressive medications:** HD–IIV3 and aIIV3 are acceptable options. No preference over other age–appropriate IIV3 or RIV3.
  - **Age 65 years or older:** Any one of HD-IIV3, RIV3, or aIIV3 is preferred. If none of these three vaccines is available, then any other age–appropriate influenza vaccine should be used.
- For the 2024–25 season, see www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm
- For the 2025–26 season, see the 2025–26 ACIP influenza vaccine recommendations.

Special situations

- **Close contacts (e.g., caregivers, healthcare workers) of severely immunosuppressed persons who require a protected environment:** should not receive LAIV3. If LAIV3 is given, they should avoid contact with/caring for such immunosuppressed persons for 7 days after vaccination.

Note: Persons with an egg allergy can receive any influenza vaccine (egg-based or non–egg based) appropriate for age and health status.

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Measles, mumps, and rubella vaccination

Routine vaccination

- **No evidence of immunity to measles, mumps, or rubella:** 1 dose
  - **Evidence of immunity:** Born before 1957 (except for health care personnel, see below), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)

Special situations

- **Pregnancy with no evidence of immunity to rubella:** MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility): 1 dose
- **Nonpregnant women of childbearing age with no evidence of immunity to rubella:** 1 dose
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm^3 for at least 6 months and no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart; MMR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm^3
- **Severe immunocompromising conditions:** MMR contraindicated
- **Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons with no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR
- **In mumps outbreak settings,** for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm

Notes

Measles, mumps, and rubella vaccination *- continued*

- **Health care personnel:**
  - **Born before 1957 with no evidence of immunity to measles, mumps, or rubella:** Consider 2-dose series at least 4 weeks apart for protection against measles or mumps or 1 dose for protection against rubella.
  - **Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart for protection against measles or mumps or at least 1 dose for protection against rubella.

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Meningococcal vaccination

Special situations for MenACWY

- **Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:** 2-dose primary series Menveo or MenQuadfi at least 8 weeks apart; 1 booster dose 5 years after primary series and every 5 years if risk remains
- **Travel in countries with hyperendemic or epidemic meningococcal disease, or for microbiologists routinely exposed to *Neisseria meningitidis*:** 1 dose Menveo or MenQuadfi; 1 booster dose 5 years after primary series and every 5 years if risk remains
- **First–year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:** 1 dose Menveo or MenQuadfi

For MenACWY recommendations **in outbreak setting** (e.g., in community or organizational settings, or among men who have sex with men) and **additional meningococcal vaccination** information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm

Shared clinical decision–making for MenB

- **Adolescents and young adults age 16–23 years (age 16–18 years preferred)* not at increased risk for meningococcal disease:** based on shared clinical decision–making
  - **Bexsero or Trumenba (use same brand for all doses):** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

*To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision–making for MenB, see www.cdc.gov/vaccines/hcp/admin/downloads/isd–job–aid–scdm–mening–b–shared–clinical–decision–making.pdf

Special situations for MenB

- **Anatomical or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, or microbiologists routinely exposed to *Neisseria meningitidis*.**
  - **Bexsero or Trumenba (use same brand for all doses including booster doses):** 3-dose primary series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3).
  - **Booster doses:** 1 booster dose one year after primary series and every 2–3 years if risk remains
- **Pregnancy:** Delay MenB until after pregnancy due to lack of safety data in pregnant women. May administer if at increased risk and vaccination benefits outweigh potential risks.

For MenB recommendations **in outbreak setting** (e.g., in community or organizational settings, or among men who have sex with men) and **additional meningococcal vaccination** information, see ww.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Adults may receive a single dose of Penbraya (MenACWY–TT/MenB–FHbp) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. For adults not at increased risk, if Penbraya is used for dose 1 MenB, then MenB–FHbp (Trumenba) should be administered for dose 2 MenB. For adults at increased risk of meningococcal disease, Penbraya may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day **and** at least 6 months have elapsed since most recent Penbraya dose.

Notes

Mpox vaccination

Special situations

- **Any person at risk for mpox infection:** complete 2-dose series, 28 days apart.

  Risk factors for mpox infection include:
  - Persons who are gay or bisexual, and other MSM, transgender or nonbinary people who in the past 6 months have had:
    - A new diagnosis of at least 1 sexually transmitted disease
    - More than 1 sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
  - Persons who are sexual partners of the persons described above
  - Persons who anticipate experiencing any of the situations described above
- **Pregnancy:** There is currently no ACIP recommendation for Jynneos use in pregnancy due to lack of safety data in pregnant women. Pregnant women with any risk factor described above may receive Jynneos.
- **Health care personnel:** Vaccination to protect against occupational risk in healthcare settings is not routinely recommended.

  For detailed information, see www.cdc.gov/mpox/hcp/vaccine-considerations/vaccination-overview.html.

Pneumococcal vaccination

Routine vaccination

- **Age 50 years or older who have:**
  - **Not previously received a dose of PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21
    - If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose
  - **Previously received only PPSV23:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21, at least 1 year after the last PPSV23 dose.
    - If PCV15 is used, no additional PPSV23 doses are recommended.
  - **Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older:** 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.
  - **Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older:** Based on shared clinical decision–making, 1 dose of PCV20 or 1 dose of PCV21 at least 5 years after the last pneumococcal vaccine dose.

Special situations

- **Age 19–49 years with certain underlying medical conditions or other risk factors** who have:**
  - **Not previously received a PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21
    - If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose
  - **Previously received only PPSV23:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21, at least 1 year after the last PPSV23 dose.
    - If PCV15 is used, no additional PPSV23 doses are recommended.
  - **Previously received PCV13 and 1 dose of PPSV23:**
    - Cochlear implant, cerebrospinal fluid leak, or an immunocompromising condition*: 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.
    - Alcoholism, chronic heart/liver/lung disease, cigarette smoking, or diabetes mellitus: no additional PCV or PPSV23 doses recommended at this time. Review pneumococcal recommendations when age 50 years or older.

Adults aged 19 years and older who have received PCV20 or PCV21: no additional pneumococcal vaccine dose recommended.

Pregnancy: no recommendation for PCV or PPSV23 due to limited data. Summary of existing data on pneumococcal vaccination during pregnancy can be found at www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm.

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Notes

Pneumococcal vaccination - *continued*

PPSV23 not available: adults aged 19 years or older who received PCV15 but have not yet completed PPSV23 series, can complete the series with either 1 dose of PCV20 or 1 dose of PCV21 if they no longer have access to PPSV23.

For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app which can be downloaded here: www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html.

***Note:** Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiencies, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.

****Note:** Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV infection, Hodgkin disease, immunodeficiencies, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, or sickle cell disease or other hemoglobinopathies.

Poliovirus vaccination

Routine vaccination

- **Adults known or suspected to be unvaccinated or incompletely vaccinated:** administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.* Unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children.

Special situations

- **Adults at increased risk for exposure to poliovirus who completed primary series*:** may administer one lifetime IPV booster.

***Note:** Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

For detailed information, see www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

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Respiratory syncytial virus vaccination

Routine vaccination

- **Pregnant women of any age:**
  - **Pregnant at 32 weeks 0 days through 36 weeks and 6 days gestation from September through January in most of the continental United States*:** 1 dose **Abrysvo**. Administer RSV vaccine regardless of previous RSV infection.
  - Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab (RSV monoclonal antibody) is recommended to prevent severe respiratory syncytial virus disease in infants.
  - **All other pregnant women:** RSV vaccine not recommended
  - **Subsequent pregnancies:** additional doses not recommended. No data are available to inform whether additional doses are needed in subsequent pregnancies. Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab.

***Note:** Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climate) should follow guidance from public health authorities on timing of administration. Refer to the 2025 Child and Adolescent Immunization Schedule for considerations regarding nirsevimab administration to infants.

Age 75 years or older

- **Unvaccinated:** 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended
- **Previously vaccinated:** additional doses not recommended. No data are available to inform whether additional doses are needed.

Notes

Respiratory syncytial virus vaccination - *continued*

Special situations

- **Age 60–74 years:**
  - **Unvaccinated and at increased risk of severe RSV disease**:** 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended.
  - **Previously vaccinated:** additional doses not recommended. No data are available to inform whether additional doses are needed.

Persons 60 years and older can get RSV vaccine at any time but it is best to administer in late summer and early fall before RSV spreads in communities—ideally August through October in most of continental United States. For further guidance, see www.cdc.gov/mmwr/volumes/73/wr/mm7332e1.htm.

****Note: *People can self–attest to the presence of a risk factor.* The following medical and other conditions increase the risk of severe RSV disease:**

- Chronic cardiovascular disease e.g., heart failure, coronary artery disease, congenital heart disease. Excludes isolated hypertension.
- Chronic lung or respiratory disease e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, cystic fibrosis
- End stage renal disease or dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end–organ damage
- Diabetes mellitus requiring treatment with insulin or sodium–glucose cotransporter 2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness e.g., post–stroke dysphagia, amyotrophic lateral sclerosis, muscular dystrophy. Excludes history of stroke without impaired airway clearance.
- Chronic liver disease e.g., cirrhosis
- Chronic hematologic conditions e.g., sickle cell disease, thalassemia
- Severe obesity (body mass index ≥ 40 kg/m2)
- Moderate or severe immune compromise
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk of severe disease due to viral respiratory infection e.g., frailty, concern for presence of undiagnosed chronic medical conditions, residence in a remote or rural community where escalation of medical care is challenging.

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Tetanus, diphtheria, and pertussis vaccination

Routine vaccination

- **Completed primary series and received at least 1 dose Tdap at age 10 years or older:** Td or Tdap every 10 years thereafter
- **Completed primary series and did NOT receive Tdap at age 10 years or older:** 1 dose Tdap, then Td or Tdap every 10 years thereafter
- **Unvaccinated or incomplete primary vaccination series for tetanus, diphtheria, or pertussis:** administer remaining doses (1, 2, or 3 doses) to complete 3-dose primary series. 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks later, and a third dose of Td or Tdap 6–12 months later (Tdap is preferred as first dose and can be substituted for any Td dose), then Td or Tdap every 10 years thereafter.

Special situations

- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- **Wound management:** Persons with 3 or more doses of tetanus–toxoid–containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus–toxoid–containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus–toxoid–containing vaccine. Tdap is preferred for persons who have not previously received Tdap or whose Tdap history is unknown. If a tetanus–toxoid–containing vaccine is indicated for a pregnant woman, use Tdap. For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm

Notes

Varicella vaccination

Routine vaccination

- **No evidence of immunity to varicella:** 2-dose series 4–8 weeks apart if previously did not receive varicella–containing vaccine (VAR or MMRV [measles–mumps–rubella–varicella vaccine] for children); if previously received 1 dose varicella–containing vaccine, 1 dose at least 4 weeks after first dose.
  - **Evidence of immunity:** U.S.–born before 1980 (except for pregnant women and health care personnel [see below]), documentation of 2 doses varicella–containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease.

Special situations

- **Pregnancy with no evidence of immunity to varicella:** VAR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose if previously received 1 dose varicella–containing vaccine or dose 1 of 2-dose series (dose 2: 4–8 weeks later) if previously did not receive any varicella–containing vaccine, regardless of whether U.S.–born before 1980.
- **Health care personnel with no evidence of immunity to varicella:** 1 dose if previously received 1 dose varicella–containing vaccine; 2-dose series 4–8 weeks apart if previously did not receive any varicella–containing vaccine, regardless of whether U.S.–born before 1980.
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm^3 with no evidence of immunity:** Vaccination may be considered (2 doses 3 months apart); VAR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm^3.
- **Severe immunocompromising conditions:** VAR contraindicated

Zoster vaccination

Routine vaccination

- **Age 50 years or older*:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of zoster vaccine live (ZVL, Zostavax) vaccination.

***Note:** Serologic evidence of prior varicella is not necessary for zoster vaccination. However, if serologic evidence of varicella susceptibility becomes available, providers should follow ACIP guidelines for varicella vaccination first. RZV is not indicated for the prevention of varicella, and there are limited data on the use of RZV in persons without a history of varicella or varicella vaccination.

Special situations

- **Pregnancy:** There is currently no ACIP recommendation for RZV use in pregnancy. Consider delaying RZV until after pregnancy.
- **Immunocompromising conditions (including persons with HIV regardless of CD4 count)**:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon). For detailed information, see www.cdc.gov/shingles/hcp/vaccine–considerations/immunocompromised–adults.html

****Note:** If there is no documented history of varicella, varicella vaccination, or herpes zoster, providers should refer to the clinical considerations for use of RZV in immunocompromised adults aged ≥19 years and the ACIP varicella vaccine recommendations for further guidance: www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

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Appendix Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4–1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024–25 Influenza Season | MMWR (cdc.gov), *and* Contraindications and Precautions for COVID–19 Vaccination

Vaccines and Other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
COVID–19 mRNA vaccines [Pfizer–BioNTech, Moderna]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID–19 vaccine[3]	• Diagnosed non–severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID–19 vaccine[3]; or non–severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID–19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID–19 vaccine • Multisystem inflammatory syndrome in children (MIS–C) or multisystem inflammatory syndrome in adults (MIS–A) • Moderate or severe acute illness, with or without fever
COVID–19 protein subunit vaccine [Novavax]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a Novavax COVID–19 vaccine[3]	• Diagnosed non–severe allergy (e.g., urticaria beyond the injection site) to a component of Novavax COVID–19 vaccine[3]; or non–severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of a Novavax COVID–19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID–19 vaccine • Multisystem inflammatory syndrome in children (MIS–C) or multisystem inflammatory syndrome in adults (MIS–A) • Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg)	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture–based inactivated injectable (ccIIV3) [Flucelvax]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[4] of ccIIV3	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV3) [Flublok]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[4] of RIV3	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV3) [Flumist]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg) • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear, or any other cranial CSF leak • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days.	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons aged 5 years or older • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild–type influenza virus infection [e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)] • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
3. See package inserts and FDA EUA fact sheets for a full list of vaccine ingredients. mRNA COVID–19 vaccines contain polyethylene glycol (PEG).
4. Vaccination providers should check FDA–approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. See Package inserts for U.S.–licensed vaccines.

Appendix

Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Vaccine	Contraindicated or Not Recommended[1]	Precautions[2]
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • Pregnancy: PreHevbrio is not recommended due to lack of safety data in pregnant women. Use other hepatitis B vaccines if HepB is indicated[4]	• Moderate or severe acute illness with or without fever
Hepatitis A–Hepatitis B vaccine (HepA–HepB) [Twinrix]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long–term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody–containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon–gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever
Meningococcal ACWY (MenACWY) (MenACWY–CRM) [Menveo] (MenACWY–TT) [MenQuadfi]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For MenACWY–CRM only: severe allergic reaction to any diphtheria toxoid– or CRM197–containing vaccine • For MenACWY–TT only: severe allergic reaction to a tetanus toxoid–containing vaccine	• Moderate or severe acute illness with or without fever
Meningococcal B (MenB) MenB–4C [Bexsero] MenB–FHbp [Trumenba]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB–4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY–TT/MenB–FHbp) [Penbraya]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction to a tetanus toxoid–containing vaccine	• Moderate or severe acute illness, with or without fever
Mpox [Jynneos]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness, with or without fever
Pneumococcal conjugate (PCV15, PCV20, PCV21)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria–toxoid–containing vaccine or to its vaccine component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (e.g., anaphylaxis) to a vaccine component	• Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus–toxoid–containing vaccine • History of Arthus–type hypersensitivity reactions after a previous dose of diphtheria–toxoid containing or tetanus–toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus–toxoid–containing vaccine • Moderate or severe acute illness with or without fever • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized
Varicella (VAR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long–term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody–containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin–containing products • Moderate or severe acute illness with or without fever
Zoster recombinant vaccine (RZV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever • Current episode of herpes zoster

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip–recs/general–recs/contraindications.html.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip–recs/general–recs/contraindications.html.
3. Vaccination providers should check FDA–approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.–licensed vaccines are available at www.fda.gov/vaccines–blood–biologics/approved–products/vaccines–licensed–use–united–states.
4. For information on the pregnancy exposure registry for persons who were inadvertently vaccinated with PreHevbrio while pregnant, please visit www.prehevbrio.com/#safety.

EXHIBIT 5

Final Agenda

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention
Atlanta, Georgia 30329

Wednesday, June 25, 2025

10:00	**Opening Remarks**	Dr. Martin Kulldorff (ACIP Chair)
10:15	**Welcome and Roll Call**	Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
10:35	**Update on Work Groups**	Dr. Martin Kulldorff (ACIP Chair)
11:00	**COVID-19 Vaccines**	
	Introduction	Dr. Adam MacNeil (CDC/NCIRD)
	COVID-19 epidemiology	Dr. Adam MacNeil (CDC/NCIRD)
	COVID-19 vaccine effectiveness update	Dr. Adam MacNeil (CDC/NCIRD)
	COVID-19 safety update	Dr. Sarah Meyer (CDC/NCEZID)
	COVID-19 vaccine coverage and implementation	Dr. Georgina Peacock (CDC/NCIRD)
	Evidence to recommendations (partial)	Dr. Adam MacNeil (CDC/NCIRD)
1:00	***Lunch***	
1:30	**Agency Updates**	*CDC, CMS, FDA, HRSA, IHS, NIH*
2:00	**RSV Vaccines- Maternal/Pediatric**	
	Introduction	Dr. Adam MacNeil (CDC/NCIRD)
	Updates on uptake of maternal vaccine and nirsevimab	Dr. Georgina Peacock (CDC/NCIRD)
	Effectiveness and impact of RSV prevention products in infants during the 2024-2025 season	Dr. Adam MacNeil (CDC/NCIRD)
	Updates on safety of maternal vaccine and nirsevimab	Dr. Malini DeSilva (HealthPartners), Dr. Matthew Daley (Kaiser Permanente Colorado)
	Updates and summary of the Evidence to Recommendation Framework for clesrovimab	Dr. Adam MacNeil (CDC/NCIRD)
	Updates on clinical considerations for clesrovimab	Dr. Adam MacNeil (CDC/NCIRD)
	Proposed Recommendations	Dr. Adam MacNeil (CDC/NCIRD)
	Updates to RSV vaccines VFC resolution	Dr. Georgina Peacock (CDC/NCIRD)
4:00	***Break***	
4:15	Public Comment	
5:00	**Votes**	
	RSV Vaccines- Pediatric	Dr. Adam MacNeil (CDC/NCIRD)
	RSV Vaccines- VFC	Dr. Georgina Peacock (CDC/NCIRD)
5:30	**Adjourn**	

Final Agenda

Thursday, June 26, 2025

8:00	**Welcome and Roll Call**	Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
8:15	**Influenza Vaccines**	
	Introduction	Dr. Vivien Dugan (CDC/NCIRD)
	Flublok in older children and adolescents: immunogenicity and safety	Dr. Pedro Folegatti (Sanofi Pasteur)
	Estimates of influenza burden and burden averted through vaccination	Dr. Vivien Dugan (CDC/NCIRD)
	Proposed recommendations for 2025-26	Dr. Vivien Dugan (CDC/NCIRD)
	Presentation regarding thimerosal in vaccines	Lyn Redwood, RN, MSN
	Proposed recommendations regarding thimerosal containing influenza vaccine	Dr. Martin Kulldorff (ACIP Chair)
10:15	***Break***	
10:30	**Chikungunya Vaccines**	
	Introduction	Dr. Lyle Petersen (CDC/NCEZID)
	EtR (partial) for use of live attenuated and virus-like particle chikungunya vaccines in U.S territories	Dr. Lyle Petersen (CDC/NCEZID)
	Safety update on live attenuated chikungunya vaccine and use among older persons	Dr. Lyle Petersen (CDC/NCEZID)
10:45	**Anthrax Vaccine**	Dr. Brendan Jackson (CDC/NCEZID)
10:50	**MMRV Vaccine**	
	Presentation on MMRV vaccine in children under under 4 years of age	Dr. Martin Kulldorff (ACIP Chair)
	Proposed recommendations regarding MMRV in children under 4 years of age	Dr. Martin Kulldorff (ACIP Chair)
11:20	***Break***	
11:30	Public Comment	
12:15	***Break***	
12:30	**Votes**	
	Influenza Vaccines	Dr. Vivien Dugan
	Thimerosal containing influenza vaccine recommendations	Dr. Martin Kulldorff (ACIP Chair)
1:00	**Adjourn**	

Acronyms

CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
COVID-19	Coronavirus disease 2019
EtR	Evidence to Recommendations Framework
FDA	Food and Drug Administration
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
MMRV	Measles, Mumps, Rubella, Varicella Vaccine
NCIRD	National Center for Immunization & Respiratory Diseases
NCEZID	National Center for Emerging and Zoonotic Diseases
NIH	National Institutes of Health
RSV	Respiratory Syncytial Virus
VFC	Vaccines for Children

EXHIBIT 6

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

JUNE 25-26, 2025
MEETING SUMMARY

Trade names are used for identification purposes only and do not indicate endorsement.

WEDNESDAY: JUNE 25, 2025

WELCOME AND INTRODUCTIONS

Call to Order/Roll Call

Dr. Martin Kulldorff, Chair of the ACIP, convened the meeting on June 25, 2025. He welcomed the members, thanked the current and former committee members and CDC staff, and emphasized the committee's commitment to evidence-based vaccine recommendations. Dr. Kulldorff stressed the importance of open scientific inquiry, rebuilding public trust, and addressing vaccine safety transparently to support public health.

Dr. Mina Zadeh (ACIP Executive Secretary, CDC) made opening announcements about the availability of presentation slides on the ACIP website, the scheduled oral public session, and the written public comment process. She reviewed conflict of interest policies for ACIP members. A list of Members, Ex Officios, and Liaison Representatives is included in the appendices at the end of this summary document. She welcomed the new committee members who introduced themselves: Dr. Martin Kulldorff, Dr. Joseph Hibbeln, Dr. Retsef Levi, Dr. Robert Malone, Dr. Cody Meissner, Dr. James Pagano, and Dr. Vicky Pebsworth. While no conflicts of interest were identified for the first day of the meeting, Dr. Vicky Pebsworth disclosed that she owns stock in a healthcare sector fund that includes holdings relevant to ACIP discussions, including vaccine manufacturers. However, the value of this stock falls below the Office of Government Ethics' de minimis threshold. Dr. Pebsworth confirmed that she understood, and therefore, she is permitted to participate fully in the ACIP meeting.

UPDATE ON WORK GROUPS

Dr. Kulldorff emphasized the critical role of ACIP work groups, which are composed of national experts who investigate vaccine-related issues and provide recommendations to the committee. New chairs are being appointed to lead these groups, while many current members will continue their work to ensure continuity and progress. There are currently 11 active work groups focusing on vaccines for chikungunya, COVID-19, cytomegalovirus, HPV, influenza, meningococcal disease, pneumococcal disease, and RSV. Dr. Kulldorff announced plans to establish new work groups, including one to evaluate the cumulative childhood and adolescent vaccine schedules. This group will assess potential interactions between vaccines, the total number of vaccines administered, ingredient amounts, and the timing of administration. The National Academy of Medicine has previously called for additional research in this area. Another new work group will review vaccines that have not been formally reassessed in over seven years, a practice intended to be routine but not yet systematically implemented. Future topics for review may include the timing of the hepatitis B birth dose, whether separate MMR and varicella vaccines should be preferred over the combined MMRV due to seizure risks, and the possibility of considering alternative MMR vaccines used in other countries. Dr. Kulldorff emphasized the importance of collaboration, open scientific discussion, and a commitment to evidence-based medicine in enhancing public health outcomes.

COVID-19 VACCINES

Dr. Adam MacNeil (CDC/NCIRD) provided a recap to summarize events of the past year. Last June, ACIP recommended the 2024–2025 COVID-19 vaccination for all individuals aged 6 months and older. In August, the FDA authorized or approved Moderna, Pfizer, and Novavax COVID-19 vaccines, and in September, ACIP's recommendations and CDC vaccination guidance were published in the Morbidity and Mortality Weekly Report (MMWR).

At the October 2024 ACIP meeting, the committee recommended additional doses for adults aged 65 and older and for individuals aged 6 months and older with moderate or severe immunocompromise. These recommendations were published in the MMWR in December 2024. As has been customary following changes in recommendations, CDC updated its interim clinical considerations accordingly.

The CDC updated its recommendations in May 2025. Per HHS directive, guidance shifted to shared clinical decision-making for healthy children aged 6 months through 17 years, and no recommendation was provided for pregnant individuals. Also in May, the FDA approved Novavax's NUVAXOVID (2024–2025 Formula) and Moderna's MNEXSPIKE (2024–2025 Formula) for individuals aged 12–64 at high risk for severe COVID-19, and for all individuals aged 65 and older.

On May 22, 2025, FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) met to discuss strain selection for the 2025–2026 COVID-19 vaccine formula. FDA subsequently advised manufacturers to use a monovalent JN.1-lineage-based antigen composition, preferably the LP.8.1 strain.

Dr. MacNeil provided an overview of the current routine COVID-19 vaccine schedule by age group. Children aged 6 months to 4 years who are unvaccinated may receive a multidose initial series with a 2024–2025 COVID-19 mRNA vaccine, using shared clinical decision-making. Those who have previously completed an initial series may receive one dose of a 2024–2025 mRNA vaccine from the same manufacturer, under shared clinical decision-making.

Individuals aged 5–17 years may receive one age-appropriate dose of a 2024–2025 COVID-19 vaccine using shared clinical decision-making. Adults aged 18–64 years should receive one dose of any 2024–2025 COVID-19 vaccine, while those aged 65 and older should receive two doses of any 2024–2025 COVID-19 vaccine, spaced six months apart.

The current recommendations for individuals with moderate or severe immunocompromise were also reviewed. Those who are unvaccinated should receive a multidose vaccination series with an age-appropriate 2024–2025 COVID-19 vaccine, followed by one additional 2024–2025 vaccine dose six months after completing the initial series.

Individuals who have previously completed an initial series should receive two doses of an age-appropriate 2024–2025 COVID-19 vaccine, spaced six months apart. Additional age-appropriate 2024–2025 COVID-19 vaccine doses may be administered under shared clinical decision-making.

It was noted that COVID-19 vaccines have had interim recommendations since 2020, developed with the understanding they would be revisited as new information became available.

In recent years, the work group explored non-universal recommendations, which would apply only to specific age or risk groups. At the ACIP meetings in September 2023 and June 2024, the work group presented interpretation summaries outlining discussions on universal versus non-universal policy options for the 2023–2024 and 2024–2025 vaccines, respectively.

Based on the available evidence and implementation considerations, a universal recommendation was ultimately supported. Since November 2024, the work group has discussed recommendations for the 2025–2026 season. At the April 2025 ACIP meeting, members considered adopting a non-universal recommendation.

Dr. MacNeil summarized that between November 2024 and June 2025, the COVID-19 work group reviewed epidemiology and disease burden, vaccine effectiveness, safety, and implementation considerations. At the most recent work group meeting on June 5 and follow-up polling, the group agreed on recommendation categories for the 2025–2026 COVID-19 vaccines. These include age-appropriate vaccination for all infants and children aged 6–23 months, as well as for individuals aged 2–64 years who are at high risk for severe COVID-19 (including pregnant individuals), those at high risk of exposure, and those who desire additional protection under shared clinical decision-making. The group also supported a recommendation for two doses of the 2025–2026 COVID-19 vaccine for adults aged 65 and older, as well as for individuals aged 6 months and older with moderate or severe immunocompromise.

Dr. Adam MacNeil (CDC/NCIRD) provided an update on the current epidemiology of COVID-19. CDC estimates that since October 1, 2024, there have been between 9.8 and 16.1 million COVID-19–associated illnesses, 2.4 to 3.8 million outpatient visits, 270,000 to 440,000 hospitalizations, and 32,000 to 51,000 deaths related to COVID-19.

Long COVID remains a significant public health concern. 2023 national surveys estimated that approximately 9.2 million adults and 0.3 million children in the United States had long COVID. Among adults, 3.6% reported current long COVID symptoms and 8.4% reported ever having long COVID. Among children, 0.4% reported current symptoms, and 1.4% reported having the condition at some point in their lives. More than three in five adults and nearly four in five children with long COVID reported experiencing activity limitations due to their symptoms.

COVID-NET, a population-based surveillance system that monitors laboratory-confirmed COVID-19–associated hospitalizations, was used for the presentation. It is part of the Respiratory Virus Hospitalization Surveillance Network, along with RSV-NET and FluSurv-NET, and includes >300 hospitals in 185 counties across 13 states. The surveillance area represents approximately 10% of the U.S. population. Hospitalizations are included if a positive COVID-19 test occurs within 14 days before admission or during hospitalization. Basic demographic data are collected for all patients, and detailed clinical data are gathered from a random sample stratified by age and site. Seasons are defined in the presentation as July 2024–June 2025 for rates, and clinical data reflect the most recent 12-month period, from April 2024 through March 2025.

COVID-19–associated hospitalization rates tend to peak both in the winter and the summer. This pattern differs from RSV and influenza, which generally follow a more consistent seasonal trend with a single peak, typically in the winter. Cumulative COVID-19–associated hospitalization rates for the July 2024–May 2025 period were higher during summer and fall 2024 and lower during the winter months compared to July 2023–June 2024. From July 2024 to April 2025, a period that included a high severity influenza season, more infants <1 year and adults ≥75 years of age had hospitalizations associated with COVID-19 than influenza. Cumulative COVID-19-associated hospitalization rates are highest among adults aged ≥75 years, followed by adults aged 65–74 years and infants aged <6 months.

The weekly number of COVID-19–associated deaths reported to the CDC in the United States from June 8, 2024, to June 7, 2025, showed a decreasing trend and remained low in the winter. Deaths during the winter were lower than those reported in the summer and fall of 2024. The number of deaths with COVID-19 listed as the underlying cause of death from July 2024 to June 2025 showed that while COVID-19 causes deaths across all age groups, 70% occurred in

adults aged 65 and older. Death certificate data likely underestimates COVID-19-associated deaths. Among in-hospital deaths in patients with laboratory-confirmed SARS-CoV-2, the proportion with a COVID-19 cause of death listed decreased from 95% in 2020 to 60% in 2022–2023. CDC estimates that since October 1, 2024, between 32,000 and 51,000 people have died in the United States from COVID-19.

The highest rates for COVID-19 in the New Vaccine Surveillance Network were observed in infants <6 months of age.

More than half of pediatric COVID-19-associated hospitalizations in COVID-NET occur in children aged <2 years. COVID-19 causes severe disease in infants younger than 6 months, who have the highest rates of COVID-19–associated hospitalization among all pediatric age groups. During July 2024 to May 2025, the cumulative COVID-19–associated hospitalization rate among infants was 268 per 100,000, comparable to the rate of 266 per 100,000 among adults aged 65–74 years. As noted earlier in the presentation, hospitalization rates are higher among those aged >75 years and lower among those aged <65 years.

Among infants <6 months old who were recently hospitalized for COVID-19, 22% were admitted to the ICU, 71% had no underlying medical conditions, and only 3.5% had any record of maternal COVID-19 vaccination during pregnancy. No COVID-19 vaccine products are approved for use in infants <6 months, so any protection must come from transfer of maternal antibodies, either from vaccination during pregnancy or prior infection.

Among vaccine-eligible children and adolescents ages 6 months–17 years, 41% of COVID-19-associated hospitalizations occurred among children ages 6–23 months.COVID-19-associated cumulative hospitalization rates are highest among the youngest age groups. The youngest age groups have comparable rates of cumulative COVID-19-associated hospitalization to some adult age groups, but direct comparisons are challenging. While most adults aged 50–64 years admitted for COVID-19 had underlying medical conditions, more than half of children aged 6–23 months were otherwise healthy prior to their COVID-19 hospitalization.

Among children aged 6–23 months hospitalized for COVID-19, 54% had no underlying medical conditions. Among those with an underlying condition, the most common was prematurity. In the three older pediatric age groups (ages 2–17 years), >70% of hospitalized children and adolescents had at least one underlying condition, with asthma or reactive airway disease and neurologic disorders being the most common. The proportion of hospitalized children with no underlying medical conditions decreases with increasing age.

One in four children aged <18 years hospitalized for COVID-19 required ICU admission. Among children <2 years who were admitted to the ICU, the majority (53%) had no underlying medical conditions. 89% of COVID-19 vaccine-eligible children and adolescents who were hospitalized with COVID-19 had no record of receiving the most recent recommended COVID-19 vaccines.

From July 2024 to June 2025, the number of COVID-19–associated deaths among children <2 years was similar to the number of influenza-associated deaths. Among children aged 2–17 years, influenza-associated deaths were higher. COVID-19 deaths are likely underestimated, as pediatric flu deaths were nationally notifiable during this period, while pediatric COVID-19 deaths were not.

Since March 2020, 128 COVID-19–associated deaths among children and adolescents have occurred within the COVID-NET catchment area, either during hospitalization or within 30 days after discharge. Of the 25 pediatric deaths reported since July 2023, 10 occurred during the most recent 12-month period from April 2024 through March 2025. These are raw counts, and the COVID-NET catchment area represents approximately 10% of the U.S. population.

Among the 25 deaths since July 2023, 52% were in children <2 years, and 72% had at least one underlying condition. Of the 16 children eligible for COVID-19 vaccination, 14 had no vaccination record, and none were up to date. Death certificate data reporting to COVID-NET is delayed. Among the 25 most recent deaths with complete mortality data, 28% had COVID-19 listed as a specific cause of death, while an additional nine deaths were attributed to other respiratory or circulatory causes.

Dr. MacNeil summarized that most pediatric COVID-19 hospitalizations occur in children <2 years old, and many of these children have no underlying medical conditions, including 71% of infants <6 months and 54% of children aged 6–23 months. Hospitalization rates are highest among infants <6 months, followed by those aged 6–23 months. Rates among infants <6 months of age are comparable to those of adults aged 65–74 years. No COVID-19 vaccine products are approved for infants <6 months, so any protection must come from maternal antibody transfer through vaccination during pregnancy or prior infection. Outcomes among hospitalized children can be severe, with 1 in 4 admitted to the ICU. COVID-19–associated deaths continue to occur among infants and children, and the majority of hospitalized, vaccine-eligible children and adolescents had no record of receiving the most recently recommended vaccine.

Adults ages ≥65 years comprise more than 2/3 of all COVID-19–associated hospitalizations among adults. Most adults hospitalized for COVID-19 have ≥1 underlying medical condition; a majority have ≥2. Among adults hospitalized for COVID-19, 15% were admitted to the intensive care unit (ICU). During this period, 85% of all adults hospitalized with COVID-19 who died in-hospital were ages ≥65 years.

Moving to COVID-19 hospitalizations among adults. Among adults hospitalized for COVID-19 from October 2024 through March 2025, vaccination status varied by age group. For adults aged 65 years or older hospitalized for COVID-19, 65% had received neither the 2023–2024 nor the 2024–2025 COVID-19 vaccine. One-third of the patients had received at least one dose of the 2024–2025 vaccine before admission, and 17% had received two doses.

Pregnancy status was collected for women aged 15–49 years who were hospitalized with a laboratory-confirmed SARS-CoV-2 infection. Of those hospitalized, 28.5% were pregnant, and 50% of these had COVID-19-related signs or symptoms. Among 131 hospitalized pregnant women with confirmed infection and symptoms, 50% had no underlying medical conditions. At discharge, 68% were no longer pregnant. Among these, 83% had a healthy newborn, 11% had a preterm birth, 1% had an ill infant, and 5% experienced pregnancy loss. Vaccination coverage was low, with 92% having no record of receiving a COVID-19 vaccine since July 1, 2023, and only 5.8% having received a recommended 2024–2025 COVID-19 vaccine dose.

Dr. MacNeil summarized the adult data by noting that rates of COVID-19–associated hospitalization are highest among the oldest adult age groups. Adults aged ≥65 years accounted for 72% of adult COVID-19—associated hospitalizations, and those aged ≥75 years made up 50%. Although hospitalization rates have decreased over time, cumulative rates among adults aged 75 years and older remain high. The risk of COVID-19–associated hospitalization continues year-round, with peaks in both winter and summer.

Among adults aged ≥65 years hospitalized with COVID-19, 65% had no record of receiving one or more doses of the recommended 2024–2025 COVID-19 vaccine before admission. Most adults hospitalized for COVID-19 had at least one underlying medical condition, and the majority had two or more.

Among SARS-CoV-2-positive pregnant women admitted from April 2024 to March 2025 with COVID-19–related symptoms at admission, half had no underlying medical conditions, and 92% had no record of COVID-19 vaccination since July 1, 2023.

The last part of the epidemiology presentation was on SARS-CoV-2 genomics. Since SARS-CoV-2 emerged in late 2019, the virus has continued to evolve with accumulating substitutions in the spike protein, which binds to the ACE2 receptor and is the main target for neutralizing antibodies. Over time, there have been periods of gradual genetic drift as well as more significant shifts when new lineages emerged with numerous changes.

The first major shift occurred in late 2021 to early 2022, with the transition from the Delta variant to Omicron. Subsequent shifts included the emergence of XBB lineages from BA.4 and BA.5 viruses, and more recently from XBB to JN.1. These shifts necessitated updates to the COVID-19 vaccine formulation to ensure continued protection.

In winter 2023-2024, we observed a strain replacement of XBB.1.5-like viruses to JN.1-like viruses. Since the emergence of JN.1, SARS-CoV-2 lineages have continued to evolve from this variant, but no complete strain replacement has been observed. All lineages that have predominated since the emergence of JN.1 are currently descendants of JN.1.

LP.8.1, XFC, and NB.1.8.1 are JN.1 lineage viruses. When comparing amino acid substitutions in the spike protein to the 2024–2025 COVID-19 vaccine formulation, there are only 2 to 4 changes in the receptor binding domain. In contrast, circulating viruses last summer had 13 or more changes in the spike receptor binding domain compared to the vaccine formulation at that time.

Dr. MacNeil summarized that current circulating SARS-CoV-2 viruses are descendants of JN.1, with 2 to 3 substitutions in the spike receptor binding domain compared to the KP.2 spike. These viruses are effectively neutralized by serum from individuals who received the 2024–2025 COVID-19 vaccine. Antigenic cartography shows that JN.1 viruses are antigenically similar. In May 2025, FDA's VRBPAC reviewed genomic and phenotypic data and unanimously recommended a monovalent JN.1-lineage vaccine for the 2025–2026 vaccine. FDA has advised manufacturers to use a JN.1-based vaccine, preferentially using the LP.8.1 strain.

Dr. Adam MacNeil (CDC/NCIRD) provided an update on vaccine effectiveness. For respiratory viruses, the CDC primarily uses case-control studies, including the test-negative design (TND), to measure vaccine effectiveness (VE). In the TND, individuals seeking care for respiratory illness are included. Cases are those who test positive for SARS-CoV-2, and controls are those who test negative.

Controls represent the population from which cases arise and help estimate COVID-19 vaccine coverage among people seeking care for respiratory illness. By comparing vaccination status between cases and controls, we determine VE. Higher vaccine coverage among controls suggests the vaccine provides protection. Because both groups sought care for similar symptoms, this design helps reduce confounding factors, such as age and geography, thereby clarifying the relationship between vaccination and illness.

VE results were shared from three CDC platforms. The VISION Network, one of the platforms, encompasses data from over 300 emergency departments (ED) and urgent care (UC) clinics, as well as more than 200 hospitals nationwide. It uses a test-negative design to evaluate VE among individuals of all ages with COVID-19–like illness. Cases tested positive for SARS-CoV-2 and did not positive for RSV or influenza. Controls tested negative for SARS-CoV-2 did not test positive for influenza or RSV, depending on age. Vaccination status is confirmed through electronic health records and immunization registries.

The second VE platform, the Overcoming COVID-19 Network, focuses on children, with enrollment at 26 pediatric hospitals across 20 states. The analysis presented assessed the effectiveness of COVID-19 vaccination during pregnancy in preventing COVID-19–related hospitalizations in infants under 6 months of age.

The third VE platform, the IVY Network, includes 26 hospitals across 20 states. Like VISION, IVY uses a test-negative design but with active enrollment, including patient interviews and nasal swabs. The analysis focused on adults aged ≥18 years hospitalized with COVID-19–like illness. Cases tested positive for SARS-CoV-2, while controls tested negative for SARS-CoV-2, influenza, and RSV. Vaccination history was determined through medical records, registries, and plausible self-report, with specimens collected for central testing and sequencing.

COVID-19 VE measurement approaches have evolved over the years. Initially, absolute VE was used to compare outcomes in vaccinated versus unvaccinated individuals. During the bivalent vaccine era, relative VE was also measured, comparing outcomes between different vaccine types (e.g., bivalent vs. original monovalent). For the 2023–24 and 2024–25 COVID-19 vaccines, VE estimates combine both approaches by comparing disease frequency in individuals who received the current vaccine with that in individuals who did not, regardless of their prior vaccination or infection history. This method aligns with how seasonal influenza VE is measured and reflects the added benefit of annual vaccination.

COVID-19 vaccination coverage in children remained low during both the 2023–24 and 2024–25 seasons. Coverage was similar across both years, with the lowest rates observed among children aged 6 months to 4 years in the 2024–25 season.

COVID-19 vaccine uptake among adults aged ≥18 years was just under 25% by the end of August 2024 for the 2023-2024 vaccine and the end of April 2025 for the 2024-2025 vaccine. Coverage for the 2024–2025 vaccine began increasing slightly earlier due to earlier recommendations and availability, but reached a similar overall level to 2023-2024 coverage by the end of April 2025.

Among Medicare fee-for-service beneficiaries aged ≥65 years, overall COVID-19 vaccination coverage for the 2024–25 season reached 28% by January 2025. Coverage was highest in beneficiaries with immunocompromising conditions (32%) and lowest in those without underlying medical conditions (24%).

For the 2023–24 season, COVID-19 VE against ED and UC visits was evaluated through August 2024 in VISION. The reference group included individuals who did not receive a 2023–24 vaccine. For those aged ≥5 years, this included unvaccinated individuals and those who had only received monovalent or bivalent doses. For children aged <5 years, both vaccinated and comparison groups had to complete an initial series. VE was generally comparable across age groups, with estimates for children being similar or higher than those for adults, consistent with trends observed in previous seasons.

For the 2024–25 season, COVID-19 VE against ED and UC visits was assessed for the 7 to 179 days post-vaccination period in VISION. Due to the lower number of COVID-19 cases, VE could not be stratified by time since the doses were administered. Overall, VE appeared similar or higher in children compared to adults, consistent with findings from the 2023–24 season.

Between March 2022 and May 2023, maternal COVID-19 vaccination was shown to be effective in protecting infants under 6 months of age from COVID–19–associated hospitalization, based on data from the Overcoming COVID-19 Network. Infants in this age group are not eligible for vaccination and are at higher risk of severe disease. VE was 54% during the first two months of life and 35% during the first five months. Effectiveness declined with time since maternal vaccination, consistent with patterns seen in older children and adults.

Among pregnant women aged 18–45 years in VISION, COVID-19 VE against ED and UC visits was highest when the dose was received during pregnancy, providing 52% protection. A dose received <6 months before pregnancy provided 28% protection, while a dose given ≥6 months before pregnancy was not statistically different from zero. These data, collected during 2022 and 2023 when Omicron was the dominant variant, reflect the pattern seen in non-pregnant adults and children, where more recent vaccination offers the greatest protection.

For the 2023–24 monovalent COVID-19 vaccines, VE in pregnant women (median 77 days post-vaccination) was similar to VE in non-pregnant women aged 18–45 years (median 83 days post-vaccination) in VISION. Due to limited statistical power, VE by time since dose could not be assessed.

During the 2024–25 season, COVID-19 VE against ED and UC encounters among adults aged ≥18 years was 34% overall for the 7–179 days following vaccination in VISION. VE was 36% for 7–59 days, 35% for 60–119 days, and 28% for 120–179 days post-vaccination. VE was similar between adults aged 18–64 years and those aged ≥65 years. Among individuals in the reference group who did not receive a 2024–25 COVID-19 vaccine, the median time since their last dose was approximately 1,000 days.

COVID-19 VE against hospitalization among adults aged ≥65 years without documented immunocompromising conditions was similar in both the VISION and IVY networks. During the 7–179 days after vaccination, VE was 44% in VISION and 46% in IVY. VE started at 46% in VISION and 42% in IVY, declining to 32% and 40% respectively, during the 120-179 days post-vaccination. Wider confidence intervals for later periods reflect smaller numbers of vaccinated cases and controls 4–6 months before their encounter.

Among adults aged ≥65 years, COVID-19 VE against critical illness remained relatively stable over time in both the VISION and IVY networks. In VISION, critical illness was defined as ICU admission or in-hospital death. VE remained consistent even 120–179 days after vaccination, suggesting durable protection against severe outcomes. In IVY, VE during the 7–179 days post-vaccination was assessed for three escalating outcomes: acute respiratory failure, ICU admission or death, and invasive mechanical ventilation or death. VE was highest for the most severe outcome, with 70% protection against invasive mechanical ventilation or death.

Among adults aged ≥65 years with immunocompromising conditions, COVID-19 VE against hospitalization during the 2024–25 season was 38% in VISION and 36% in IVY. Although IVY did not have sufficient statistical power to estimate VE by time since dose, VISION appear to show a trend of increasing VE over time. This pattern has been observed previously and is likely due to faster waning of infection-induced immunity in immunocompromised individuals, making the reference group less protected over time. VE in this group was similar to that in non-immunocompromised adults, indicating the vaccine is providing meaningful protection.

A sub-analysis from the IVY Network assessed COVID-19 VE against hospitalization by viral lineage, using whole genome sequencing to confirm KP.3.1.1 and XEC lineages. VE was calculated separately for each lineage, with controls defined as patients with COVID-like illness who tested negative for SARS-CoV-2, influenza, and RSV. VE was similar across lineages, with overlapping confidence intervals. Point estimates were 45% for KP.3.1.1 (median 56 days since vaccination) and 34% for XEC (median 87 days), with the difference likely due to time since vaccination.

Dr. MacNeil concluded that, for both the 2023–24 and 2024–25 seasons, in-season COVID-19 vaccination provided additional protection compared to no in-season dose. This included protection against COVID-19–associated ED and UC visits among children and adults, hospitalizations among adults aged ≥65 years with and without immunocompromising

conditions, and critical illness in older adults. Protection was generally similar across age groups and appeared to be higher and more durable for more severe outcomes.

VE should be interpreted as the added benefit of the 2023–24 or 2024–25 COVID-19 vaccination in a population with high levels of infection-induced, vaccine-induced immunity, or both. Prior SARS-CoV-2 infection contributes to protection against future illness, but this protection, like that from vaccination, wanes over time. Increased SARS-CoV-2 circulation in late summer 2024, just before the approval of the 2024–25 vaccines, may have raised population-level immunity against JN.1 lineage strains, potentially contributing to lower VE estimates during the season.

Dr. Kulldorff asked about vaccine efficacy results from randomized, double-blind, placebo-controlled trials, which are considered the gold standard in medical research. He noted his appreciation for the focus on hospitalizations and deaths, emphasizing that these are the most important outcomes when evaluating COVID-19 vaccines.

Dr. MacNeil responded that many of the randomized controlled trials were conducted in largely SARS-CoV-2 naïve populations, whereas the current context involves individuals with multiple exposures to vaccines, prior infection, or both. As a result, clinical trial data are not directly comparable to present-day vaccine effectiveness estimates. Instead, current efforts focus on monitoring the real-world impact of COVID-19 vaccines. Across age groups, the added benefit of recent vaccination has generally ranged from 30% to 50%, reflecting the value of continued vaccination in populations with existing immunity.

Dr. Kulldorff responded by emphasizing the importance of having a control group that represents the general population in observational studies. He noted that this is best achieved through cohort studies. In case-control studies, controls should ideally be drawn from the general population. He expressed concern about the test-negative design, where controls are individuals with non-COVID respiratory illnesses, which may represent a distinct population with different vaccination behaviors. He asked whether most of the presented results were based on the test-negative design or if any were derived from cohort studies or traditional case-control designs.

Dr. MacNeil acknowledged that case-control studies have limitations compared to traditional cohort studies. He explained that all platforms used for the presented data rely on case-control designs, with most using a test-negative design. This approach allows for efficient data collection in large populations without being cost-prohibitive. He noted that with sufficient sample sizes, these designs can produce relatively accurate estimates of VE.

Dr. Meissner raised a concern about the definition of COVID-19–associated hospitalizations used in the data. He noted that many slides referenced hospitalization rates based on a positive RT-PCR test for SARS-CoV-2 but emphasized that this does not necessarily mean the patient was hospitalized due to COVID-19. He pointed out that being hospitalized with COVID-19 is different from being hospitalized for COVID-19. Citing a study previously conducted by the Commonwealth of Massachusetts, he mentioned that less than half of patients with a positive test were being treated for COVID-19, suggesting that the presented hospitalization numbers may overestimate the burden of severe COVID-19 illness.

Dr. Taylor explained that COVID-NET comprises two components: population-based hospitalization rates based on laboratory-confirmed SARS-CoV-2 positive tests, and clinical data from a filtered sample of hospitalizations. While the rates include all lab-confirmed cases regardless of the reason for admission, the clinical data focus only on hospitalizations where COVID-19 was identified as the likely cause. He noted that this distinction is reflected in the footnotes on the slide. Dr. Taylor also referenced a peer-reviewed study published in *Influenza*

and Other Respiratory Viruses, which found that during the 2022–2023 period, 86 percent of adult hospitalizations with lab-confirmed COVID-19 were attributable to the virus. Attribution was based on factors such as illness related to COVID-19 at admission, treatment during hospitalization, or discharge diagnoses indicating conditions like pneumonia or ARDS.

Dr. Meissner responded by noting that the severity of COVID-19 has decreased since the 2022–23 period. He acknowledged that hospitalization rates are now much lower. He suggested that this could be due to viral mutations leading to less severe illness, increased population-level immunity from vaccination or prior infection, or a combination of both. He also raised a similar concern regarding COVID-19–associated deaths, questioning how many occurred in individuals with symptoms consistent with a viral infection versus those who were classified as COVID-19 cases solely due to a positive test upon hospital admission, as some hospitals require routine testing for all admitted patients.

Dr. Taylor responded that this is an important question and shared that an analysis is currently underway to examine deaths using the most recent years of death certificate data. The team is in the mid-stages of this work and plans to present its findings to ACIP once they are available. He also noted that, early in the pandemic, all hospital admissions were routinely screened for COVID-19; however, this is no longer standard practice in most hospitals. Preliminary data from the 2021–22 and 2022–23 seasons suggest that the proportion of hospitalizations attributable to COVID-19 has slightly increased over time. This is likely due to reduced screening, meaning that those now tested for COVID-19 are more likely to have symptoms consistent with COVID-19 illness, rather than being asymptomatic.

Dr. Meissner noted that, based on the most recent CDC data, hospitalization rates for children aged 0–4 years are less than one per 100,000. For children under six months, the rate is approximately 1.6 per 100,000. He asked if this was an accurate interpretation and emphasized that, in his view, COVID-19 is currently a very rare cause of hospitalization in both young children and adults.

Dr. MacNeil responded by emphasizing the importance of considering overall cumulative numbers, noting that COVID-19 continues to pose a substantial burden, particularly among the youngest and oldest age groups. He added that comparisons to influenza, as shown in the earlier slides, highlight that COVID-19 still presents areas for concern.

Dr. Meissner questioned whether Dr. MacNeil felt the rates were accurate.

Dr. MacNeil emphasized that COVID-NET has been a robust platform, capturing data from approximately 10% of the U.S. population and allowing for strong characterization of illness. He noted that while modeled national estimates based on this data come with some uncertainty, the confidence intervals are reasonable, and the resulting burden estimates fall within a reliable and consistent range.

Dr. Meissner commented on the reference to influenza, noting that while early comparisons between COVID-19 and influenza were common, including himself, it has become clear that the two viruses behave quite differently. He explained that orthomyxoviruses, like influenza, differ from coronaviruses in how they mutate and spread. He referred to the concepts of antigenic shift and drift, suggesting that continued comparisons may not be appropriate, as the viruses are fundamentally different.

Dr. MacNeil acknowledged Dr. Meissner’s point, clarifying that the intent was not to suggest that the pathophysiology of influenza and COVID-19 are the same, but rather to compare the overall population burden. He agreed that it's a valid distinction. He added that it may also be appropriate to consider using different terminology for COVID-19, rather than borrowing terms like "drift" and "shift" from influenza. He explained that the key point is the observation of large,

sudden changes in circulating COVID-19 variants that allow the virus to evade pre-existing immunity. He noted that it may be worth further discussion with influenza experts about adopting more accurate terms for these rapid changes in dominant COVID-19 variants.

Dr. Levi questioned the test-negative design, noting that it compares the proportion of vaccinated individuals among SARS-CoV-2–positive patients with those who test negative. He proposed that a lower vaccination rate in the positive group might still be consistent with vaccines increasing overall susceptibility to multiple respiratory viruses, with vaccinated people appearing in both groups but slightly less often among the positives. Such a scenario, he argued, could create the appearance of vaccine effectiveness even if vaccination provides no benefit or increases vulnerability. He added that some of the data presented suggest this may be occurring, as the rate of hospitalization among people with updated vaccination appears higher than their relative proportion in the general population. He stated this should raise concern and prompt further consideration of alternative explanations beyond vaccine efficacy.

Dr. Link-Gelles explained that the goal of the TND is to use controls that represent the vaccination coverage in the population from which the cases originated. A key strength of TND is that controls have the same symptoms as the cases and seek care and testing at the same facilities, making them population-based in this context. She emphasized that while the controls are not representative of the general population, they are representative of individuals who would have been hospitalized if they had COVID-19. In this analysis, controls are often older adults hospitalized with acute respiratory illness, so their vaccination coverage would not be expected to match that of the broader, generally healthier U.S. population. Due to this design, the controls are considered suitable for estimating the relative impact of vaccination.

Dr. Hoeg expressed concerns about the potential for confounding in the test-negative design, echoing the points raised by Dr. Kulldorff and Dr. Levi. She questioned why patients who test positive for influenza and, in people aged ≥60 years, RSV, are excluded if the goal is to compare groups with similar symptoms, with one group testing positive for COVID-19 and the other not. She noted that these groups may differ in meaningful ways, making it difficult to ensure they are truly comparable. Dr. Hoeg emphasized the importance of randomized controlled trials in minimizing bias and avoiding uncertainty about whether observational data accurately reflects VE.

Dr. Link-Gelles responded that including individuals who test positive for another vaccine-preventable disease as controls or cases could introduce bias into the study. She explained that vaccine status is correlated across diseases, and individuals who test positive for influenza or RSV are often less likely to have received those vaccines, which also makes them less likely to have received the COVID-19 vaccine. This correlation can distort the results. She cited published literature supporting this concern and explained that, for this reason, controls who test positive for influenza or RSV are excluded. She also noted that the study teams work closely with sites to ensure that cases and controls have similar symptoms, and they have analyzed and published data confirming that symptom profiles and severity are balanced between groups.

Dr. MacNeil added that while randomized clinical trials are valuable, there are real-world limitations related to time and cost. He emphasized that the test-negative design provides a robust and efficient method for generating real-world vaccine effectiveness data promptly. For example, reviewing VE data from the most recent season in June would not be feasible using randomized trials due to the time required for enrollment, follow-up, and analysis. He noted that for the CDC, the test-negative design is a practical and effective approach to assess the real-world impact rapidly.

Dr. Levi commented on the genomic evolution of SARS-CoV-2 variants, noting that while there is continuous evolution, two major jumps stand out. He raised two questions related to this

observation. First, he asked whether any analysis has been done to compare this pattern to other viruses, such as influenza, to determine how common such large evolutionary jumps are. Second, he inquired about the evolutionary pressures that might be driving these shifts, as such changes typically result from natural selection. He also questioned whether there has been any analysis of a possible connection between vaccination policies and the observed evolution of the variants, noting that the pattern appears striking.

Dr. MacNeil responded that the evolution of COVID-19 has indeed been full of surprises, with the emergence of major variants, such as Omicron, representing sudden and significant changes. He noted that these large shifts likely reflect a combination of selective pressures within the human population, such as pre-existing immunity, as well as unique characteristics of the virus itself. He emphasized that the situation is complex and dynamic. Dr. MacNeil also emphasized the importance of ongoing genomic surveillance and real-time sequencing, which enable experts to detect and monitor variant changes as they emerge. He emphasized the importance of maintaining this capacity to respond quickly to any unexpected shifts in the virus.

Dr. Meissner added to the discussion by noting the increasing complexity of SARS-CoV-2 evolution, particularly the emergence of convergent evolution, where different strains develop the same mutations in specific regions of the spike protein. He emphasized that this makes the situation even more challenging to analyze. Shifting to the topic of study design, Dr. Meissner acknowledged that the case-control approach, including the test-negative design, is not perfect and carries certain limitations, such as a potential bias toward individuals who are more likely to seek medical care. However, he pointed out that it remains the most practical option for evaluating vaccine effectiveness within a limited timeframe, as is done with influenza vaccines, which are updated annually. He concluded that, despite its flaws, the case-control design is a well-established method for evaluating vaccines.

Dr. Kulldorff emphasized the importance of distinguishing between traditional case-control studies and the test-negative design. He noted that, methodologically, these are very different approaches and that the quality of the information they produce can vary significantly.

Dr. Taylor clarified a question regarding the COVID-NET hospitalization rates presented earlier by Dr. MacNeil. He explained that the figures shown on the slides represent cumulative rates, which are the sum of weekly hospitalization rates over a period from July 2024 through May 2025. For children <6 months, the cumulative hospitalization rate was 268 per 100,000, comparable to the rate among adults aged 65 to 74 years. For children aged 6 to 23 months, the cumulative rate was 100 per 100,000, similar to the rate for adults aged 50 to 64 years, which was 103 per 100,000. Dr. Taylor emphasized that while weekly rates may seem small, the cumulative rates provide a more accurate picture of disease burden over time.

Dr. Levi asked whether the proportions of COVID-19–associated hospitalizations by age group differ from overall hospitalization patterns for all causes. Specifically, he questioned whether the distribution seen here deviates from general hospitalization trends across age groups or if it is consistent with typical patterns.

Dr. Taylor responded that COVID-NET, as one of the RESP-NET platforms, is specifically designed to collect data on SARS-CoV-2–positive, COVID-19–associated hospitalizations. As such, it does not include data on all-cause hospitalizations and cannot be used to directly compare COVID-19 hospitalization rates to general hospitalization rates across age groups. He noted that while previous ACIP meetings have included analyses comparing underlying conditions among adults hospitalized with COVID-19 to those in the general population, COVID-NET data do not support comparisons between COVID-specific and general hospitalization patterns.

Dr. Sarah Meyer (CDC/NCEZID) shared an update on how the CDC monitors vaccine safety. The CDC and interagency partners launched a comprehensive vaccine safety monitoring program for COVID-19 vaccines. A wide range of potential safety outcomes has been rigorously assessed through complementary passive and active surveillance systems. Myocarditis has been causally linked to mRNA COVID-19 vaccines. Common adverse events, such as local and systemic reactions and allergic responses, have also been observed. The CDC continues to actively monitor the safety of COVID-19 vaccines.

Vaccine safety monitoring is essential throughout the vaccine life cycle, from early research and clinical trials to regulatory review. After a vaccine is authorized or approved, the CDC begins safety monitoring in coordination with the FDA, the Indian Health Service, the Department of Defense, and the Department of Veterans Affairs.

The CDC employs a robust, complementary system of layered safety monitoring to promptly identify and evaluate potential concerns, enabling public health officials and policymakers to take timely action. Most systems have been in place for decades, but the CDC continues to improve existing systems and develop new ones to fill gaps, such as v-safe, which was launched to monitor the safety of COVID-19 vaccines.

The Vaccine Adverse Event Reporting System (VAERS) is the nation's early warning system for vaccine safety, co-managed by the CDC and the FDA. It relies on spontaneous reports from across the country to detect potential safety signals, including rare events. Healthcare providers and manufacturers are required by the National Childhood Vaccine Injury Act to report certain adverse events; however, patients or their family members can also submit reports. It's essential to note that reporting an event to VAERS does not necessarily mean that the vaccine caused it. VAERS is used for signal detection and hypothesis generation, not to determine causality.

The Vaccine Safety Datalink (VSD) is a collaborative system that generates high-quality data on vaccine safety. It includes 13 integrated healthcare organizations and serves approximately 15.5 million people annually. VSD uses active surveillance through electronic medical records and chart reviews, enabling rapid monitoring of both prespecified and unexpected events. Unlike VAERS, which is primarily used for signal detection, VSD can detect and assess safety signals. The network is also known for its strong expertise, which has led to the development of innovative methods for monitoring vaccine safety.

The Clinical Immunization Safety Assessment (CISA) Project is a network that supports vaccine safety from the individual to the population level. It includes eight medical research centers with vaccine safety experts and specialists. CISA provides clinical consultations on complex immunization issues to support patient care and research real-world vaccine safety questions not addressed in pre-licensure trials. CISA consultants also help inform the CDC’s public health guidance on clinical immunization safety issues.

V-safe After Vaccination Health Checker is the CDC’s newest tool for direct-to-consumer vaccine safety monitoring. It is a smartphone and web-based, self-reported active monitoring system established during the COVID-19 pandemic. v-safe can provide early information on reactogenicity and other health events, especially for new vaccines and populations not included in clinical trials. For example, it helped enroll over 23,000 pregnant women into a voluntary registry to monitor maternal and neonatal outcomes after COVID-19 vaccination. V-safe is flexible, quickly deployable, and plays a key role in emergency preparedness and response. It is also integrated with VAERS to streamline reporting serious adverse events.

These systems support the CDC’s comprehensive approach to COVID-19 vaccine safety, which includes surveillance of reported events, epidemiologic studies, clinical research, and a pregnancy registry. The approach also utilizes rapid cycle analysis, data mining of over 60,000

outcomes, and patient surveys to identify and assess potential safety concerns and health impacts following vaccination.

An overview of the extensive body of evidence on COVID-19 vaccine safety was provided. Since the rollout in December 2020, data have been documented in 17 Vaccine Safety Technical Work Group reports, 28 presentations to federal advisory committees, 29 publications in the MMWR, 114 peer-reviewed manuscripts, and through nearly 10 million participants enrolled in v-safe. This information was collected during the largest vaccination effort in U.S. history, with approximately 1 billion doses distributed.

Dr. Meyer recapped that three types of COVID-19 vaccines were authorized or approved for use in the United States: mRNA vaccines by Pfizer-BioNTech and Moderna, a protein-based vaccine by Novavax, and a viral vector-based vaccine by Janssen. The use of the Janssen vaccine became limited in April 2021 after the VAERS system detected six reports of thrombosis with thrombocytopenia syndrome (TTS). In response, the FDA and the CDC issued a 10-day pause in its use. By December 2021, ACIP issued a preferential recommendation for mRNA vaccines, and in June 2023, the EUA for Janssen was revoked. The vaccine is no longer in use in the United States. This situation highlighted how federal safety systems worked together to identify and address a concern regarding vaccine safety promptly.

Dr. Meyer noted that post-authorization safety data for Novavax remain limited due to its later authorization in July 2022 and low uptake in the U.S. Therefore, the remainder of the discussion focused on the safety of mRNA COVID-19 vaccines, which are supported by a large and growing body of evidence.

The CDC has evaluated at least 65 specific outcomes to assess the safety of the COVID-19 vaccine using a variety of systems and epidemiologic methods. Since December 2020, weekly rapid cycle analyses (RCAs) in the Vaccine Safety Datalink have tracked up to 23 prespecified outcomes in over 12 million people, based on clinical trial data, known vaccine risks, and biological plausibility.

Automated statistical testing compares rates of outcomes in post-vaccination risk intervals with those in comparison periods. When a signal is detected, further analysis or chart review is conducted. The system is designed to be sensitive, and not all signals indicate a true safety concern.

Between 2020 and 2025, eight statistical signals were identified through VSD's weekly rapid cycle analyses. These included acute myocardial infarction, venous thromboembolism, immune thrombocytopenic purpura, ischemic stroke, seizure, Guillain-Barré syndrome, Bell's palsy, and myocarditis.

When a signal is detected, the CDC conducts further investigations to determine if it reflects a true safety concern or a false positive. These follow-up steps include chart reviews, trend and cluster analyses, additional studies such as self-controlled case series, and a review of data from other monitoring systems, including VAERS and partner databases managed by the FDA and VA.

After completing these investigations, the CDC determined that there is an increased risk of myocarditis following mRNA COVID-19 vaccination. No clear or consistent evidence of a safety concern was found for the other outcomes mentioned.

Using data from the Vaccine Safety Datalink, the CDC assessed the incidence of myocarditis within seven days of COVID-19 vaccination among individuals aged 12–39 years, by season and dose. Rates were highest in males, peaking among those aged 16–17 years. Myocarditis was rare in children <12 years and in adults >50 years. The risk was highest after the second

dose in the primary series but remained elevated after the first monovalent booster. In later seasons, incidence declined and approached the background rate of <2 cases per million. Similar patterns have been observed in VAERS reports. Several factors may explain the decline in myocarditis rates in recent years, including increased overall population immunity, a longer interval between doses, and fewer people receiving more than one dose per year.

The FDA recently shared updated data on myocarditis and pericarditis following mRNA COVID-19 vaccination from the Biologics Effectiveness and Safety (BEST) system during the 2023–2024 season. In April, the FDA issued safety labeling change notification letters to vaccine manufacturers, instructing them to include new information on myocarditis and pericarditis. FDA approved safety labeling updates for Comirnaty and Spikevax to reflect this new safety information.

CDC follow-up studies show that most adolescents and young adults have recovered from myocarditis after receiving an mRNA COVID-19 vaccine. These studies included individuals aged 12–29 years with a VAERS report filed between January and November 2021, along with input from their healthcare providers. Based on assessments by cardiologists or other providers, 83% were considered fully or probably recovered within 90 days of symptom onset, and by one year, at least 90% had recovered.

Most individuals showed improvement in symptoms, as well as in cardiac imaging and testing results. A subset who underwent cardiac MRI one year after onset most commonly showed late gadolinium enhancement, which may suggest the presence of fibrosis. However, the clinical significance of this finding is unclear, as most were considered recovered and had been cleared for all activity. There were no known deaths or cardiac transplants in this group.

COVID-19 vaccine safety data for children aged 6 months to 11 years show a low risk of myocarditis, particularly in those under 5 years. No statistical signals for myocarditis have been detected in the Vaccine Safety Datalink, and no confirmed cases have been reported in VAERS or the VSD for children under 5. VSD rapid cycle analyses also found no increased risk for 22 other prespecified outcomes. Most cases of MIS-C after vaccination had evidence of prior SARS-CoV-2 infection.

The majority of COVID-19 vaccine reports submitted to VAERS for children <12 years were related to vaccine administration errors. From October 2021 to April 2025, approximately 74% of reports for children aged 6 months to 4 years and 70% for those aged 5 to 11 years involved errors, such as expired product, incorrect dose or formulation, administration to the wrong age group, or preparation issues. Few of these reports included an actual adverse event. The high number of administration error reports likely reflects the complexity of the pediatric COVID-19 vaccination program, particularly early in the rollout when dosing, recommendations, and storage requirements varied by product. CDC is expanding its efforts to prevent vaccine administration errors in collaboration with the FDA.

CDC has actively assessed the safety of COVID-19 vaccines in pregnant women through multiple efforts. A voluntary pregnancy registry enrolled over 23,000 pregnant participants to monitor outcomes. Additionally, the CDC has conducted seven observational studies using survey and medical record data. In the Vaccine Safety Datalink, over 45,000 pregnant women have been evaluated through 11 cohort, case-control, and surveillance studies to date.

Across these CDC studies, the evidence shows no increased risk of adverse maternal outcomes associated with COVID-19 vaccination, including 25 medically attended adverse events, serious acute events, pregnancy-related conditions, or maternal ICU admissions. Vaccination was also not associated with adverse pregnancy outcomes such as miscarriage,

stillbirth, preterm birth, or small for gestational age. Additionally, no association was found between maternal vaccination and major birth defects, neonatal ICU admission, or infant death.

The CDC has conducted studies to address public concerns about the safety of the COVID-19 vaccine. In response to reports of abnormal uterine bleeding, analyses using VAERS, VSD, and v-safe found no association between vaccine availability and the incidence of medically attended abnormal uterine or postmenopausal bleeding. The vaccine was also not linked to increased bleeding severity. CDC also assessed reports of tinnitus using data from VAERS and VSD. No safety signals were detected, and findings did not support an increased risk of tinnitus following COVID-19 vaccination.

CDC monitors death reports following mRNA COVID-19 vaccination through VAERS. As of May 30, 2025, 19,417 domestic deaths had been reported after vaccination. Under FDA emergency use authorizations and CDC provider agreements, healthcare providers were required to report all deaths occurring within 30 days after COVID-19 vaccination, regardless of cause or circumstances. This requirement does not apply to other vaccines.

VAERS is not designed to assess causality. CDC evaluated deaths reported following mRNA COVID-19 vaccination through January 31, 2023. During this period, the CDC received 17,631 domestic VAERS reports of death following COVID-19 vaccination. After clinical review, 52 were excluded as they did not represent actual deaths, 1,790 involved non-mRNA vaccines, and 2,940 lacked a confirmed cause of death.

This left 12,849 reports with confirmed causes of death, identified through autopsy, death certificate, medical records, or the VAERS report. Among these, 78% were aged ≥65 years, 15% were 50–64, 6% were 18–49, and 5% were <18 years.

CDC assessed all reported deaths in the general U.S. population during this period using death certificate data from the National Center for Health Statistics' multiple cause of death database, categorized by ICD-10 codes. Observed-to-expected ratio analyses were conducted for each age group by comparing the number of cause-specific deaths reported to VAERS within 42 days of mRNA COVID-19 vaccination to the number of expected deaths in the general U.S. population.

CDC found that reported death rates after mRNA COVID-19 vaccination were below background rates in the general U.S. population. The most common causes of death reported to VAERS, such as heart disease, COVID-19, cerebrovascular disease, and general signs and symptoms like shock, were consistent with the leading causes of death nationally. In children, congenital malformations were also reported, and among adults aged ≥18 years, malignant neoplasms were included.

Across all age groups, the observed-to-expected death ratio was <1, indicating fewer reported deaths than expected within 42 days of vaccination. Despite the limitations of VAERS, these findings suggest no association between mRNA COVID-19 vaccination and increased mortality.

In addition to reviewing VAERS reports, the CDC conducted two self-controlled case series evaluations using the Vaccine Safety Datalink, one in the general population aged 12 years and older and one in Medicare beneficiaries aged 65 years and older. Pfizer and Moderna vaccines were analyzed separately. Both studies found no increased risk of non-COVID-19 mortality, all-cause mortality, cardiac-related mortality, or non-COVID-19 cardiac-related mortality within 28 days following vaccination. Relative incidence rates were significantly <1 in all cases.

These findings are consistent with results from a separate cohort analysis in the VSD. The robust methods used across these analyses provide strong evidence of no increased risk of death after mRNA COVID-19 vaccination and suggest a potential protective effect.

CDC uses data mining in the Vaccine Safety Datalink to detect unexpected adverse events following COVID-19 vaccination. This approach evaluates over 60,000 possible outcomes within 70 days of vaccination using tree-based analysis of ICD-10 codes. Assessments have been conducted for the primary series, initial booster, and bivalent booster. No new safety concerns have been identified beyond known events such as myocarditis, pericarditis, allergic reactions, and common local or systemic reactions.

Dr. Meyer summarized that several adverse events have been identified following mRNA COVID-19 vaccination. Most, such as local and systemic reactions, acute allergic reactions, syncope, and shoulder injuries, are common to many vaccines. Myocarditis and pericarditis have also been observed specifically following COVID-19 vaccination. These conclusions are based on the evaluation of at least 65 specific safety outcomes, data mining of over 60,000 potential outcomes, investigation of multiple statistical signals, and numerous epidemiologic studies.

These findings align with the National Academies of Sciences, Engineering, and Medicine's consensus report on the adverse effects of COVID-19 vaccines, commissioned by HRSA and published in 2024. The report reviewed over 400 studies on vaccine safety. It concluded that there is evidence supporting a causal association between mRNA COVID-19 vaccines and myocarditis. It also found that the evidence favors rejecting a causal link between vaccination and six other outcomes: Guillain-Barré syndrome, Bell’s palsy, TTS, myocardial infarction, ischemic stroke, and female infertility. For 13 other outcomes, the evidence was deemed inadequate to accept or reject a causal relationship.

COVID-19 vaccines have been evaluated under the most extensive vaccine safety monitoring program in U.S. history. This surveillance quickly identified and characterized the risk of myocarditis following mRNA vaccination. No other confirmed safety concerns have been identified beyond those commonly seen with other vaccines, such as local reactions, systemic symptoms, or allergic responses. CDC continues to prioritize COVID-19 vaccine safety, with at least 30 ongoing studies or monitoring activities.

Dr. Hibbeln stated that he has long been interested in risk-benefit evaluations and asked whether a broad summary of the data presented would be accurate. He noted that the evidence suggests a minimal to no risk of death from receiving a COVID-19 vaccine, whereas Dr. MacNeil’s presentation indicated a substantial risk associated with not being vaccinated. He asked whether it would be reasonable to describe the benefit of vaccination as a 40- to 50-percent reduction in risk, with essentially zero risk of death from the vaccine. He framed this as a general assessment of the overall risk-benefit balance.

Dr. Meyer responded that several studies have been conducted to evaluate the risk of mortality following COVID-19 vaccination, and no increased risk has been observed. In VAERS analyses comparing observed to expected deaths, the data did not show a higher-than-expected number of deaths. Similarly, evaluations using the Vaccine Safety Datalink found no increased risk of mortality after vaccination. From a safety perspective, the data support confidence that COVID-19 vaccines are not associated with an increased risk of death. Regarding the overall risk-benefit assessment, Dr. Meyer noted interest in hearing the committee’s evaluation of those factors.

Dr. MacNeil added a rough estimate to illustrate the potential impact of vaccination on COVID-19 mortality. Using a hypothetical scenario, if there were about 40,000 COVID-19-related deaths in a year and none of those individuals had been vaccinated, then applying the observed vaccine effectiveness, approximately half, or about 20,000, of those deaths might have been prevented. This was presented as a general approximation to highlight the potential benefit of vaccination in reducing deaths.

Dr. Malone asked for clarification on the safety monitoring timeframes presented. Specifically, the question focused on whether the post-vaccination periods, defined as either 28 days or 42 days, apply to individuals who have completed at least two doses. Dr. Malone requested clarification on how "post-vaccination" is defined in the context of the data that was shared.

Dr. Meyer responded that the analyses included individuals who had received at least one dose of a COVID-19 vaccine. For the VSD analyses, three separate evaluations were conducted: one after completion of the primary series, one following the original booster, and one after receiving the Omicron booster.

Dr. Malone followed up by asking whether the analysis of adverse event associations, like the mortality analysis, was also limited to a 28-day post-vaccination window.

Dr. Weintraub explained that analyses for the Vaccine Safety Datalink were set up to examine 21-day and 42-day risk intervals following doses one and two of the primary series. This approach has been consistently applied with each new vaccine recommendation, including the most recent season. The 42-day window also allows for scanning of shorter time intervals within that period to identify potential clusters of increased risk, using Martin Kulldorff's clustering method. It is standard practice to use a 42-day risk interval and to compare it to a historical control period, typically days 43 to 84 after vaccination.

Dr. Malone commented on the presentation of the adverse events assessed, noting that the slide listing the 65 outcomes was difficult to interpret. He suggested that it would be helpful if the information were structured more clearly, such as in alphabetical order, to better understand the full range of events evaluated. Based on his review, he inferred that hypertension, tachycardia, and POTS were included in the analyses and were not found to be associated with COVID-19 vaccination.

Dr. Meyer responded by explaining that both VAERS and the Vaccine Safety Datalink (VSD) use prespecified lists of outcomes to monitor and flag for further review. In addition to tracking prespecified outcomes, VSD also investigates other emerging concerns as needed.

Dr. Meyer acknowledged that the slide listing the 65 outcomes was intended to provide a brief overview and could be made clearer. A more detailed list can be shared if needed. She also noted that data mining is used to detect unexpected outcomes without specifying them in advance. None of the conditions mentioned, including POTS, appeared as signals in the data mining. While some studies on outcomes, such as POTS, have been referenced in the National Academies report, the available data are limited. Based on the CDC's comprehensive approach, including both targeted analysis and broad surveillance, the primary safety concerns identified remain myocarditis and common vaccine-related reactions.

Dr. Malone emphasized the public's need for transparency and recommended that a clear, comprehensive list of all safety outcomes and analyses be made publicly available. He also asked whether potential lot-to-lot variability in vaccine manufacturing had been examined, noting that such variability could mask clusters of adverse events when data are viewed in aggregate, and requested details on how this issue has been addressed.

Dr. Meyer responded that the CDC works closely with interagency partners on vaccine safety, with each agency having distinct roles. She noted that lot-specific issues are typically assessed by the FDA and deferred to FDA colleagues for any additional information on that topic.

Dr. Meissner emphasized that physicians are trained to report any adverse event (AE) after vaccination to VAERS, regardless of causality. Given the high volume of vaccinations, many reported AEs are unrelated to the vaccine. He clarified that VAERS is not used to determine incidence rates but to detect safety signals, which are then evaluated further using systems like

VSD. He noted most VAERS reports do not indicate a causal relationship. Dr. Meissner then asked Dr. Meyer about the long-term follow-up of myocarditis cases, particularly regarding individuals with late gadolinium enhancement on cardiac MRI, which may suggest scarring and potential risk for arrhythmias or sudden death. He also inquired about data from manufacturers on troponin levels and markers of subclinical myocarditis, which he understood had been requested but had not yet been reported.

Dr. Meyer responded that some studies have evaluated subclinical myocarditis, including those that measure biomarkers such as troponin in asymptomatic individuals. These studies have not shown adverse clinical outcomes in those cases. However, the long-term significance remains uncertain and requires ongoing monitoring. CDC is closely tracking this issue, and FDA is conducting similar studies with comparable findings. This information is expected to be included in upcoming safety labeling updates, and both the CDC and the FDA plan to continue long-term monitoring.

Dr. Levi questioned whether traditional vaccine safety surveillance methods, which focus on short-term adverse events, are sufficient for COVID-19 vaccines, given evidence that residual mRNA and spike protein may persist in the body for months. He suggested this could reduce the sensitivity of current approaches and called for broader methods. He cited a VA study showing higher adverse events with Pfizer compared to Moderna. He emphasized the importance of accounting for factors like the healthy vaccinee effect when comparing mortality rates. He asked whether surveillance systems are adapting to address the unique characteristics of COVID-19 vaccines.

Dr. Meyer responded that the United States has one of the strongest vaccine safety systems in the world and expressed confidence in its current approach. However, efforts are ongoing to identify ways to improve the system, especially in monitoring long-term outcomes after vaccination. She noted that detecting long-term effects is challenging because, over time, confounding factors such as infections or unrelated health events make it more difficult to separate vaccine-related effects from other causes. Dr. Meyer welcomed input from the committee on how to enhance long-term safety monitoring.

Dr. Malone followed up by emphasizing that the pharmacokinetics of mRNA vaccines differ significantly from traditional vaccines. He noted that prolonged antigen presence in the body, up to 700 days according to a Yale study, is unprecedented in vaccinology. This extended exposure has been linked in animal models to immune system effects such as broad immunoglobulin class switching, which are not currently captured by existing safety monitoring systems. Dr. Malone suggested these changes could affect overall immune function and influence vulnerability to other infectious diseases. He related this concern to Dr. Levi's earlier question about vaccine effectiveness estimates. While acknowledging the rigor of the current safety framework, he encouraged expanding safety analyses to consider the unique profile of mRNA vaccines, including the potential for delayed or immune-related effects. He recommended broadening the scope of monitoring to include potential long-term immunologic risks and benefits, which could help address public concerns and improve understanding of these products.

Dr. Meyer explained that since vaccination efforts began in December 2020, the CDC has maintained robust monitoring for several years. The current systems are designed to detect any adverse events, including those that may be cumulative over time or result from multiple doses. If there were any emerging safety concerns or effects on organ systems, the existing surveillance infrastructure would be well-positioned to identify them.

Dr. Thornburg noted that preclinical animal studies have shown spike protein detection up to nine days after injection, but not in the liver, and no detection beyond that time. In humans,

limited data from an autopsy study of 20 individuals revealed that vaccine mRNA was detected only in axillary nodes within 30 days post-vaccination, and not in the spleen or mediastinal lymph nodes. Protein was not detected in lymph nodes, the left ventricle, liver, or other organs, with only nonspecific staining observed.

Dr. Georgina Peacock (CDC/NCIRD) presented on COVID-19 vaccine coverage and implementation. One of the primary data sources used by the Immunization Services Division at CDC to assess vaccine coverage, including COVID-19 vaccination, is the National Immunization Survey (NIS). The NIS is a random-digit-dial cellular telephone survey of U.S. adults aged ≥18 years across all states, 5 local jurisdictions, and U.S.-associated territories. For children, data is reported by a parent or guardian. All responses are self-reported. The survey collects data from about 15,000 adults per week or around 60,000 adults per month. The data is weighted to represent the non-institutionalized U.S. population.

From September 2024 through April 2025, COVID-19 vaccination coverage for at least one dose reached 44% among adults aged 65 years and older and 23% among adults aged 18 years and older.

COVID-19 vaccination coverage among older adults increased between the 2023–2024 and 2024–2025 seasons. For adults aged 65–74, coverage increased by nearly 5 percentage points, while adults aged 75 years or older saw an increase of about 8 percentage points by the end of the 2024–25 season.

As of April 2025, approximately 5.6% of children under 4 years old were up to date with COVID-19 vaccination for the 2024–2025 season. Among children aged 5–17 years, about 16% had received at least one dose since August 2024. Overall, 13% of children aged 6 months to 17 years were up to date with their COVID-19 vaccination for the 2024–2025 season.

Among immunocompromised adults who received their first 2024-2025 COVID-19 vaccine dose in August or September 2024, 8% were fully vaccinated with two doses by the end of March 2025. When stratified by age, full-vaccination coverage was 16.6% for adults aged 50–64, 2.4% for those aged 18–49, and 0.8% for adults aged 65 years and older.

Dr. Peacock summarized that COVID-19 vaccination coverage for older adults improved in the 2024–2025 season compared to the previous year. Coverage among adults aged 18 years and older remained similar between seasons, and approximately 13% of children aged 6 months to 17 years were up to date with their COVID-19 vaccinations by the end of April 2025.

Dr. Levi asked about vaccine uptake among healthcare professionals, as their vaccination behaviors can influence public trust and recommendations.

Dr. Peacock responded that data on COVID-19 vaccination rates among healthcare professionals is not included in the specific dataset presented. However, the National Immunization Survey and other sources do collect this information. Dr. Peacock offered to bring relevant data to a future ACIP meeting or share it with the work group, noting that it is not currently available for discussion.

Dr. Meissner noted that COVID-19 vaccine uptake remains low, with less than 20% coverage among young children and even among high-risk adults over 75. He asked whether low public uptake influences the recommendations made by ACIP, specifically if low vaccination rates among children affect whether ACIP continues to recommend the vaccine for that group.

Dr. Peacock responded that this is a discussion for the committee to consider. She noted being encouraged by the increase in vaccination among adults over 65, especially those over 75. She suggested that this may reflect healthcare providers recommending the vaccine to patients with

a higher risk of hospitalization or death. She added that the final recommendation ultimately comes from the committee.

Dr. Meissner expressed concern that if the CDC issues recommendations that the public does not follow, it could erode confidence in those recommendations. He acknowledged that there may not be an easy solution but emphasized the importance of considering public acceptance when developing guidance.

Dr. Kulldorff emphasized that the committee must base its recommendations on evidence-based medicine. However, he acknowledged that the low COVID-19 vaccination rates among children likely reflect a lack of trust among many parents in the recommendations issued by the ACIP. He agreed that Dr. Meissner raised an important and timely concern.

Dr. Daskalakis added that part of the evidence-to-recommendation framework used in the work group includes an assessment of both feasibility and acceptability. He clarified that these factors have historically been part of all vaccine-related discussions and are built into the process that informs committee discussions and ultimately leads to recommendations.

Dr. Meissner asked whether there is a defined threshold at which continuing to make a recommendation may no longer be beneficial, particularly if uptake remains persistently low.

Dr. Daskalakis responded that this is precisely why the committee holds these discussions. As feasibility, acceptability, and uptake are reviewed within the work group, that information is brought to the committee for consideration. Based on this feedback, the committee ultimately makes recommendations, which can then be further reviewed.

Dr. Pebsworth expressed concern about the low uptake of COVID-19 vaccines and the high volume of reports submitted to VAERS compared to other vaccines. She noted that, as of her last review, approximately 1.6 million reports had been submitted, and cited studies suggesting that only about 10% of adverse events are typically reported, raising the possibility of underreporting. Given these concerns, she emphasized the importance of transparency and access to data not typically shared, including findings from preclinical animal studies, reproductive toxicity data, and biodistribution studies. She believes these data could help clarify current uncertainties.

Dr. Meyer addressed concerns about underreporting in VAERS by clarifying that studies often cited to support underreporting typically include mild events, such as sore arms or rashes, which are often not reported. She noted that CDC research has shown significantly higher reporting rates for serious adverse events. For example, VAERS captures up to 76% of anaphylaxis cases and up to 64% of Guillain-Barré Syndrome cases, depending on the vaccine. She added that similar findings have been observed for intussusception after rotavirus vaccination and vaccine-associated polio. Dr. Meyer emphasized that the CDC is confident that a majority of serious adverse events are reported to VAERS.

Dr. Levi acknowledged improvements in reporting but maintained that underreporting of adverse events, particularly myocarditis, likely still exists across systems. He emphasized that comparing rates from VAERS, clinical diagnoses, and studies measuring biomarkers, such as troponin levels, before and after vaccination, reveals discrepancies. While the underreporting may not be to the extent of 10%, it remains significant. He also noted that some serious adverse events appear in VAERS at rates exceeding those seen with other vaccines, even after adjusting for the number of doses administered, which may indicate a signal that warrants further investigation.

Dr. Adam MacNeil (CDC/NCIRD) concluded the COVID-19 session with a partial presentation on evidence-to-recommendations (EtR). The EtR framework outlines key domains used to guide

decision-making, including public health problem, benefits and harms, values, acceptability, feasibility, resource use, and equity. Each domain is linked to specific guiding questions. The first two domains, public health problem and benefits and harms, were reviewed and discussed by the workgroup. The remaining domains and final polling were scheduled for the final workgroup call.

The work group has consistently reviewed data related to the public health problem and benefits and harms domains of the EtR framework. Most recently, summaries of these domains were discussed during the May 29 and June 5 work group calls. These domains are largely informed by the epidemiology, vaccine effectiveness, and safety data previously presented, and were reflected in the June 12 ACIP meeting presentations. The work group had planned to review the remaining EtR domains and complete final polling before the ACIP meeting. However, because the scheduled work group call did not take place, the EtR was not finalized, and final polling was not conducted.

Dr. MacNeil summarized the work group's considerations on the public health problem, noting that while the burden from COVID-19 has declined year over year since 2021, substantial illness and death continue. Hospitalization and death rates remain highest among adults 65 years and older and infants six months and younger. Children under two years have the highest illness and death rates among pediatric groups, though deaths can occur at any age. Maternal vaccination remains the best protection for pregnant women and infants under six months who are not eligible for vaccination.

For the benefits and harms domain, the work group concluded that the 2024–2025 COVID-19 vaccination provides clear benefits in reducing hospitalizations and severe disease, particularly in adults. The vaccine has demonstrated consistent effectiveness across age groups based on prior formulations. Safety surveillance has identified myocarditis and pericarditis following mRNA vaccination, but no other serious risks have been confirmed beyond typical vaccine-related reactions. The work group also recognized that pregnant individuals face higher risks from COVID-19, and maternal vaccination offers protection to infants under six months, who are not yet eligible for vaccination.

Dr. Kulldorff thanked the presenters for their informative updates and acknowledged the thoughtful discussion that followed. He noted that no vote was scheduled on the topic and that the committee looks forward to receiving the working group's report before the next meeting. He expressed appreciation for both the CDC presenters and the many contributors behind the scenes.

AGENCY UPDATES

The Centers for Disease Control and Prevention (CDC)

Dr. Demetre Daskalakis from the National Center for Immunization and Respiratory Diseases (NCIRD) provided an update on current domestic outbreaks. He reported that as of the meeting date, the CDC has identified 1,227 measles cases across 37 U.S. jurisdictions in 2025, with 23 outbreaks accounting for 89% of cases. A significant portion of these cases is linked to a large outbreak in the Southwest, with Texas reporting 750 cases across 35 counties and New Mexico reporting 81 cases. There are signs that the outbreak is plateauing, with a decline in new cases in the Southwest. However, the CDC continues to monitor for global introductions of measles into the U.S., though recent cases have resulted mainly in short, self-limiting transmission chains. The overall risk to the U.S. population remains low; however, continued vigilance is

necessary, particularly in under-immunized populations. Dr. Daskalakis also provided an update on H5N1 (Avian influenza). Historically associated with birds and poultry, H5N1 was detected in cattle in 2024, resulting in over 1,000 affected herds. There have been 70 human cases, primarily among individuals with direct contact with animals. Recent data show a decrease in infections among both non-human mammals and birds, with no new human cases reported in over 15 weeks. He credited the USDA's early detection efforts, including bulk milk testing, for this progress. Dr. Daskalakis concluded by noting that the CDC remains focused on seasonal respiratory virus preparedness, including COVID-19, influenza, and RSV, to ensure Americans have the tools to prevent these infections.

Dr. Chris Braden, Principal Deputy Director of the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) provided additional updates on outbreak investigations. NCEZID is currently monitoring several foodborne outbreaks, including Salmonella linked to pistachio cream and eggs, which were detected through the PulseNet system. This system utilizes whole-genome sequencing to identify related cases. Dr. Braden also highlighted a cluster of systemic illnesses in Massachusetts linked to unauthorized Botox injections by an unlicensed provider. The CDC is supporting this investigation by supplying botulinum antitoxin, which is stored at CDC quarantine stations nationwide. Additionally, Dr. Braden noted emerging concerns regarding the New World screwworm, an animal parasite making its way from Central America into Mexico. Although primarily an animal health issue, human cases can occur, resulting in severe myiasis (infestation of live tissue). CDC is collaborating with the USDA to monitor this situation, as it poses risks to animal agriculture and, to a lesser extent, human health.

Food and Drug Administration (FDA)

Dr. Tracy Beth Hoeg from the FDA provided several updates. She began by addressing a recent FDA announcement regarding a safety label change for mRNA COVID-19 vaccines to reflect the ongoing risk of myocarditis, particularly in males ages 12 to 24. FDA data from 2023 and 2024 identified a myocarditis rate of 27 cases per million in this group. She clarified that this differs from the CDC's reported rate of 2 cases per million, as the FDA's data are more stratified explicitly by age and sex. Additionally, FDA data showed instances of late gadolinium enhancement on MRI six months post-vaccination, suggesting potential myocardial damage of uncertain clinical significance. Based on these findings, the FDA implemented the safety label change.

Dr. Hoeg also noted that the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) recommended the JN.1 variant antigen for the 2025 to 2026 COVID-19 vaccine, consistent with the previous year, due to slower viral mutation rates. The FDA has approved two updated vaccines, Numovoxid and MN.X Spike, both with narrowed indications for individuals ages 12 to 64 with at least one risk factor for severe COVID-19, and for adults 65 and older. Both manufacturers have committed to post-marketing randomized controlled trials to evaluate vaccine efficacy, particularly in adults ages 50 to 64.

Dr. Hoeg also referenced a recent FDA decision to pause use of the live chikungunya vaccine in adults 60 and older due to reports of 17 adverse events, including two deaths. She concluded by highlighting a study by Albertson et al., published in *Infectious Diseases and Therapy*, that

addresses subclinical myocarditis post-vaccination in individuals ages 5 to 30. This study fulfills part of a post-marketing requirement and provides additional data on this safety concern.

Indian Health Services (HIS)

Dr. Matthew Clark from IHS provided an update on vaccination efforts in tribal communities. He emphasized that IHS is working closely with federal, tribal, and urban Indian organization partners to mitigate the risk of vaccine-preventable illnesses among vulnerable populations. In alignment with its mission, IHS is committed to raising health status and improving health outcomes in American Indian and Alaska Native communities through a comprehensive approach. This includes promoting healthy lifestyles, supporting traditional culture and healing, providing preventive screenings, and managing both acute and chronic diseases. As a health care system serving 2.1 million American Indian and Alaska Native beneficiaries, vaccination remains a key component of IHS's strategy. The agency advances this work through proactive education, informed consent, and respect for the values of patients, their families, and the communities they serve. Dr. Clark noted that tribal communities face unique challenges that impact access to preventive care, and IHS is actively collaborating with tribal health partners to identify vaccine priorities and establish best practices that meet the specific needs of Indian Country.

RSV VACCINES-MATERNAL/PEDIATRIC

Dr. Adam MacNeil (CDC/NCIRD) introduced the Maternal/Pediatric RSV Vaccine Work Group. RSV is the leading cause of hospitalization in U.S. infants, with most infected in their first year and nearly all by age two. About 2 to 3% of young infants are hospitalized, and 80% of those have no underlying conditions. All young infants are at risk for severe RSV. Before 2023, no long-acting preventive products were available.

In 2023, two products to prevent severe RSV in infants were approved by the FDA and recommended by the CDC and the ACIP. All infants should be protected through either maternal RSV vaccination or a long-acting monoclonal antibody. Pregnant women should receive one dose of the maternal RSV vaccine between 32 and 36 weeks of pregnancy. Nirsevimab is recommended for infants younger than 8 months entering their first RSV season and for some children aged 8 to 19 months at increased risk entering their second season.

A new long-acting monoclonal antibody, clesrovimab, is a third option to protect infants from severe RSV disease. Clesrovimab was approved by the FDA on June 9, 2025, for use in infants born during or entering their first RSV season.

The work group and ACIP have been reviewing data on clesrovimab since September 2024. In September, the work group reviewed safety and efficacy data from Merck. In October, ACIP reviewed these data along with the work group's interpretation. From November 2024 through April 2025, the work group reviewed the GRADE assessment and the EtR framework for clesrovimab.

Since the April 2025 ACIP meeting, the work group has reviewed data on the uptake, safety, and effectiveness of the maternal RSV vaccine and the long-acting monoclonal antibody from the 2024–2025 season.

Dr. MacNeil shared that the session would include updates on current RSV prevention products, including uptake, effectiveness, and impact, and safety data for the maternal RSV vaccine and long-acting monoclonal antibody. The session would also cover the evidence-to-recommendation framework for clesrovimab, the work group's interpretations, and clinical considerations for clesrovimab.

Dr. Georgina Peacock (CDC/NCIRD) presented on the implementation and uptake of Nirsevimab and maternal vaccination for infant protection from RSV. Data sources include the National Immunization Survey, a random-digit-dial cellular phone survey of U.S. adults aged 18 and older across jurisdictions and territories; Immunization Information Systems (IIS), which are confidential, population-based databases that record immunizations administered by participating providers. CDC funds 64 jurisdictions to operate IIS, which provide monthly aggregate data for COVID-19, influenza, and RSV, as well as quarterly de-identified line-level data. The Vaccine Safety Datalink (VSD) provides vaccination coverage estimates based on electronic health records, including maternal RSV vaccination coverage.

Immunization Information Systems data show monthly administration of nirsevimab to infants under eight months of age during the 2024–2025 RSV season. More infants received protection through nirsevimab in the second season than in the first season, 2023–2024.

Infants born during the 2023–2024 RSV season (October to March) typically received nirsevimab closer to birth, while those born before September received it more than one month after birth. This pattern aligns with the availability and recommendations for nirsevimab, which typically begin shortly before the RSV season in most states.

During the second season of implementation, more infants born during the RSV season received nirsevimab within the first month of life compared to the 2023–2024 season. This suggests an improved understanding of administration guidance among healthcare providers and better access to nirsevimab.

From September 2024 through January 2025, 38.5% of pregnant women ages 18 to 49 received the RSV vaccine. Coverage varied by race and ethnicity, ranging from 25.7% among Black pregnant women to 52.6% among Asian pregnant women. These patterns are consistent with other vaccines during pregnancy, which typically show higher coverage among Asian and White non-Hispanic women and lower coverage among Black non-Hispanic and Hispanic/Latino women. Fifty-seven percent of infants born between April 2024 and March 2025 were protected against RSV through either maternal vaccination or receipt of nirsevimab.

For infants who become eligible, nirsevimab is recommended within the first week of life for those born between October and March in most of the continental United States. Birthing hospitals play a vital role in ensuring timely administration, especially for infants without commercial insurance. Approximately 45% of U.S. children ages 0 to 17 lack commercial insurance and are less likely to be seen by a primary care provider within one week of birth.

Providing nirsevimab in the hospital helps prevent missed opportunities for RSV immunization and supports coordination of care with pediatricians.

Participation in the Vaccines for Children (VFC) program by birthing hospitals promotes access to all ACIP-recommended vaccines. It allows newborns to receive necessary immunizations, such as nirsevimab and hepatitis B, before hospital discharge without upfront costs to the hospital for VFC-eligible children. This supports equitable, high-quality care for all infants at risk for RSV, regardless of insurance status.

In 2023, only 10% of U.S. birthing hospitals were enrolled in the VFC program when nirsevimab was added to the routine schedule. Through updated policies, new partnerships, and strong outreach, enrollment has grown to over 1,000 hospitals in under two years.

For the 2025–2026 RSV season, the supply of monoclonal antibodies is expected to meet demand and arrive earlier than in the previous season, supporting broad availability and a smooth program rollout. CDC is working with state partners, professional organizations, and the Indian Health Service to improve access and uptake of both maternal vaccines and infant monoclonal antibodies. Preseason technical assistance is underway to support ordering and logistics. Increased availability of 50 mg doses of nirsevimab is expected early in the season, and the newly licensed clesrovimab will be available once added to the CDC's VFC contracts.

Dr. Peacock summarized that during the 2024–2025 season, more infants born during the RSV season received nirsevimab within their first month of life compared to the previous year. This improvement was likely due to greater awareness among healthcare providers and families, as well as better supply availability. Maternal vaccination and RSV monoclonal antibodies protected 57% of infants born between April 2024 and March 2025, demonstrating the value of offering both options. Increased enrollment of birthing hospitals and improved early supply should enhance access to RSV protection in the upcoming season.

Dr. Adam MacNeil (CDC/NCIRD) presented the effectiveness and impact of RSV prevention products in infants during the 2024–2025 season. The CDC utilized data from three primary networks to evaluate RSV product effectiveness (PE) in the U.S., all based on variations of the case-control design. Two networks, VISION and NVSN, used a test-negative design, where infants with acute respiratory illness who received medical care (emergency department visit, hospitalization, or ICU admission) and were tested for RSV. Those who tested positive (cases) were compared to those who tested negative (controls) in terms of their RSV immunization status. The third, the Overcoming COVID-19 Network, used a matched case-control design comparing RSV-positive children with ICU admissions with matched RSV-negative controls. In all three networks, effectiveness was estimated by comparing the odds of RSV immunization between RSV-positive and RSV-negative infants. Each network has unique strengths: VISION uses electronic health records from emergency departments and hospitals in six states, NVSN conducts active surveillance in seven pediatric academic centers, and the Overcoming Network collects data from 26 pediatric intensive care units across 23 states.

Each network verified immunization status through electronic health records and immunization registries; NVSN and the Overcoming Network also included provider records and parental reports. VISION and NVSN analyzed data from October 2024 to March 2025, while Overcoming

analyzed data from December 2024 to April 2025. In all platforms, cases were children who have tested positive for RSV. NVSN systematically tested all enrolled children, including those who have not undergone clinical testing. Controls were children who tested negative for RSV; in NVSN, this may have included children without clinical testing. The Overcoming Network enrolled matched controls based on site, age, and date of hospitalization of cases.

All three studies included infants who were <8 months old on October 1, 2024, or born after that date during the study period. For maternal RSV product effectiveness, VISION included infants born on or after September 14, 2024, which is 14 days after vaccine availability in most of the U.S., while NVSN included infants under 6 months of age during the study period. All analyses used multivariable logistic regression, adjusting for site, age in months, and enrollment timing. VISION analyses also adjusted for race, ethnicity, and sex. For nirsevimab effectiveness, NVSN and Overcoming analyses also adjusted for presence of at least one high-risk medical condition. Overcoming analyses additionally adjusted for the Social Vulnerability Index, and NVSN also accounted for race and ethnicity and insurance status in the maternal vaccine analysis.

Nirsevimab showed strong effectiveness against RSV-associated emergency department visits during infants' first RSV season. In the VISION analysis of over 4,000 ED visits, 79% of RSV-positive children did not receive nirsevimab, compared to 64% of RSV-negative children. In the NVSN analysis of nearly 500 ED visits, 86% of RSV-positive children did not receive nirsevimab, compared to 56% of RSV-negative children. Among immunized children, the median time since the last dose was 68 days. The adjusted product effectiveness against RSV-associated ED visits was 63% in VISION and 76% in NVSN, with overlapping 95% confidence intervals, indicating consistent protection across both networks.

In the VISION analysis of over 600 hospitalizations, 81% of RSV-positive children did not receive nirsevimab, compared to 55% of RSV-negative children. In the NVSN analysis of nearly 700 hospitalizations, 89% of RSV-positive children had not received nirsevimab, compared to 61% of RSV-negative children. Among those who had received the antibody, the median time since dose was 61 days in VISION and 52 days in NVSN. The adjusted effectiveness against RSV-associated hospitalization was 79% in VISION and 82% in NVSN, with overlapping 95% confidence intervals.

In the VISION analysis of 374 ICU admissions, 86% of RSV-positive infants had not received nirsevimab, compared to 55% of RSV-negative infants. In NVSN, 92% of RSV-positive infants did not receive the antibody, compared to 56% of RSV-negative infants. The Overcoming platform showed similar results, with 87% of RSV-positive infants having not received nirsevimab versus 56% of RSV-negative infants. Among those who had received nirsevimab, the median time since dose at ICU admission was 56 days in VISION, 52 days in NVSN, and 50 days in Overcoming. Adjusted product effectiveness against RSV-associated ICU admission was estimated at 82% for VISION, 88% for NVSN, and 88% for Overcoming, with overlapping 95% confidence intervals across all three platforms.

During the 2024–2025 RSV season in the United States, the effectiveness of the maternal RSV vaccine against RSV-associated emergency department (ED) visits in infants during their first season was assessed using data from the VISION platform. Among nearly 1,000 ED visits, 79%

of RSV-positive infants did not have evidence of maternal RSV vaccination, compared to 65% of RSV-negative infants. Among infants whose mothers had received the vaccine, the median number of days since birth was 53, and the median number of days since maternal vaccination was 85. The estimated vaccine effectiveness against RSV-associated ED visits was 54%, with a 95% confidence interval of 35% to 67%.

During the 2024–2025 RSV season, maternal RSV vaccine effectiveness against infant hospitalization was 79% in the VISION network and 70% in NVSN, with overlapping confidence intervals. In both networks, over 80% of RSV-positive infants had no documented maternal vaccination. Among vaccinated groups, the median time since birth was around one month, and the median time since maternal vaccination was just over 70 days.

When interpreting these real-world product effectiveness findings, it's important to consider that differences in enrollment and population across systems may limit comparability. While study design and analysis help control confounders such as health-seeking behavior, residual confounding is still possible, although a variety of sensitivity analyses were performed to assess the influence of known confounders. There is also a risk of misclassifying RSV immunization status, although multiple data sources were used to verify immunization records.

RSV product effectiveness estimates align with clinical trial efficacy data for both nirsevimab and maternal RSV vaccination, particularly in terms of hospitalization and ICU admissions. Although ED visits were not measured in clinical trials, the real-world data suggest both products are effective in preventing RSV-associated emergency visits, hospitalizations, and severe illness. Ongoing monitoring will be important to evaluate additional outcomes.

To assess the impact of RSV prevention products on pediatric RSV-associated hospitalizations in the U.S., data were analyzed from two active, population-based surveillance systems. RSV-NET, part of the RESP-NET system, monitors RSV, influenza, and COVID-19 hospitalizations across all ages in 13 states. The second system, NVSN, tracks hospitalizations among children with acute respiratory illnesses across seven U.S. pediatric medical centers.

An ecological analysis was conducted to assess changes in pediatric RSV-associated hospitalization rates before and after the introduction of RSV prevention products. RSV hospitalization rates from pre-pandemic seasons (2018–2020 for RSV-Net, 2017–2020 for NVSN) were compared to rates from the 2024–2025 season, the second year of product availability. Seasons from 2020–2023 and 2023–2024 were excluded due to pandemic disruptions and limited product uptake, respectively. Weekly and monthly hospitalization rates were analyzed, and cumulative rates were compared across seasons. Rate ratios and relative rate reductions were calculated to assess the impact of RSV prevention products. Analyses focused on three age groups with different RSV prevention options: infants 0–7 months (eligible for maternal vaccine or nirsevimab), children 8–19 months (limited eligibility for nirsevimab based on risk conditions), and children 20–59 months (not eligible for RSV prevention products, used as a comparison group).

During the 2024–2025 RSV season, prevention products were available before the season began in most states, with coverage increasing over time. By March 2025, nirsevimab coverage

among infants aged 0–7 months ranged from 21% to 48% across reporting jurisdictions. As of January 2025, 39% of pregnant women aged 18–49 had received the RSV vaccine.

The ecological analysis compared RSV hospitalization rates among infants (0 to 7 months), toddlers (8 to 19 months), and preschoolers (20 to 59 months) before and after the introduction of RSV prevention products. Historically, infants have experienced the highest hospitalization rates, followed by toddlers and preschoolers, with rates remaining relatively consistent within each age group. During the 2024–2025 season, new RSV prevention products became available for infants and some high-risk toddlers, while preschoolers remained ineligible for these products. By comparing changes in hospitalization rates within each age group, the analysis assessed whether the declines among infants eligible for prevention were greater than declines in the other two age groups, which would suggest a population-level impact of the new products.

Results from the analysis showed that the two networks identified over 20,000 RSV-associated hospitalizations in children under five across the compared periods. In the 2024–2025 season, the proportion of children aged <5 years with an RSV-associated hospitalization who were aged 0 to 7 months decreased from 51% to 29% in RSV-NET and from 46% to 38% in NVSN in 2024-2025 compared to prior seasons before the introduction of prevention products. The median age at hospitalization also nearly doubled, from 7.7 to 15.4 months in RSV-NET and from 6.3 to 12.7 months in NVSN. This indicated that children hospitalized with RSV during the 2024–2025 season were typically older than in prior seasons.

Cumulative adjusted RSV-associated hospitalization rates in the 2024–2025 season were compared to those in prior seasons before product introduction across three age groups. Among infants aged 0 to 7 months, rates dropped from 17 to 10.5 per 1,000 in RSV-NET and from 16 to 11 per 1,000 in NVSN, corresponding to a 38% and 31% reduction in hospitalization rates, respectively. No reductions occurred among children aged 8 to 19 months or 20 to 59 months, suggesting the observed decline was limited to the age group eligible for RSV prevention products.

Among infants aged 0 to 7 months, further analysis showed that RSV-associated hospitalization rates were reduced by nearly half among those aged 0 to 2 months. In the 2024–2025 season, rates among infants aged 0 to 2 months dropped by 47% in RSV-NET and 46% in NVSN compared to prior seasons.

Dr. MacNeil concluded that two population-based surveillance networks demonstrated significant reductions in RSV-associated hospitalizations during the 2024–2025 season among infants eligible for preventive products, with decreases of 38% and 31% among those aged 0 to 7 months compared to prior seasons before product introduction. The greatest reductions were observed in infants aged 0 to 2 months, the group at the highest risk for hospitalization, highlighting the importance of timely protection through maternal vaccination during pregnancy or the administration of nirsevimab in the first week of life. Ongoing monitoring of RSV disease trends, including severity and age distribution, remains crucial for evaluating the long-term impact.

Dr. Levi emphasized the need for more detailed analyses to better understand the impact of RSV prevention products. He suggested evaluating whether certain groups, such as preterm infants or those with comorbidities, benefit more than healthy, full-term infants. He also recommended assessing broader outcomes, such as all-cause lower respiratory tract infections and overall respiratory infections, to ensure that reductions are not due to changes in testing practices. Additionally, he proposed examining hospitalization severity, including length of stay and type of care provided, to capture the overall clinical benefit better.

Dr. MacNeil acknowledged the importance of reducing all respiratory infections, not just RSV, and emphasized that preventing infant and pediatric hospitalizations is highly valuable. RSV alone accounts for a large portion of hospitalizations in newborns, so RSV prevention products are already having a meaningful public health impact. Regarding more granular analyses, such as subgroup evaluations, it was noted that these would be useful. Still, limitations in statistical power may affect the ability to explore them in greater depth.

Dr. Hibbeln noted that combining small-sample clinical trials with large-scale ecological studies can be a challenging task. Still, it appears that both types of studies show similar effect sizes for RSV prevention products. He asked for confirmation on whether that observation is accurate.

Dr. MacNeil confirmed that although the clinical trials were not conducted in the United States, and some differences exist, the overall magnitude of effect appears consistent. The observed real-world impact aligns with expectations based on the clinical trial results.

Dr. Hibbeln noted that the major event between the two ecological studies was the COVID-19 pandemic and asked whether there is any evidence of an interaction or a potential protective effect of COVID-19 vaccination on RSV hospitalizations or related outcomes.

Dr. MacNeil responded that, biologically, there would not be a direct effect of COVID-19 or COVID-19 vaccination on RSV, as the two viruses are very different and unrelated in their mechanisms of infection.

Dr. Malone noted that monoclonal antibodies are particularly vulnerable to viral drift and suggested that it could be beneficial if the two available monoclonals target different epitopes. He asked whether there is information available on whether these two monoclonals are directed at distinct regions of the virus.

Dr. MacNeil explained that both monoclonal antibodies target the larger prefusion protein. However, there is a possibility that if resistance develops against one, the other could still offer protection. This consideration was part of the work group's rationale and deliberation in recommending the inclusion of a second monoclonal antibody.

Dr. Malone expressed support for the approach and noted that the discussion highlights the significant viral and infectious pressure currently present. He asked whether there is active monitoring in place to track changes that could impact the effectiveness of monoclonal antibodies due to viral drift.

Dr. MacNeil explained that RSV infects individuals multiple times throughout their lives, resulting in the continuous circulation of the virus. Because of this, protecting a relatively small population

is not expected to create significant population-level selective pressure. He added that while some genomic monitoring of RSV is conducted, widespread ecological selective pressure is not anticipated, since the virus continues to be transmitted broadly among the general population.

Dr. Malone noted that drug-drug interactions will be an important issue for ACIP to consider moving forward. He pointed out that among those receiving monoclonal antibody products, some infants are likely fully vaccinated under the standard birth schedule, while others may not be. If that is the case, he suggested it would be valuable to collect and analyze data comparing safety and effectiveness between these groups. He emphasized that demonstrating no difference in outcomes between those who receive standard vaccinations concurrently and those who do not would be useful if such monitoring is not already in place.

An SME clarified that the two monoclonal antibodies bind to different locations on the virus. While some viruses are known to drift away from the effectiveness of monoclonal antibodies, these monoclonals are likely less prone to such drift due to the virus's evolutionary characteristics. However, genetic surveillance is ongoing to monitor changes and ensure continued effectiveness.

Dr. Levi emphasized the importance of monitoring how vaccine efficacy changes over time, even within a single season. Referring to the maternal RSV vaccine data, he noted that between days 180 and 360, a signal appeared suggesting negative efficacy, with more hospitalizations occurring among vaccinated individuals compared to those who were not vaccinated. He acknowledged that RSV is a challenging virus that often responds unpredictably to interventions and stressed the need for careful interpretation and a deeper understanding of potential explanations for these findings.

Dr. MacNeil acknowledged that the effectiveness of RSV prevention products wanes over time. He emphasized that the goal is to protect infants during their most vulnerable period, particularly in the first two months of life, before their immune systems are fully developed. By providing protection early, the aim is to help children reach an age where, like healthy teenagers or adults, they may still get infected with RSV but are far less likely to develop severe disease. The primary objective is to reduce the risk of serious outcomes during the earliest and highest-risk stage of life.

Dr. Picaro addressed the question about monitoring protection beyond 150 days, explaining that the current challenge stems from the way these products are administered, typically at the beginning of the RSV season. As coverage increases over time, the number of children who have reached 120 to 180 days post-immunization during the observation period decreases. This limits the ability to assess long-term protection in current analyses. He noted that this challenge is tied to the seasonal nature of product rollout. However, he expressed hope that data from regions where RSV circulates more consistently throughout the year may help answer questions about the duration of protection.

Dr. Malini DeSilva (HealthPartners) shared updates on prenatal RSVpreF vaccine safety. Established in 1990, the Vaccine Safety Datalink (VSD) is a collaborative project between CDC's Immunization Safety Office and integrated healthcare organizations in the United States. The VSD primarily monitors vaccine safety through observational, multi-site studies that utilize

real-world data. It includes data on approximately 15.5 million individuals annually, representing about 4.5% of the U.S. population, with an annual birth cohort of roughly 115,000 live births. Data are organized using a common data model with standardized coding systems. Currently, 13 VSD sites provide clinical, methodological, and data expertise, with 11 of those sites contributing data.

The prenatal RSV vaccine was recommended for use by the ACIP in September 2023 for administration between 32 and 36 weeks of gestation, with seasonal use from September through January. In the phase 3 RSVpreF clinical trial, non-significant imbalances were observed among vaccinated women compared to placebo recipients in rates of preterm birth, gestational hypertension, and preeclampsia.

Prenatal RSVpreF vaccine safety outcomes evaluated in this study included acute outcomes occurring within 42 days of vaccination. These outcomes were preterm birth, small for gestational age at birth, stillbirth, and hypertensive disorders of pregnancy. Hypertensive disorders were assessed both as a combined outcome and as individual conditions, including gestational hypertension, preeclampsia, eclampsia, and HELLP syndrome.

A target trial emulation design was used to compare RSVpreF-vaccinated and unvaccinated pregnant women at each gestational week, aiming to mimic a randomized trial using observational data. The study included pregnant women aged 16–49 years with a gestational age of 32 to less than 37 weeks between September 22, 2023, and January 31, 2024 (or February 29, 2024, for two sites). Vaccinated individuals were matched one-to-one with unvaccinated individuals by site and likelihood of vaccination, based on the same gestational week. Outcomes were tracked from the index date through two weeks after pregnancy ended. Unvaccinated matches were assigned the same index date as their vaccinated counterpart, and pairs were censored if the unvaccinated individual later received the vaccine.

Risk ratios with 95% confidence intervals were estimated using a log-binomial model with robust variance, adjusting for nulliparity. For small-for-gestational-age infants at birth, matched sets were excluded if infant weight was missing for either infant. For hypertensive disorders of pregnancy, matched sets were excluded if disease onset occurred on or before the index date for either pregnant woman.

The analysis included 13,966 matched pairs; however, the cohort does not represent unique individuals, as some initially unvaccinated participants were later vaccinated and subsequently rematched. While overall characteristics were similar, RSV-vaccinated women were generally older than their unvaccinated matches. The vaccinated group had a higher proportion of Asian patients and a lower proportion of Black and Hispanic patients. Additionally, 98.5% of the vaccinated group had received at least one other vaccine during pregnancy, compared to 81% in the unvaccinated group. A higher percentage of nulliparous women was also observed in the vaccinated group.

The analysis found no significant differences in the risk of acute safety outcomes between RSVpreF-vaccinated pregnant women and their unvaccinated matches across all evaluated time intervals (1–6 days, 1–21 days, and 1–42 days).

The analysis found no association between RSVpreF vaccination during pregnancy and the risk of preterm birth, small for gestational age at birth, or stillbirth. However, there was a statistically significant association between RSVpreF vaccination and hypertensive disorders of pregnancy. The adjusted risk ratio for any hypertensive disorder was 1.09, with significant associations observed for both preeclampsia and gestational hypertension.

Among individuals with diagnosed hypertensive disorders of pregnancy, rates of cesarean delivery and post-birth hospitalization admissions were similar between RSVpreF-vaccinated and unvaccinated groups. Lengths of stay over 3 days were slightly higher in the vaccinated group, except for infants delivered by cesarean. Overall, the findings suggest comparable severity of hypertensive disorders of pregnancy between the two groups.

In the phase 3 clinical trial of the RSVpreF vaccine administered during pregnancy, there were more cases of gestational hypertension and preeclampsia among vaccine recipients compared to placebo recipients. However, these differences were not statistically significant.

A retrospective observational cohort study of patients who delivered at 32 weeks and 0 days gestation or later at two New York City hospitals between September 22, 2023, and January 31, 2024, found a significant association between RSVpreF vaccination and hypertensive disorders of pregnancy using a time-dependent Cox regression model. However, this association was not significant in either unadjusted or adjusted multivariable logistic regression models. In stratified analyses by site and insurance status, the association persisted only among patients with private insurance and at one of the two hospitals.

Dr. DeSilva concluded that the RSVpreF vaccine is not associated with increased risk for acute safety outcomes, preterm birth, small for gestational age at birth, or stillbirth. However, the vaccine is associated with a small but statistically significant increased risk for hypertensive disorders of pregnancy. These findings are consistent with results from the Phase 3 clinical trial and a large observational study; however, the association may be influenced by residual confounding or outcome misclassification. Importantly, the severity of hypertensive disorders appeared similar between vaccinated and unvaccinated individuals based on rates of cesarean delivery, post-birth hospital admissions, and length of stay. Results from the 2024–2025 season are pending and will provide additional insight into the safety of the prenatal RSV vaccine.

Dr. Matthew Daley (Kaiser Permanente Colorado) presented on monitoring the safety of nirsevimab in infants born through <8 months. Nirsevimab is a long-acting monoclonal antibody recommended for the prevention of RSV disease in infants. It is intended for infants from birth to under 8 months of age who have not received the RSV vaccine during pregnancy, as well as for select high-risk infants aged 8 to 19 months. Phase 3 clinical trials demonstrated high efficacy, and post-licensure data showed strong effectiveness. Although there was a severe shortage during the 2023–2024 season, uptake remained high within the VFC and VSD populations. A total of 72 percent received either nirsevimab or the maternal RSV vaccine.

The safety profile of nirsevimab is based on three randomized clinical trials, which included both healthy and high-risk infants. Across these trials, 3,184 infants received nirsevimab, 1,284 received a placebo (with a 2-to-1 randomization), and 304 received palivizumab, another monoclonal antibody targeting RSV. Adverse events were generally balanced between the

nirsevimab and comparator groups. Seven infants who received nirsevimab experienced rashes, primarily papular or maculopapular in nature. Importantly, no cases of anaphylaxis, serious hypersensitivity reactions, or immune complex diseases were reported.

Although clinical trials provided important safety data, additional post-licensure monitoring is needed to assess rare adverse events and evaluate safety when nirsevimab is administered during routine care in the general population. The objective of this study was to examine the safety of nirsevimab by analyzing prespecified adverse events among recipients in the Vaccine Safety Datalink (VSD). While nirsevimab is a passive immunization, the CDC and ACIP specifically requested that the VSD evaluate its safety.

The VSD is an observational system that utilizes EHR data from a birth cohort of approximately 115,000 individuals annually. It integrates data from electronic health records, claims, immunization registries, and diagnosis codes across inpatient, emergency, and outpatient settings. A key strength of VSD is its ability to conduct rapid manual medical record reviews to validate diagnoses and ensure accuracy. It also uses advanced analytic methods, including self-controlled designs, to address confounding.

During the 2023–2024 season, 36,719 infants received nirsevimab in the VSD. Prespecified adverse events were monitored using a self-controlled risk interval analysis, with results stratified by age group. No increased risk was identified for seizures, ITP, drug reactions, fever, or sepsis. No cases of anaphylaxis were reported. Some non-anaphylactic allergic reactions, primarily hives, occurred on the same day as administration. This finding is consistent with those from the clinical trials.

For the 2024–2025 season, this analysis included all VSD-contributing sites and focused on infants from birth to under 8 months of age who received nirsevimab between October 1, 2024, and February 1, 2025. All exposed infants were included, regardless of whether they received vaccines on the same day. Continuous health insurance enrollment through the control window was required to track both nirsevimab administration and potential adverse events. A self-controlled risk interval design was used. Infants whose mothers received an RSV vaccine during pregnancy were excluded from the study.

Self-controlled designs, such as the self-controlled risk interval, are commonly used in vaccine safety studies. These methods compare the risk of adverse events during a period shortly after vaccination with that of a later period in the same individual. This controls for fixed characteristics, such as chronic conditions, that could bias the results. These designs are useful because people who receive vaccines often differ from those who do not, and those differences may not be fully captured in health records.

Age was a significant factor in the design of this study. Diagnoses in the first month of life often reflect conditions related to pregnancy, delivery, or newborn care. Healthcare use and insurance enrollment patterns also differ in this period. Additionally, except for the birth dose of hepatitis B, routine vaccines are not given before 38 days of age. For these reasons, safety analyses were done separately for newborns (0 to 37 days) and older infants (38 days to 8 months).

The study assessed seizures, immune thrombocytopenia (ITP), drug reactions, fever, and sepsis using self-controlled risk interval designs. Anaphylaxis and non-anaphylactic serious allergic reactions were monitored by tracking case counts. Autoimmune and immune complex diseases are also planned for evaluation through a case-control study at the end of surveillance, as these outcomes are rare in infants and may have a delayed onset.

A total of 117,427 neonates and infants from birth to under 8 months of age were identified. Following enrollment criteria, 43,532 received nirsevimab. Exclusions included 1,663 infants with prenatal exposure to RSV vaccine, as some may still qualify for nirsevimab under specific clinical circumstances. Additional exclusions were made for infants who received nirsevimab at the end of the 2023–2024 season. The final safety analysis included 9,855 neonates (0 to 37 days old) and 28,054 infants (38 days to under 8 months old).

Nirsevimab was administered to infants at various ages from birth to under 8 months, with no single peak age. Dosing clustered in the first week of life and at typical well-child visit intervals, including 2 weeks, 2 months, 4 months, and 6 months of age.

Among neonates aged 0 to 37 days, administration frequently occurred on the day of birth, often with the hepatitis B vaccine. On day one, most neonates received nirsevimab alone, though some also received hepatitis B. For the remainder of the neonatal period, nirsevimab was typically given without same-day hepatitis B vaccination.

Among neonates aged 0 to 37 days, nirsevimab was often administered on the same day as the hepatitis B vaccine, particularly on the day of birth. Among infants aged 38 days to under 8 months, 84 percent received nirsevimab on the same day as other vaccines. The most common same-day combination included nirsevimab with hepatitis B, rotavirus, DTaP, Hib, pneumococcal, and polio vaccines.

No significant increased risk of seizures was observed in either the 2023–2024 or 2024–2025 seasons. Medical record reviews showed that some reported cases were not true seizures, while others were related to known genetic seizure disorders.

Regarding ITP, a single case was identified within the risk window among infants aged 38 days to under 8 months. No cases were observed in the neonatal group.

With respect to drug reactions, there were zero cases in both the risk and control windows for both the neonatal group and the older infant group.

Among neonates aged 0 to 37 days, there were four cases of sepsis or fever in the risk window and nine in the control window, yielding a relative risk of 0.44. This outcome was not evaluated in older infants due to differences in clinical management of fever by age. An exploratory analysis showed a numerical imbalance in sepsis workups, such as blood or spinal fluid cultures, between risk and control windows. However, medical record review found no consistent concerns, with cultures often performed for reasons other than fever. No increased risk of sepsis or fever was identified.

For anaphylaxis, no cases were reported in either the neonatal group (0 to 37 days) or the older infant group. For non-anaphylactic serious allergic reactions, there were 14 cases in the

neonatal group and 4 in the older group. These were primarily diagnosis codes for urticaria (hives) occurring on the same day as nirsevimab administration.

Dr. Daley summarized that among a combined population of 74,000 neonates and infants exposed to nirsevimab over two seasons, there was no increased risk of seizures, ITP, drug reactions, fever, or sepsis. No cases of anaphylaxis were reported. A small number of non-anaphylactic allergic reactions were observed, primarily coded as urticaria or hives, without more serious hypersensitivity in the same children. These findings support a reassuring safety profile for nirsevimab in routine clinical practice. Additional data collection is underway for later-season use, so these results should be considered preliminary.

Nirsevimab safety surveillance is ongoing. Three assessments were planned: post-2023–2024 results (already shared with the ACIP RSV Work Group), a preliminary 2024–2025 assessment (presented here), and a final cumulative analysis through July 2025. Medical records will be manually reviewed for any cases of anaphylaxis or other outcomes of concern. A case-control study of autoimmune and immune complex diseases was also planned, but only two cases were identified in 2024–2025, both related to isoimmunization and not associated with nirsevimab. As a result, this analysis could not be conducted, but the absence of cases is reassuring.

Dr. Adam MacNeil (CDC/NCIRD) shared the updates and summary of the Evidence to Recommendation (EtR) framework for clesrovimab. The policy question under consideration is whether clesrovimab should be recommended for all infants under 8 months of age born during or entering their first RSV season.

For the public health problem domain, Dr. MacNeil shared that RSV places a significant burden on young children. Without preventive products, the CDC estimates RSV caused approximately 2 million medical visits, 58,000 to 80,000 hospitalizations, and 100 to 300 deaths annually in U.S. children under five. Most infants are infected in their first year of life, with 2 to 3 percent of young infants hospitalized. Hospitalization risk is highest in the first months of life and declines with increasing age. About 80 percent of children hospitalized for RSV have no underlying medical conditions; therefore, all young children are at risk for hospitalization. When asked if RSV disease among infants <8 months of age is of public health importance, the work group unanimously voted “yes.”

The benefits and harms domain addressed three key questions: 1) the magnitude of anticipated benefits; 2) the magnitude of anticipated harms; and 3) whether the benefits outweigh the harms. To assess this, a GRADE analysis was conducted to evaluate the certainty of evidence for both beneficial and harmful outcomes. The PICO components (population, intervention, comparison, outcomes) were defined as follows: the population included all infants under 8 months of age born during or entering their first RSV season; the intervention was clesrovimab; the comparison was a placebo. Beneficial outcomes assessed included RSV-associated medically attended lower respiratory tract infections (LRTIs), hospitalizations, ICU admissions, all-cause medically attended LRTIs, and all-cause LRTI-associated hospitalizations. The harmful outcome evaluated was serious adverse events.

For RSV-associated medically attended lower respiratory tract infection (LRTI), the efficacy was 60%. In the certainty assessment, there was concern for indirectness because the trial excluded

infants eligible for palivizumab and was conducted during a season with disrupted RSV circulation due to COVID-19. This concern was noted for all outcomes but was deemed not serious. For RSV-associated LRTI with hospitalization, the efficacy was 91%. For RSV-associated LRTI with ICU admission, the efficacy was estimated to be 100%. There was serious concern for imprecision as the confidence interval contained estimates for which different policy decisions may be considered.

For harms, the relative risk of serious adverse events was evaluated through 365 days in the trial. The estimated relative risk was 0.93, with a 95% confidence interval ranging from 0.77 to 1.2, which included 1, suggesting that serious adverse events occurred at a similar proportion in those who received clesrovimab and those who did not. However, there was a serious concern for imprecision in this estimate, as too few infants were included to capture rare serious adverse events.

GRADE findings showed that clesrovimab was effective in preventing RSV-associated medically attended LRTI and RSV-associated hospitalization, with high certainty. It was effective in preventing ICU admissions due to RSV-associated LRTI with moderate certainty. It was not effective in preventing all-cause medically attended LRTI, with moderate certainty, but was moderately effective in preventing all-cause LRTI-associated hospitalization, with high certainty. No increase in serious adverse events was observed in the clesrovimab group compared to the placebo group with moderate certainty.

Beyond trial outcomes, additional benefits of having a second long-acting monoclonal antibody option include: having another product with a different binding site in case of resistance mutations, supply shortages, and pricing competition. Rates of injection site and systemic reactions were similar between groups (29.9% for clesrovimab vs. 30.9% for placebo), mostly mild or moderate. Fever rates were also similar (3.7% vs. 4.0%), suggesting no increased risk with clesrovimab.

Based on the data presented, the work group concluded that clesrovimab is an effective long-acting monoclonal antibody for preventing severe RSV disease in young infants during their first RSV season. As the second approved product of its kind, it may be helpful in mitigating any supply disruptions and potential resistance to any single product. Clesrovimab demonstrated a favorable safety profile, with no increase in serious or solicited adverse events, including fever. However, rare events may not have been detected due to the trial's size. The majority of the work group agreed that the anticipated benefits were large and the harms minimal. The group unanimously concluded that the benefits outweigh the risks.

For the values domain, data was presented on parents' and caregivers' views of the benefits of clesrovimab relative to its harms. A national survey conducted from December 2022 to January 2023 among pregnant and postpartum women found that 31% knew a baby hospitalized with RSV, 38% believed their baby would become moderately or severely ill if infected, and 69% were concerned about possible hospitalization. In a study conducted in April and May in Cascadia on parental preferences for RSV products, 37% preferred maternal vaccination, 12% preferred the infant monoclonal antibody, 3% preferred neither, and 48% had no preference, suggesting that either option may be acceptable to parents. Preliminary data from the National

Immunization Survey showed that as of February, 50% of infants under 8 months had received a long-acting monoclonal antibody, and another 7% of caregivers reported definite intentions to do so.

The work group felt that parents and caregivers probably viewed the desirable effects of clesrovimab as large relative to the undesirable effects. When asked whether there was important uncertainty or variability in how much parents and caregivers value the prevention of severe RSV disease, the majority of the work group felt there was probably not significant uncertainty or variability.

In the acceptability domain, data assessed whether clesrovimab is acceptable to key stakeholders, primarily providers and professional organizations. In a survey of 200 U.S. pediatricians conducted in October 2024, about 75% reported offering a long-acting monoclonal antibody in their practice. Over 90% agreed or strongly agreed that it is safe for infants, effective against severe RSV disease, and that they felt confident recommending and co-administering it with other vaccines. National organizations, including the American Academy of Pediatrics, the American Academy of Family Physicians, and the National Foundation for Infectious Diseases, have endorsed clesrovimab. The majority of the work group felt that clesrovimab is acceptable to key stakeholders. A minority of the work group said it is probably acceptable.

In the feasibility domain, the data focused on whether clesrovimab is practical to implement for all infants under 8 months of age born during or entering their first RSV season. If recommended by ACIP, clesrovimab would become the second long-acting monoclonal antibody included in the Vaccines for Children (VFC) program, which provides vaccines at no cost to eligible children. The product is a single-dose immunization, administered regardless of infant weight, which may simplify delivery. However, stocking could be a challenge for providers who also need to carry nirsevimab for high-risk children aged 8 through 19 months. Some may prefer to stock only one long-acting RSV monoclonal antibody. In a 2024 survey of pediatricians, the most frequently reported implementation challenges were determining maternal RSV vaccination status (34%), the financial burden of purchasing the product, and reimbursement issues from private insurers. The majority of the work group felt that clesrovimab is, or probably is, feasible to implement.

For the resource use domain, a cost-effectiveness model was developed by the University of Michigan and the CDC, building on methods previously used to evaluate nirsevimab. The model was updated with key inputs for clesrovimab, including its effectiveness and anticipated cost per dose. In the base case scenario, assuming 50% coverage of clesrovimab among an annual birth cohort and continued use of palivizumab for eligible high-risk infants, the model estimated prevention of approximately 120,000 outpatient visits, 43,500 emergency department visits, 20,000 hospitalizations, 4,500 ICU admissions, 20 deaths, and nearly 3,500 quality-adjusted life years (QALYs) gained.

Estimated incremental cost-effectiveness ratios were roughly $3,000 per outpatient visit prevented, $8,200 per emergency department visit prevented, $17,500 per hospitalization prevented, $80,000 per ICU admission prevented, and $104,500 per quality-adjusted year of life (QALY) gained. Extensive sensitivity analyses were conducted using a wide range of input

values. Results were sensitive to assumptions about inpatient costs, quality of life losses, and product price.

The majority of the work group felt that clesrovimab use among all infants under 8 months of age born during or entering their first RSV season is, or probably is, a reasonable and efficient allocation of resources at an average cost of $458 per dose.

Dr. MacNeil summarized the work group's discussion, considerations, and interpretation of the data. The group found that the phase 2b/3 trial of clesrovimab demonstrated high efficacy in preventing severe RSV through 150 days. Serious adverse events appeared to be balanced between the clesrovimab and placebo groups, although rare events may not be detectable in a trial of this size. The group noted that while clesrovimab has a shorter half-life than nirsevimab, its efficacy appeared sustained through 150 days. Direct comparisons between the two products are limited due to differences in trial endpoints; a head-to-head study would be needed to evaluate comparative efficacy.

The group emphasized the value of having multiple long-acting monoclonal antibody products and manufacturers, as this diversification supports resilience in the face of potential resistance or supply shortages and may help drive price competition. RSV remains the leading cause of hospitalization in infants, and immunization can significantly reduce this burden. To achieve a meaningful public health impact, timely administration is critical. For infants born outside the RSV season, high coverage before the season begins is essential. For those born during the season, administration should ideally occur within the first week of life, preferably during the hospitalization for birth.

When asked about the balance between desirable and undesirable effects, the work group concluded that the desirable consequences clearly outweigh the undesirable ones. In the final poll, the work group unanimously supported recommending clesrovimab for all infants under 8 months of age born during or entering their first RSV season.

Dr. Adam MacNeil (CDC/NCIRD) shared the updates on clinical considerations for clesrovimab. To summarize the effectiveness, uptake, and impact data: Nirsevimab was effective in preventing RSV-associated emergency department visits, hospitalizations, and critical illness among infants in their first RSV season. Maternal vaccination was effective against RSV-associated emergency visits and hospitalizations. An estimated 50% of infants were either born to a vaccinated mother or received nirsevimab. Following the introduction of RSV immunization, hospitalization rates declined by 30% to 40% among eligible infants and by 50% among infants aged 0 to 2 months.

The work group noted that the impact of RSV immunizations in reducing severe disease among infants during the 2024–2025 season in the RSV-NET and NVSN networks is clear. Increasing uptake is crucial to further reduce the burden of RSV. A greater impact has been observed in countries with higher immunization coverage. Maximizing availability, including providing the infant RSV antibody during the birth hospitalization, is important. Expanding birthing hospital enrollment in the VFC program is a crucial step, although challenges remain, and continued efforts are necessary to increase participation.

To summarize the FAERS post-marketing data for nirsevimab: Since approval through March 31, 2025, the most frequently reported adverse events involved RSV infections occurring after nirsevimab administration, including related symptoms and complications. No new safety

labeling updates have been made since the addition of serious hypersensitivity reactions on February 23, 2024. No additional safety signals have been identified. Errors involving incorrect dosing or product selection continue to be reported. FDA will continue routine pharmacovigilance for nirsevimab.

The VSD nirsevimab safety study for the 2024–2025 season included nearly 40,000 infants and employed a self-controlled risk interval design. No increased risk was observed for seizures, immune thrombocytopenia, drug reactions, sepsis, or fever. No cases of anaphylaxis were reported, and 18 cases of allergic reactions, primarily hives, were identified.

The work group found that FAERS and VSD safety data are reassuring and emphasized the importance of continued safety monitoring.

The VSD maternal RSV vaccine study included a matched cohort of 14,000 pregnant women who were either vaccinated or unvaccinated. No increased risk was observed for most outcomes. An association was identified between maternal RSV vaccination and hypertensive disorders of pregnancy, including preeclampsia, although the severity of the episodes of hypertensive disorders of pregnancy was similar among vaccinated and unvaccinated. VSD noted potential residual confounding, such as parity, and possible outcome misclassification due to challenges in determining the timing of onset and the absence of medical chart review.

The work group found the overall study findings reassuring, particularly the lack of association between maternal RSV vaccination and preterm birth. The group continued to conclude that the benefits of maternal RSV vaccination clearly outweigh the potential risks. Opinions were divided on the importance of the observed association with hypertensive disorders of pregnancy. Some members were not concerned, noting the small effect size, the absence of an increase in severity among vaccinated individuals, and the lack of association with preterm birth. The American College of Obstetricians and Gynecologists agreed with this assessment. Some were concerned that an imbalance of HDP was seen in multiple studies (phase 3 clinical trial, published retrospective cohort study, post-marketing study), and felt it was important that healthcare providers discuss the potential risk of HDP with pregnant women.

Clesrovimab is a long-lasting monoclonal antibody manufactured by Merck and is a form of passive immunization. It is administered as a single 105 mg dose in a 0.7 mL prefilled syringe, with the same dose recommended for all infants born during or entering their first RSV season, regardless of weight.

Dr. Adam MacNeil (CDC/NCIRD) presented the proposed recommendations. Clesrovimab and nirsevimab are recommended for use in infants under 8 months of age who are born during or entering their first RSV season. There is no preferential recommendation between the two products.

Only nirsevimab is recommended for children aged 8 through 19 months who are at increased risk of severe RSV disease and entering their second RSV season. Infants eligible for nirsevimab in their second season may have received either clesrovimab or nirsevimab during their first season. There are no safety or effectiveness concerns with using clesrovimab in the first season and nirsevimab in the second.

The proposed use of RSV antibody immunizations in infants, including nirsevimab or clesrovimab, is largely consistent with current nirsevimab recommendations. One dose is recommended for infants under 8 months of age during or entering their first RSV season, typically October through March in most of the continental U.S., if the mother did not receive RSV vaccine during pregnancy, if maternal vaccination status is unknown, or if the infant was born less than 14 days after maternal vaccination. Use may also be considered for infants born to mothers with reduced immune response or impaired antibody transfer, or for infants with

conditions that lead to loss of maternal antibodies, or infants with substantially increased risk for severe RSV disease.

To prevent severe RSV in infants, most will not need both maternal vaccination and an RSV antibody. Pregnant women should work with their healthcare provider to choose one of the two options.

Maternal RSV vaccine is recommended from September through January, and infant RSV antibodies are recommended from October through March. For infants already born before October, the optimal time to administer RSV antibody is just before the start of the season. In areas with varying RSV seasonality, providers should follow guidance from their state, local, or territorial health authorities.

Administration errors have occurred, including the incorrect distribution of RSV immunization products to the wrong population. Only RSV antibodies should be given to infants. RSV vaccines, such as Abrysvo, Arexvy, and mResvia, should not be administered to children. Only Abrysvo is approved for use in pregnant women. Arexvy and mResvia should not be given during pregnancy. Older adults may receive any of the three approved RSV vaccines. RSV antibodies should not be administered to pregnant women or older adults.

If an infant or child receives either nirsevimab or clesrovimab, palivizumab is not recommended during the same RSV season. Clesrovimab will be administered in the same manner as nirsevimab, as an intramuscular injection into the vastus lateralis muscle of the anterolateral thigh. The gluteal muscle should not be used for administration. It is acceptable to administer infant RSV antibodies concurrently with routine vaccines.

Clesrovimab should be stored in a refrigerator and used within 48 hours of being removed. It should not be frozen, shaken, or exposed to light.

If RSV antibodies are administered alone, suspected adverse events should be reported to MedWatch. If they are given at the same time as any vaccine, suspected adverse events should be reported to the VAERS. Additional reporting to MedWatch is not necessary in that case.

Proposed Recommendation:

> ACIP recommends that infants aged<8 months born during or entering their first RSV season who are not protected by maternal vaccination receive one dose of clesrovimab.

Dr. Georgina Peacock (CDC/NCIRD) shared updates on the RSV vaccines VFC resolution. The purpose of the resolution is to update the existing policy to include an additional long-acting monoclonal antibody for the prevention of RSV.

The first component of the resolution addresses the RSV maternal vaccine. There are no changes to the eligible groups, recommended schedule, or dosing intervals. However, the name of the individual product has been replaced with a product group name to reflect the availability of two licensed products. There are also no changes to the dosage, contraindications, or precautions.

The second component of the resolution has been retitled to reflect a product group name instead of a specific product. The eligible groups remain unchanged, as does the list of children at increased risk for severe RSV disease. The recommended schedule and intervals for nirsevimab are unchanged. A new row has been added to the table to include clesrovimab, the newly licensed long-acting monoclonal antibody for RSV prevention. As noted, clesrovimab is not indicated for use during a second RSV season.

Table notes have been added to define long-acting monoclonal antibodies and to provide a link to published information on the timing of administration. The language below the table has also been updated to reference the product group rather than an individual product. There are no changes to dosage, contraindications, or precautions.

Finally, ACIP recommendations published within six months of the resolution will be incorporated by reference, except for changes related to eligible groups.

Proposed Recommendation: VFC update

Approve the updated Vaccines for Children (VFC) resolution for prevention of RSV.

Dr. Levi acknowledged the consensus that RSV is a serious illness, particularly for young infants and those with underlying health conditions or born preterm. He expressed hope that newly developed RSV therapies will help prevent severe outcomes, including hospitalizations and deaths. However, he raised concerns based on clinical trial data related to the safety of these products. In the Melody trial, which tested nirsevimab in healthy infants, there were five deaths in the immunized group and none in the placebo group. Although serious adverse events (SAEs) were balanced overall, nervous system-related SAEs appeared more frequently in the immunized group. He noted that two deaths due to gastroenteritis in healthy infants were particularly unusual. In the Medley trial, which involved high-risk infants and compared nirsevimab to palivizumab, the imbalance in deaths continued (five in the immunized group versus one in the comparator group), with similar patterns in nervous system SAEs and gastroenteritis cases. The Harmony trial, conducted in Europe, showed no deaths in either group but still reflected a higher rate of SAEs in the immunized group, particularly involving the nervous system. Dr. Levi also highlighted data from the clinical trial of clesrovimab, the product under current consideration. In that trial, there were seven deaths in the immunized group compared to three in the control group. Nervous system SAEs were reported in 25 immunized infants versus four in the control group, and gastroenteritis cases occurred in 30 versus 10 infants. He pointed out the higher dose used for clesrovimab (105 mg) compared to nirsevimab (50 to 100 mg), suggesting the need to examine potential dose-related effects. Additionally, early reports from the Melody trial suggested that immunized infants had longer hospital stays upon admission, raising concerns about the potential for immunization-enhanced disease. Dr. Levi concluded by asking whether these patterns, though based on small numbers, might signal potential safety concerns. He noted that post-marketing analyses presented so far have been limited in scope and duration, and he urged CDC and committee colleagues to consider whether the observed imbalances warrant further investigation alongside the recognized benefits.

A representative from Merck Research Laboratories spoke about clesrovimab, a monoclonal antibody recently licensed by the FDA for the prevention of RSV disease in infants entering their first RSV season. The representative explained that the FDA conducted a thorough review of the product's safety and efficacy data and that Merck had shared detailed materials with the ACIP working group during its deliberations in November of the previous year. They emphasized that all adverse events reported during the clinical trials were extensively evaluated, and none were found by investigators to be related to RSV or the intervention given to the infants. No patterns or trends were observed in terms of cause, affected organ systems, or timing of events. The representative also pointed out that the main trial in healthy infants, known as Protocol 4 or

CLEVER, used a 2:1 randomization ratio, which should be considered when interpreting event numbers.

A member of the Maternal/Pediatric Workgroup addressed concerns about deaths observed in the pivotal Phase 2b/3 trial of clesrovimab. They noted that deaths were evaluated as potential harm over the 365 days following immunization. The events were balanced between the clesrovimab and placebo groups when accounting for the study's 2:1 randomization ratio. Specifically, there were seven deaths in the clesrovimab group and three in the placebo group, which aligns with the expected distribution based on the trial design. No patterns were observed in the cause or timing of deaths that suggested a link to the intervention.

An ex officio member clarified that clesrovimab was approved by the Center for Drug Evaluation and Research (CDER). As someone who works within CDER, they explained that they preferred not to speak on behalf of the review team and instead suggested deferring to CDER for an official comment on the safety review.

Ms. Hodowanik stated that she did not have much to add beyond Merck's summary but emphasized that the FDA carefully reviewed all case narratives. She confirmed that no trends or clustering were observed in the causes of death, and there was nothing to suggest a drug-related cause in any of the cases. She also noted that clesrovimab is a monoclonal antibody and that this class of products is generally well tolerated with limited toxicity.

Dr. Levi thanked the group for their responses and acknowledged the 2:1 randomization ratio used in the trials. However, he raised a concern about a possible trend in the data. He noted that across four separate trials, the number of deaths consistently occurred more frequently in the immunized groups. While he agreed that the trials were small and not powered to detect most safety signals unless those signals were very strong, he questioned whether seeing a similar pattern across multiple studies involving two similar products should prompt further consideration. He asked the group for their thoughts on whether this recurring outcome might be meaningful.

Ms. Hodowanik responded by acknowledging that the numerical counts of deaths in the studies appeared higher in the immunized groups. Still, she emphasized that the actual percentages were very close, at 0.3% versus 0.2%. She stated that this would not be considered a meaningful difference in death rates between the study arms. She noted that these are very small numbers and do not indicate a significant trend. Additionally, she explained that the FDA placed significant weight on reviewing the narratives of each case and assessing the potential biological plausibility between the causes of death and the administration of clesrovimab. No such connections were identified in their review.

Dr. Kulldorff commented that among the four trials discussed, three involved nirsevimab, which has already been recommended by ACIP and is not under consideration for a vote in the current meeting. He noted that the observed imbalances in those trials are important and should be closely monitored moving forward, particularly regarding mortality and other potential adverse events associated with nirsevimab. He clarified that the current vote pertains to clesrovimab, and based on the data presented, mortality appeared to be more balanced between the study arms for this product. Dr. Kulldorff suggested that it is possible clesrovimab may prove to be

superior to nirsevimab, although this is not yet known. He emphasized the importance of continuing to evaluate both products during the upcoming RSV season.

Dr. Levi requested clarification to ensure his understanding was accurate. He inquired whether there is currently an ongoing trial for clesrovimab in which the most recent reporting shows eight deaths in the immunized group compared to four deaths in the non-immunized group receiving standard care. He asked if that was an accurate interpretation of the available data.

A representative from Merck confirmed that, in addition to the healthy infant study (Protocol 4, also known as CLEVER), there is an ongoing trial in at-risk infants called Protocol 7, also referred to as SMART. In this study, infants are randomized one-to-one to receive either clesrovimab or palivizumab. An interim analysis was conducted to support FDA licensure, and as noted, it showed eight deaths in the clesrovimab arm and four in the palivizumab arm. Each of these deaths was thoroughly evaluated and reviewed by an independent external data monitoring committee. As with the earlier trial, no deaths were attributed to the study intervention. There was no evidence of clustering by cause, system organ class, or timing of the events. The representative emphasized that these events are rare and that the study remains ongoing.

Dr. Meissner stated that these issues were thoroughly discussed within the workgroup, which included over 60 members. He emphasized that the group carefully reviewed all available data in detail and appreciated Dr. Levi's close examination of the records. However, he noted that the workgroup was comfortable with the findings from the clesrovimab trials. He acknowledged that studies involving high-risk infants, including those born preterm, involve a particularly fragile population where unexpected deaths can unfortunately occur in both treatment and control groups. Dr. Meissner reiterated that there was no evidence of an imbalance or pattern in serious adverse events among clesrovimab recipients. He concluded by affirming the workgroup’s confidence in the recommendation they made.

Dr. Kulldorff expressed his gratitude to the work group, noting that the effort involved not only Dr. Meissner but many others who worked very hard on this review. He also thanked his fellow ACIP committee members, noting that while the presentations from the previous day primarily focused on the maternal vaccine and nirsevimab, which had already been recommended in a prior meeting, the work group members went beyond that information. They examined the data on clesrovimab in great detail, which is the product currently under consideration and was recently approved by the FDA. He commended the committee for stepping in and conducting a very thorough review.

Dr. Malone stated that there has been very active discussion and consideration within the committee regarding this product. For the record, he emphasized that the topic has been thoroughly debated internally. Despite the short timeframe available to address it, he expressed confidence that the committee had sufficient information. He noted that the committee had rigorously considered the various aspects of the product, had been appropriately briefed on the underlying issues and science, and had taken the time to investigate and discuss the matter to the best of its ability.

Dr. Hopkins, representing the National Foundation for Infectious Diseases, emphasized that RSV is the leading cause of hospitalizations in infants in the United States. He stated that the scientific evidence clearly supports the use of maternal RSV vaccines during pregnancy, as well as monoclonal antibodies for infants whose mothers were not vaccinated. He urged ACIP to ensure that any changes to RSV recommendations remain grounded in evidence. He reaffirmed NFID's commitment to protecting infants from serious RSV-related outcomes.

Dr. Levi shared a personal perspective, noting that while he is a scientist, he is also a father of six children. He emphasized the importance of considering the parents' viewpoint when evaluating the data. Reflecting on his own experience, he explained that if he were the parent of a baby born prematurely or with underlying health conditions, he would likely choose to use these products, given the serious threat RSV can pose to vulnerable infants. However, he stated that if his child were healthy and born full-term, he would feel hesitant about using a new product, even with scientific knowledge in hand. He expressed concern about introducing an immunization for a disease that has historically presented challenges in vaccine development. Dr. Levi emphasized that, beyond metrics such as hospitalization and disease burden, it is crucial to consider how parents might perceive and respond to the available data. He concluded by acknowledging that, as a father, he would feel cautious in such a situation and wanted to share that perspective with the committee.

Dr. Pepsworth asked for clarification on the differences in health outcomes between very sick infants and healthy children. She also inquired about available data on the effectiveness and safety of clesrovimab when administered according to the current immunization schedule. Specifically, she questioned whether there is information on the safety of administering clesrovimab concurrently with other routine vaccines, including those for hepatitis B, rotavirus, DTaP, Hib, pneumococcal, polio, COVID-19, and influenza. She emphasized the importance of understanding how simultaneous administration may impact safety outcomes.

Dr. Meissner responded by explaining that approximately 80% of children hospitalized for RSV are otherwise healthy, without prematurity, congenital heart disease, or chronic lung disease. These infants typically become symptomatic when infected, and about one-third of RSV cases in children lead to lower respiratory tract infections that require medical attention, such as visits to a pediatrician or the emergency department, even if hospitalization is not required. He emphasized that it is currently not possible to predict which healthy infants will develop severe disease, making it difficult to target monoclonal antibody use solely based on known risk factors. While RSV-related deaths in infants are very rare in the United States, with fewer than 100 annually and mostly among those with comorbidities, hospitalization is the most reliable primary endpoint to assess product effectiveness, with ICU admissions also being monitored. He clarified that products like clesrovimab and nirsevimab are monoclonal antibodies administered passively and are not vaccines in the traditional sense, as they do not stimulate an immune response. He addressed maternal vaccination, stating that if a pregnant woman chooses not to receive an RSV vaccine between 32 and 36 weeks of gestation, the alternative is to administer a monoclonal antibody to the infant at birth. He added that if he were Dr. Levi's pediatrician, he would strongly recommend that his wife either receive the maternal RSV vaccine or that the newborn receive a monoclonal antibody. He expressed strong support for the progress made in

RSV prevention, crediting much of it to the work of Barney Graham, who received NIH support. He described the new monoclonal antibody products and vaccines as remarkable, both safe and effective. He stated that the work group and the FDA had conducted extensive reviews, leaving no unresolved safety or efficacy issues in his view.

Dr. Kulldorff addressed Dr. Pebsworth's question about the concomitant administration of monoclonal antibodies with routine childhood vaccines given on the same day. He noted that the work group had reviewed this issue and requested follow-up from Dr. Meissner to provide additional context and information.

Dr. Meissner explained that there are three monoclonal antibodies used for the prevention of RSV. Palivizumab was the first-generation product, introduced around 1999, while clesrovimab and nirsevimab are second-generation antibodies that incorporate specific mutations in the Fc fragment, extending their half-lives. This allows a single dose to protect throughout the RSV season. In contrast, palivizumab required monthly dosing for five months to maintain coverage during the season. He noted that there is extensive experience with palivizumab, and despite its repeated dosing schedule, no interference has been observed with any of the standard, routinely recommended childhood vaccines. Based on this experience, he expressed confidence that concomitant administration with other vaccines is not a concern.

Dr. Goldman, representing the American College of Physicians and speaking as an individual, expressed support for the intervention under consideration. He thanked Dr. Meissner for his earlier remarks and added that, as a clinician, he sees firsthand the impact of diseases when they are not prevented or treated. He emphasized that healthy children do get RSV, and some become seriously ill, are hospitalized, or even die. He cautioned against limiting interventions only to those identified as high-risk, since risk is often not fully understood until illness occurs. He noted that this product is not a vaccine but rather provides passive immunity. As a father of two children, he wished it had been available when they were born. He called the product a major advancement in medical science and urged the committee to approve the resolution to help protect children and keep them healthy.

Dr. Meyer addressed Dr. Pepsworth's earlier question about the co-administration of monoclonal antibodies with other vaccines. She noted that real-world evidence from the Vaccine Safety Datalink, presented by Dr. Daly the previous day, showed that a high proportion of infants had received clesrovimab at the same time as another routine vaccine. She then turned the discussion over to Dr. Daly to provide further details from the real-world data.

Dr. Daley explained that the safety data presented the previous day covered approximately 74,000 infants who received nirsevimab, making the dataset roughly 20 times larger than the original clinical trial. This data reflects real-world use in routine practice. He highlighted that among the neonate cohort, 20 percent received same-day hepatitis B vaccination, and among the older infant group, 84 percent received same-day vaccination with routine childhood vaccines. He concluded that the safety evidence, particularly for infants aged 37 days to less than 8 months, does include and support safety with simultaneous vaccination.

Dr. Malone shared a concern raised by colleagues in the medical community, particularly among primary care providers, about the possibility that monoclonal antibody products may simply

delay RSV infection from the first year of life to the second. He noted that Dr. Meissner had previously discussed the current understanding of RSV pathophysiology and asked him to address this issue. Specifically, he requested that Dr. Meissner explain the role of terminal micro airway development in infants and how it relates to the effectiveness and implications of administering this product during early infancy.

Dr. Meissner explained that the most severe RSV disease typically occurs in the first 90 days of life, as this is when infants are at the highest risk of hospitalization. The increased risk is due to the small size of their bronchioles, which are the narrow airways that conduct air into the alveoli, the tiny air sacs in the lungs where oxygen and carbon dioxide are exchanged. In very young or preterm infants, these small airways can become completely blocked by inflammation during an RSV lower respiratory tract infection. By the second year of life, a child's airways are larger, making it much less likely that a small amount of inflammation will cause significant respiratory distress. Monoclonal antibodies are given to healthy infants to prevent RSV infection during the highest-risk period, particularly the first 90 days. Dr. Meissner noted that these antibodies do not fully prevent infection but instead reduce the likelihood of lower respiratory tract disease, allowing the child to build natural immunity. This may offer protection in the second year of life. Even if infection shifts to the second year, it is generally less problematic because the airways are larger and better able to tolerate inflammation without becoming obstructed.

Dr. Meissner recognized the contributions of Jefferson Jones, who led the work group throughout the process and was praised for doing an exemplary job.

Dr. Levi encouraged CDC colleagues to expand post-marketing analyses to include data on deaths and a broader range of potential adverse events. He emphasized the importance of understanding the risks alongside the benefits, regardless of the decision to use the product. He emphasized the importance of transparency in assessing the trade-offs involved. While he acknowledged that the analysis presented the previous day was very well done, he noted that it was limited in scope, focusing only on specific periods and certain adverse events, and expressed hope that future analyses would be more comprehensive.

Dr. Kulldorff expressed his deep appreciation to the work group for their thorough efforts, to the CDC staff for their support, and especially to his fellow committee members. He acknowledged that, despite very short notice, the group fully engaged with the review of clesrovimab, which was only approved by the FDA 16 days prior. He recognized the challenge of gathering and reviewing a large amount of information in a limited timeframe and thanked everyone for their commitment to carefully evaluating all the available data.

Vote: RSV Maternal/Pediatric Vote

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the RSV Maternal/Pediatric vaccine into the record:

> *ACIP recommends infants aged <8 months born during or entering their first RSV season who are not protected by maternal vaccination receive one dose of clesrovimab.*

Motion/Vote: RSV Vaccines

Dr. Malone motioned to approve the recommended voting language, stating, "ACIP recommends infants aged <8 months born during or entering their first RSV season who are not protected by maternal vaccination receive one dose of clesrovimab." Dr. Pagano seconded the motion. No COIs were declared. The motion carried with 5 in favor and 2 opposed. The disposition of the vote was as follows:

5 Favored: Malone, Hibbleln, Pagano, Meissner, Kulldorff
2 Opposed: Levi, Pebsworth
0 Abstained:

Vote: RSV Maternal/Pediatric-VFC Vote

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP VFC vote for RSV Maternal/Pediatric into the record:

Approve the updated Vaccines for Children (VFC) resolution for prevention of RSV.

Motion/Vote: RSV Vaccines

Dr. Malone motioned to approve the recommended updated Vaccines for Children (VFC) resolution for prevention of RSV. Dr. Pagano seconded the motion. No COIs were declared. The motion carried with 15 in favor and 0 opposed. The disposition of the vote was as follows:

7 Favored: Malone, Hibbleln, Pagano, Levi, Meissner, Pebsworth, Kulldorff
0 Opposed:
0 Abstained:

*Dr. Pebsworth disclosed that she owns shares in a healthcare sector fund that includes holdings relevant to ACIP discussions, including vaccine manufacturers. However, the value of these holdings falls below the de minimis threshold set by the Office of Government Ethics. Based on this, she confirmed her understanding that she is permitted to participate in the ACIP meeting fully.

PUBLIC COMMENT

The floor was opened for public comment on June 25, 2025. The comments made during the meeting are summarized in this document. Members of the public were also invited to submit written public comments to ACIP through the Federal eRulemaking Portal under Docket Number ID CDC-2025-0024. Visit regulations.gov for access to read the comments received.

Kim Mack Rosenberg, Esq.
Children's Health Defense and Mack Rosenberg Law LLC

A representative from Children's Health Defense provided public comment expressing concern over the misuse of ACIP's best practice guidelines by several states, including California and New York, to restrict medical exemptions for school vaccine requirements. The commenter noted that ACIP guidelines define contraindications and precautions broadly, recognizing that the lists are not exhaustive and cannot account for every circumstance in which a child may need a medical exemption. However, many states and school districts are limiting exemptions to only those explicitly listed, or even further restricting them to cases of anaphylaxis, disregarding other serious medical risks identified by treating physicians. The speaker urged ACIP to amend its best practices guidelines or issue a public statement clarifying that the CDC is not authorized to provide individualized medical advice and that clinical decisions regarding exemptions should be made by treating physicians using CDC guidance, medical history, and clinical judgment. The commenter shared the case of a 16-year-old student in New York with multiple health conditions, including acquired von Willebrand's disease and a history of severe vaccine reactions. Despite certifications from six licensed physicians stating that a third hepatitis B vaccine dose could endanger her life, her school district denied the exemption because her conditions are not explicitly listed as contraindications by ACIP. The commenter emphasized that similar cases occur frequently, and some children have suffered serious injuries after being forced to vaccinate against medical advice. The speaker concluded by urging ACIP to act promptly to clarify its guidelines and protect both vulnerable students and physician autonomy.

Chrissie Juliano, MPP
Big Cities Health Coalition

Chrissie Juliano, Executive Director of the Big Cities Health Coalition (BCHC), provided public comment expressing concern over Secretary Kennedy's recent dismissal of all 17 prior ACIP members, including Dr. Mysheika Roberts, Columbus Health Commissioner and BCHC board member, who was scheduled to join the committee. Juliano emphasized the critical role of local health departments in vaccination efforts and the trusted relationships they build with communities. She stressed that ACIP's independent, science-based vaccine recommendations have guided public health for over 60 years, and sudden leadership changes risk increasing confusion and public distrust at a time when vaccine confidence is already fragile. She highlighted the resurgence of vaccine-preventable diseases, such as measles, and underscored the importance of maintaining equitable access to routine vaccines. Juliano urged the new committee members to continue ACIP's tradition of making decisions based on science and evidence to protect public health.

Dr. Mary Koslap-Petraco
Pediatric Nurse Practitioner House Calls

Dr. Mary Koslap-Petraco, a pediatric nurse practitioner with over 30 years of experience, provided public comment expressing concern about the recent dismissal of 17 ACIP members. She stated that the former members had the expertise to design vaccine studies and voiced concern that the current committee has misinterpreted VAERS data, which provides safety signals but does not establish causality. Dr. Koslap-Petraco emphasized the need to keep COVID-19 vaccines available for children who need them, noting that misinformation has led parents to lose trust in healthcare providers. She shared personal experiences with vaccine-preventable diseases in her own family. She warned that if access to vaccines is reduced, more children will suffer and die from diseases that are currently preventable. As a Vaccines for

Children (VFC) provider, she urged ACIP to continue ensuring that all children have access to life-saving vaccines.

Marcia Cohen Zakai
Private Citizen

Marcia Cohen Zakai provided public comments, questioning the recent dismissal of all 17 ACIP members and calling the action unjustified, while raising concerns about its impact on public trust. She referenced a letter from the California Medical Association, the American Medical Association, and over 100 other medical organizations urging the reinstatement of the dismissed members. Zakai stressed that ACIP's evidence-based recommendations have historically ensured access to FDA-approved vaccines through a transparent process, and that the current vacancies risk creating confusion and undermining vaccine confidence. She warned that this could lead to preventable illness, disability, and death. Zakai emphasized the urgent need for expert vaccine guidance, especially amid ongoing COVID-19 and measles outbreaks, to protect the public and maintain widespread access to life-saving vaccines.

Caroline Brown, MD
The Children's Clinic of Winston Salem

Dr. Caroline Brown, a general pediatrician from North Carolina, provided public comment expressing deep concern about declining vaccination rates and the resurgence of vaccine-preventable diseases. Drawing from nearly two decades of clinical experience, she described firsthand encounters with severe illness in children, including cases of RSV, pertussis, and complications from diseases now preventable by vaccines. She noted that when she trained in the early 2000s, routine spinal taps were performed on febrile infants to rule out meningitis. Still, vaccines like Hib and pneumococcal conjugate have since spared many children from such procedures and outcomes. Dr. Brown reported that just one day before the meeting, the first confirmed case of measles was announced in her county. She has since been responding to concerned parents in her community. She emphasized that measles was eradicated in the United States 25 years ago. Still, its return is a direct result of declining vaccine uptake driven by misinformation, some of which she stated is amplified by members of the committee itself.

Dr. Alexandra Jones Packham
Private Citizen

Dr. Alexandra Jones Packham, a recent medical school graduate and incoming resident in internal medicine and pediatrics, provided public comment. She shared that she is currently pregnant and due in the middle of respiratory season, giving her a unique perspective as both a future pediatrician and a soon-to-be mother. Reflecting on her medical training, she described her experience in the pediatric ICU during the winter, where she saw numerous cases of bronchiolitis caused by RSV and influenza. She emphasized the limited treatment options for these infections, noting that supportive care is often the only intervention available while the body fights off the virus. Dr. Packham observed that during her rotations, every child she saw hospitalized with a severe respiratory infection had not been vaccinated against the pathogen involved, either due to parental choice or because they were too young to qualify for vaccination. She highlighted the effectiveness of vaccines and RSV monoclonal antibodies in preventing severe illness and stated her intention to receive the RSV, flu, and COVID-19 vaccines during her pregnancy. She also plans to ensure her child gets all recommended vaccines and antibody protections when eligible. Dr. Packham concluded by stressing the

importance of providing parents with the opportunity to discuss vaccination with their pediatricians and that vaccines and antibodies remain accessible and covered by insurance.

Diana Figueroa, LVN
Kaiser Permanente

Diana Figueroa, a licensed vocational nurse (LVN) with 16 years of experience, including 14 years in pediatric care, provided public comment. She expressed concern over the recent termination of 17 ACIP members, describing it as a poor decision given their extensive vetting and history of making evidence-based vaccine recommendations. She stated that the removal of these members undermines trust in the vaccine decision-making process and increases the risk of health policy being influenced by unqualified individuals making decisions based on personal opinions rather than scientific evidence. Ms. Figueroa also addressed shared clinical decision-making, noting that it creates barriers for LVNs and LPNs like herself to administer requested vaccines, ultimately delaying patient care. She emphasized that the healthcare system is already overwhelmed and that preventative care, including immunizations, is critical to reducing costly hospitalizations for both chronic and infectious diseases. She urged the FDA and CDC not to create additional barriers to vaccine access. She emphasized the importance of protecting vulnerable populations, including pregnant women, newborns, the immunocompromised, the elderly, and healthy individuals who choose to be vaccinated to protect their communities. Ms. Figueroa called for the reinstatement of the previously terminated ACIP members, the removal of recently appointed unvetted members, and the restoration of prior COVID-19 vaccine recommendations for pediatric and pregnant populations, which she believes have been effective in preventing disease.

Dr. Amy Hardin
Northside Pediatrics

Dr. Amy Hardin, a pediatrician in private practice in Woodstock, Georgia, provided public comment emphasizing the critical importance of vaccines in preventing severe childhood illnesses and deaths. She reflected on her training at Emory from 1990 to 1993, when, before the introduction of Haemophilus influenzae type B (Hib) and pneumococcal vaccines, pediatricians frequently admitted children with high fevers for complete septic workups. These included blood cultures, catheterized urine samples, and spinal taps to check for meningitis and sepsis. At that time, one in 200 children under five developed invasive Hib disease, resulting in conditions such as sepsis, epiglottitis, cellulitis, and meningitis. Many children died, while others were left with lifelong disabilities, including deafness, cerebral palsy, and severe learning challenges. Dr. Hardin noted that she has not seen a single case of Hib or pneumococcal meningitis or sepsis since 1999, a year she remembers vividly because it was the last time she attended a funeral for a child who died from a vaccine-preventable disease. She recounted the death of a two-year-old boy who missed his routine vaccination and died from pneumococcal infection three months later. She expressed concern that vaccine hesitancy and misinformation are causing a resurgence of vaccine-preventable diseases. Her colleagues in Atlanta are now treating new cases of Hib meningitis, primarily in unvaccinated children whose parents were influenced by misinformation online. Dr. Hardin urged ACIP members to protect the health of America’s children by continuing to promote evidence-based vaccine policies. She concluded by affirming that vaccines are safe, effective, and lifesaving, and warned against allowing the country to return to a time when preventable childhood deaths and disabilities were common.

Adrianna Williams
Private Citizen

Adrianna Williams, a private citizen, provided public comment expressing strong opposition to vaccines, including those under discussion at the meeting. She referenced the Hippocratic Oath and stated her belief that vaccines cause harm and should be abolished. Ms. Williams asserted that there are safer, natural alternatives for disease prevention. She described vaccines as a bioweapon mechanism, claiming that cumulative harm results from the interaction of vaccine ingredients with bodily systems. She cited data from the Vaccine Adverse Event Reporting System (VAERS), reporting over 8,000 adverse events and more than 70 deaths following RSV vaccination. She specifically referenced VAERS report ID 28021 as an example of an RSV vaccine-related death. Ms. Williams urged ACIP members to listen to individuals who report vaccine injuries and called for the immediate cessation of all vaccine recommendations, beginning with the RSV vaccines under consideration at this meeting. She concluded by asking the committee to act following the principle of "do no harm" and to prioritize the health and safety of both present and future generations.

Roselie Bright, ScD
Private Citizen

Dr. Roselie Bright, a retired epidemiologist from the FDA, expressed concern about the recent erosion of scientific integrity in federal health agencies. She described how, during her career, regulatory decisions were based on transparent documentation and collaboration among experts, which built trust in the process. However, she now questions federal decisions due to political interference, mass firings of scientists, and changes to the structures of advisory committees. Bright urged continued consideration of long COVID in vaccine recommendations, universal access to COVID-19 vaccines three times per year, and the development of more effective vaccines. She called for increased transparency in ACIP meetings, including simultaneous public access to meeting materials, more time for public comment, and summaries of those comments during meetings. She also advocated reinstating the 17 removed ACIP members, requiring scientific competency for all members, and barring anyone who disregards research ethics from serving in advisory roles.

Due to time constraints, Dr. Kulldorff announced that the remaining RSV discussion will continue on July 26, 2025; summaries of those discussions are included in the RSV section above. The meeting was then recessed until July 26, 2025, at 8:00 AM EST.

THURSDAY: APRIL 26, 2025

WELCOME AND INTRODUCTIONS

Call to Order/Roll Call

Dr. Martin Kulldorff, Chair of the ACIP, convened the meeting on June 26, 2025. Dr. Mina Zadeh, ACIP Executive Secretary from the CDC, welcomed the committee, followed by a roll call from members, each of whom announced their presence.

INFLUENZA VACCINES

Dr. Vivien Dugan (CDC/NCIRD) summarized the influenza vaccine session, which covered five presentations. These included data on the immunogenicity and safety of the Flublok

recombinant influenza vaccine in older children and adolescents, updated estimates of influenza burden and the impact of influenza vaccination for the 2024–2025 influenza season, an overview of the 2024–2025 influenza season with proposed influenza vaccine recommendations for 2025–2026, a review of thimerosal preservative and proposed updates related to the use of thimerosal-containing influenza vaccines.

Dr. Pedro Folegatti (Sanofi Pasteur) presented the results of a Phase 3 immunobridging non-inferiority trial evaluating the quadrivalent recombinant influenza vaccine (RIV4), which is licensed as Flublok in older children and adolescents, compared to adults. Dr. Folegatti disclosed that he was a full-time employee of Sanofi and held shares in the company.

Recombinant protein technology has been established a proven approach to vaccine development against infectious diseases since the late 1980s, demonstrating safety and effectiveness across multiple pathogens, including hepatitis B, HPV, zoster, COVID-19, and influenza. For influenza vaccines, this technology offers several advantages: it maintains the sequence integrity of flu antigens consistent with FDA-selected strains, operates independently of egg supply, and does not involve culturing or handling live influenza viruses. As a result, there is no egg adaptation of the virus. Additionally, the recombinant influenza vaccine avoids the inactivation step, preserving the native hemagglutinin conformation of the wild-type virus, which supports a more optimal protective immune response.

Key clinical evidence supporting Flublok includes several Phase 3 trials. In a randomized controlled efficacy trial among adults aged 50 and older, Flublok provided 30 to 43% greater protection against biologically confirmed symptomatic influenza compared to a U.S.-licensed standard-dose inactivated influenza vaccine during a predominantly H3N2 mismatch season. A Phase 3 immunobridging study in adults aged 18 to 49 demonstrated non-inferior immune responses to three of four strains when compared to the same standard-dose vaccine. The trivalent formulation of Flublok was first licensed in 2013, followed by the quadrivalent version in 2016 for individuals aged 18 and older. The label has since been updated and approved by the FDA to include children aged 9 and older, based on the data presented today. As of January 31, 2025, more than 43 million doses of Flublok have been distributed globally. The vaccine has an established safety profile and is well tolerated, with no safety signals identified to date.

The study presented was part of a pediatric research plan for Flublok, developed in coordination with the FDA and international regulatory authorities. It was a Phase 3, multi-center, open-label, non-randomized immunobridging study conducted at 36 sites across Spain, Poland, the Czech Republic, and the U.S. The trial aimed to enroll up to 1,334 healthy participants aged 9 to 49 years, all of whom received a single dose of Flublok. The primary objective was to demonstrate non-inferiority of immune responses in children and adolescents (ages 9–17) compared to adults, where vaccine efficacy had already been established. Immune responses were evaluated using hemagglutination inhibition antibody titers and seroconversion rates four weeks post-vaccination. The key secondary objective was to assess the safety profile of Flublok by age group.

Participants received their vaccination on Day 1, with a baseline blood sample collected. This was followed by a safety phone call on Day 9 and a clinic visit on Day 29 for a safety review and a second blood draw. They were monitored for six months after vaccination. Solicited local and systemic adverse events were collected over a seven-day period, while unsolicited and medically attended events were tracked for 28 days. Serious adverse events and adverse events of special interest were monitored throughout the study. Key exclusion criteria included receipt of any vaccine within four weeks before or after enrollment, except for COVID-19 vaccines, which were allowed if administered at least two weeks apart from the study vaccine, and receipt of any influenza vaccine within the six months before enrollment. The primary

immunogenicity endpoints were geometric mean titer (GMT) ratios and seroconversion rates at Day 29 for each of the four influenza strains. The study was designed with 80% power to demonstrate non-inferiority based on eight tests. Non-inferiority was met if the lower bound of the 95% confidence interval for GMT ratios was greater than 0.667, and the lower bound for the difference in seroconversion rates was greater than -10%.

Of the 1,334 participants initially planned, 1,308 were enrolled between October 27, 2022, and May 1, 2023. A total of 641 participants in the 9 to 17-year-old group and 658 participants in the 18 to 49-year-old group received the vaccine. Among them, 626 children and adolescents, as well as 634 adults, provided both pre- and post-vaccination blood samples for the primary endpoint. Overall, the study achieved high and comparable retention rates across both age groups.

The study included more females than males. The mean age was 13 years in the 9 to 17-year-old group and 34 years in the 18 to 49-year-old group. Most participants were White, with Black or African American individuals making up nearly 19% of the total enrolled population. Additionally, 87% of participants identified as non-Hispanic or Latino.

The primary endpoint assessed antibody responses four weeks after vaccination, comparing the 9 to 17-year-old group with the 18 to 49-year-old group. Geometric mean titers (GMTs) on Day 29 were evaluated for all four influenza strains in the vaccine. The data showed that antibody responses were comparable between the two groups, with children and adolescents generally exhibiting higher responses than adults. The GMT ratios, along with their 95% confidence intervals, all exceeded the non-inferiority margin of 0.667. The lower bounds ranged from 1.09 for B/Yamagata to 2.76 for H3N2, demonstrating that non-inferiority was met for all strains.

Seroconversion was defined as a four-fold or greater increase in antibody titers for participants with a baseline hemagglutination inhibition (HAI) titer of 10 or higher, or a post-vaccination titer of at least 40 for those who were seronegative at baseline. The differences in seroconversion rates between the 9- to 17-year-old group and the 18- to 49-year-old group ranged from (-) 0.59% for H3N2 to 14.3% for B/Yamagata. In all cases, the lower bound of the 95% confidence interval remained above the non-inferiority margin of –10%, indicating that the primary objective of demonstrating non-inferior immune responses was achieved for all four influenza strains, based on both Day 29 geometric mean titer ratios and seroconversion rates.

For the secondary objective, 10 participants, representing less than 1% of the total enrolled population, reported at least one serious adverse event, and 5.1% reported at least one medically attended adverse event. None of these events were considered related to the study vaccine by the investigators or the sponsor. No deaths or adverse events of special interest were reported, and there were no meaningful differences in the safety profiles between the two age groups.

Expected reactions within the first seven days following vaccination were slightly less common among children and adolescents compared to adults. Grade 3 solicited events were reported in 6.5% of children and adolescents and 4.5% of adults aged 18 to 49. Similar trends were seen for both local injection site reactions and systemic reactions. Most reactions were mild or moderate, began within the first three days after vaccination, and resolved on their own within one to three days.

Local injection site reactions were most commonly reported as pain, occurring in 34.3% of participants aged 9 to 17 and 40.2% of those aged 18 to 49. Other local reactions, such as bruising, swelling, induration, and erythema, were reported occasionally, with no significant

differences between the age groups. Most local adverse reactions were mild or moderate in severity.

Myalgia, malaise, and headache were the most frequently reported systemic adverse reactions, occurring in less than a quarter of participants in both age groups. Fewer than 3% of children and adolescents reported a febrile episode following vaccination. No differences in the profile of solicited systemic reactions were observed between children, adolescents, and adults. Most events were mild or moderate and resolved on their own.

Seven participants in the 18 to 49-year-old group reported nine serious adverse events (SAEs), and three participants in the 9 to 17-year-old group reported four SAEs. None of these events were considered related to Flublok by investigators, based on their assessment of underlying conditions, concurrent therapies, and risk factors.

Dr. Folegatti concluded that Flublok elicited robust hemagglutination inhibition (HAI) immune responses in both age groups. The primary objective of demonstrating non-inferiority of immune responses in older children and adolescents compared to adults was met for all four strains, based on both geometric mean titers and seroconversion rates. The safety profile was comparable between groups; the vaccine was well-tolerated, and no safety concerns were identified.

Dr. Vivien Dugan (CDC/NCIRD) shared the severity, disease burden, and prevention burden for the 2024–2025 influenza season. The 2024–2025 influenza season in the United States received significant media attention, with many reports describing it as one of the worst in recent history. However, using data to assess seasonal severity and estimate disease burden is essential for putting each influenza season into context, as each season is often unique.

To evaluate the severity of the 2024–2025 influenza season, three surveillance indicators were used across all age groups: the percentage of influenza-like illness, the rate of influenza hospitalizations, and the percentage of influenza-associated deaths. Influenza-like illness and hospitalization rates each had two peak weeks classified as high severity, while influenza-associated deaths had five peak weeks at the high severity level. Based on these indicators, the 2024–2025 influenza season was classified as a high severity season across all age groups.

When comparing the 2024–2025 influenza season to past seasons, it was the first to be classified as high severity overall and across all age groups since the 2017–2018 season.

Data-driven burden estimates for seasonal influenza are essential because the exact number of illnesses, hospitalizations, and deaths is unknown. Several factors contribute to this uncertainty. U.S. states are not required to report individual seasonal influenza cases or hospitalizations, except for deaths in children under the age of 18. Surveillance systems in healthcare settings do not capture all influenza infections. Many individuals who fall ill do not seek medical care, and those who do may not undergo testing. Testing may occur too late for influenza to be detected, and symptoms can resemble those of other respiratory illnesses, leading to a misdiagnosis. Due to these limitations, public health officials rely on burden estimates and severity assessments based on real-world data to understand the population-level impact, identify high-risk groups, assess the strain on health systems, inform policy decisions, shape public communication, and support economic and cost-benefit analyses.

The influenza disease burden is measured by a range of clinical outcomes, including symptomatic illness, medically attended visits, hospitalizations, and deaths. Estimates are routinely calculated for five age groups: 0-4 years, 5-17 years, 18-49 years, 50-64 years, and 65 years and older. In the United States, the influenza burden is estimated both during and after

each season. Final estimates are typically available about two years after the season ends, once all necessary data sources are complete.

Influenza disease burden is estimated using a multiplier modeling approach. First, hospitalization rates from sentinel surveillance are adjusted for testing practices and test sensitivity, then multiplied by the population. Second, deaths are estimated by applying a death-to-hospitalization ratio. Third, symptomatic illnesses are calculated using a ratio of cases per hospitalization. Finally, outpatient visits are estimated by multiplying the number of symptomatic illnesses by the probability of seeking care, as determined by survey data. Current estimates do not include deaths; those will be available once hospitalization data collection is complete, likely by late September 2025.

Preliminary estimates for the 2024-2025 influenza disease burden indicate that adults aged 18 to 49 years had the highest number of symptomatic illnesses and medical visits, while adults aged 65 and older had the highest number of hospitalizations. Compared to past seasons using the same methodology, all three outcomes (symptomatic illness, medical visits, and hospitalizations) were higher than in any previous season. These estimates are still preliminary and may change as additional data for the 2024-2025 season becomes available; however, the overall disease burden was high.

Similar to the disease burden models, influenza vaccine-prevented disease burden models use additional data to produce estimates. These models combine the number of illnesses, medical visits, and hospitalizations by age group with data on vaccine coverage and vaccine effectiveness. Vaccine effectiveness against outpatient visits is used to estimate the number of illnesses and medical visits prevented, while effectiveness against hospitalization is used to estimate the number of hospitalizations prevented. When sufficient data are available, the model also includes estimates of the number of prevented deaths.

To estimate the prevented disease burden, vaccine coverage and vaccine effectiveness data from the season are applied to the disease burden estimates. This helps estimate the risk of illness, medical visits, and hospitalizations in the susceptible population. These risks are then modeled in a hypothetical population without vaccination. The difference between the observed disease burden and the estimated burden in the absence of vaccination represents the disease burden that is prevented.

Preliminary estimates for 2024 to 2025 show that the highest number of symptomatic illnesses was prevented among adults aged 18 to 49 years. The most prevented medically attended illnesses occurred in adults aged 18 to 49 and 50 to 64 years. The greatest benefit of influenza vaccination was seen in the prevention of hospitalizations among adults aged 65 and older.

For the 2024–2025 season, all three prevented outcomes were higher than in any previous season using this methodology. Although these estimates are still preliminary and may change as more data become available, they highlight the significant impact of influenza vaccination in preventing illness, medical visits, and hospitalizations. A dashboard with past season estimates of disease burden prevented by vaccination is available on the CDC's Flu Burden Prevented by Vaccination website.

Dr. Dugan concluded that influenza continues to have a significant impact on healthcare systems and population health each season. The 2024–2025 season was classified as high severity for all ages and age groups, marking the first such classification since the 2017–2018 season. The estimated influenza disease burden was the highest in the United States over the

last approximately 15 years. Influenza vaccination is estimated to have prevented around 240,000 hospitalizations, with the majority among adults aged 65 and older. Both vaccine uptake and effectiveness likely played key roles in preventing the season from being even more severe.
Dr. Vivien Dugan (CDC/NCIRD) shared an update on the 2024–2025 influenza season and the vaccine recommendations for the 2025–2026 season. The 2024–2025 U.S. influenza season was classified as high severity overall and across all age groups. This was the first high-severity season since the 2017–2018 season. Influenza A viruses were the predominant type, accounting for over 94% of the more than 98,000 specimens tested by public health labs. Influenza B viruses co-circulated at much lower levels. Both A(H1N1)pdm09 and A(H3N2) subtypes were detected, with a relatively even distribution nationwide, ranging from 47% to 52%.

Two key indicators of severity were influenza-associated hospitalizations and pediatric deaths. From October 1, 2024, through April 30, 2025, the cumulative hospitalization rate was 128.1 per 100,000, the highest since the 2010–2011 season. This surpassed the rate of 102.9 per 100,000 reported during the 2017–2018 season. As of June 14, 250 influenza-associated pediatric deaths had been reported, marking the highest number recorded in any non-pandemic season since the condition became reportable in 2004.

Influenza-associated hospitalization data from FluSurv-NET, which covers about 9% of the U.S. population, show that the cumulative hospitalization rate for the 2024–2025 season reached 128.1 per 100,000. This exceeds the 102.9 per 100,000 rate reported during the 2017–2018 season and is the highest recorded since the 2010–2011 season, excluding the 2020–2021 season when influenza activity was historically low due to the early COVID-19 pandemic.

Hospitalization rates were highest among adults aged 65 years and older, at 403.4 per 100,000. Children aged 5 to 17 years had the lowest rate, at 39.8 per 100,000. Among all hospitalized patients, 16% required admission to an intensive care unit and 6% required invasive mechanical ventilation.

An influenza-associated pediatric death is defined as a death in a person under 18 years of age that occurs during a clinically compatible illness with a positive influenza test, without a complete recovery between illness and death. This condition has been nationally notifiable since 2004. As of June 14, 2025, a total of 250 influenza-associated pediatric deaths have been reported to the CDC for the 2024–2025 season. All age groups were affected: 6% were infants aged 0 to 5 months, 14% were aged 6 to 23 months, 18% were aged 2 to 4 years, 36% were aged 5 to 11 years, and 26% were aged 12 to 17 years.

Dr. Dugan summarized that among the 250 influenza-associated pediatric deaths reported for the 2024–2025 season as of June 14, 42% had no known high-risk underlying medical conditions, and 42% had a bacterial co-infection of a sterile site. She noted that 89% of vaccine-eligible children were not fully vaccinated, a higher proportion than the 82% reported during the 2023–2024 season. This total represents the highest number of pediatric deaths reported in any non-pandemic influenza season since reporting began in 2004.

Few changes are proposed for the 2025–2026 influenza vaccination recommendations. Annual influenza vaccination remains recommended for everyone aged 6 months and older without

contraindications. As in previous years, no vaccine product is generally preferred, except for adults aged 65 years and older, for whom high-dose inactivated, recombinant, or adjuvanted inactivated vaccines are preferred when available.

All individuals should receive an age-appropriate influenza vaccine approved by the FDA. An exception applies to solid organ transplant recipients aged 18 to 64 years on immunosuppressive therapy, who may receive high-dose or adjuvanted inactivated vaccines without preference over other appropriate inactivated or recombinant vaccines. Recommendations regarding vaccine timing, vaccine selection, and contraindications and precautions remain unchanged.

There are three updates for the 2025–2026 influenza season, all reflecting recent FDA approvals. First, the influenza vaccine composition has been updated for the upcoming season. Second, FluMist, the intranasal trivalent live attenuated influenza vaccine, is now approved for self-administration by adults or caregiver administration to children. This was presented to the ACIP in April 2025. Third, the approved age indication for Flublok, the trivalent recombinant influenza vaccine, has been lowered from 18 years to 9 years. The committee reviewed these updates at the start of the session.

For the 2025–2026 season, all influenza vaccines marketed in the United States will be trivalent, as they were in the previous season. Each vaccine will contain antigens from three influenza viruses: one A(H1N1)pdm09, one A(H3N2), and one B virus.

The vaccine composition includes an updated A(H3N2) component. For A(H1N1), the FDA has recommended A/Victoria/4897/2022-like virus for egg-based vaccines and A/Wisconsin/67/2022-like virus for cell-based and recombinant vaccines. These are the same as last season. The updated A(H3N2) component is A/Croatia/10136RV/2023-like virus for egg-based vaccines and A/District of Columbia/27/2023-like virus for cell-based and recombinant vaccines. The B component remains unchanged and will include the B/Austria/1359417/2021-like virus from the B/Victoria lineage.

FluMist for self or caregiver administration was approved by the FDA in September 2024 and presented to the ACIP in April 2025. It is expected to be available for the 2025–2026 influenza season. Consumers will be able to order FluMist for delivery through an online pharmacy, which will screen for eligibility based on ACIP criteria.

For individuals aged 18 through 49 who are eligible, self-administration is permitted. For recipients aged 2 through 17 years, the vaccine may be administered by a caregiver who is at least 18 years old. FluMist remains approved for individuals aged 2 through 49 years and will continue to be available for administration by healthcare providers. No changes have been made to recommendations regarding appropriate populations, contraindications, or precautions.

The third update concerns Flublok. In March 2025, the FDA approved Flublok for use in individuals aged 9 through 17 years. Previously, it was approved only for those aged 18 and older. With this new approval, Flublok is now indicated for individuals aged 9 years and older. This change has been reflected in the updated table of available U.S. influenza vaccines for the 2025–2026 season.

Dr. Hibbeln expressed concern about the number of reported significant psychiatric adverse events, including major depression, suicidal ideation, and intentional overdose, in the 9–17 and 18–49 age groups. As a psychiatrist, he emphasized the importance of monitoring and reporting psychiatric side effects in vaccine trials. He commended Dr. Folegatti and Sanofi for identifying and reporting these events and noted the connection between the immune system and mental health. Dr. Hibbeln acknowledged the limitations of the study design and asked how it was determined that these events were unrelated to the vaccine. He also inquired whether Sanofi has plans to prospectively evaluate psychiatric outcomes, particularly suicidal ideation and overdose, in future studies.

Dr. Folegatti responded that all reported cases of suicidal ideation were classified as unrelated to vaccination. He noted that all affected participants had a prior history of mental health conditions. The study did not include specific screening for mental health disorders in its eligibility criteria. In most cases, investigators identified clear alternative triggers for the events. All SAEs observed in the study were considered to fall within expected background rates for the respective age groups. Dr. Folegatti stated that Sanofi currently has no plans to conduct additional psychiatric evaluations beyond standard post-marketing safety surveillance.

Dr. Hibbeln thanked Dr. Folegatti for his response and expressed concern about whether the reported cases involved a worsening of suicidal ideation or the enrollment of participants with pre-existing suicidal ideation. He noted that without mental health pre-screening, it is unclear how a determination could be made that these events were unrelated to the vaccine.

Dr. Malone began by expressing his enthusiasm for joining the current influenza subgroup and noted that he looks forward to future collaboration. He highlighted two influenza vaccine products discussed during the meeting. First, he praised Flublok as an innovative, cell-based vaccine manufactured using insect cells and baculovirus technology. He noted its key advantage of bypassing the need for antigen adaptation to egg or cell culture, allowing for a faster, more accurate production process that more closely matches circulating strains. Second, he acknowledged the cold-adapted live attenuated influenza vaccine (LAIV), developed by MedImmune, for its historical effectiveness in the pediatric population and its needle-free delivery method. He emphasized the importance of expanded access and ease of administration by less specialized personnel. Dr. Malone commended both manufacturers for their commitment to safe and innovative vaccine development through well-designed non-inferiority trials. He concluded with a specific question for Sanofi, asking whether any fetal-derived products are used in the manufacturing of Flublok, noting this as a potential concern in some communities.

Dr. Marais, Medical Head for Influenza and COVID Vaccines in North America, responded that no fetal-derived products are used in the manufacturing of Flublok.

Dr. Malone thanked Dr. Marais for the clarification, noting that the absence of human fetal tissue–derived material in Flublok is an important consideration for certain U.S. communities with religious concerns. He then asked whether microneutralization data had been collected for Flublok, acknowledging that while the hemagglutination inhibition (HAI) assay is the accepted correlate of protection for influenza, there has been a long-standing interest in microneutralization as an exploratory endpoint.

Dr. Folegatti explained that the study included a seroneutralization subset of approximately 400 participants, with results available for about 363 individuals. This included 185 participants aged 9 to 17 years and 178 participants aged 18 to 49 years. He reported a substantial increase in seroneutralization responses in both age groups, noting that no significant differences were observed between adolescents and adults.

Dr. Meissner posed several questions regarding the Flublok study. First, he asked why age nine was chosen as the lower limit for comparison with the 18 to 49 age group. Second, he inquired whether baseline serologic status in children affected their immune response to Flublok. Third, he noted that the immune response appeared stronger in 9 to 17-year-olds compared to older individuals, except for the B/Yamagata strain, and questioned the rationale for presenting data from a quadrivalent vaccine that included B/Yamagata, which is no longer in use. He also inquired whether the study had assessed cellular immunity, noting the uncertain role of T-cells in influenza protection. Finally, Dr. Meissner expressed interest in the potential for a comparative trial between high-dose or cell-based vaccines, such as Flublok, and standard egg-based vaccines, and asked whether such a trial is anticipated in the future.

Dr. Folegatti responded that age nine was selected for the study population because a single-dose influenza vaccine is recommended starting at that age, and children nine years and older are expected to have immune responses similar to adults. He stated that subgroup analyses were conducted to examine the influence of baseline serologic status and prior season vaccination. The results showed consistent findings regardless of baseline serostatus or prior vaccination. He confirmed that although children had higher baseline titers, the fold increase in immune response was comparable to that of adults. In response to the question about cellular immunity, Dr. Folegatti noted that the study did not assess cellular immune responses.

Dr. Folegatti, in response to Dr. Meissner's question about a head-to-head comparison between Flublok and other influenza vaccines, noted that data are available, including a cluster-randomized efficacy study conducted at Kaiser Permanente. He stated that the results showed a relative vaccine efficacy in favor of Flublok compared to the standard-dose vaccine.

Dr. Meissner clarified that this was an efficacy study, not just a serologic one.

Dr. Folegatti confirmed and offered to share the reference and additional data following the meeting. He also confirmed that immune responses to the trivalent and tetravalent vaccine formulations should be similar.

Dr. Malone asked the CDC to confirm whether current methods for estimating influenza disease burden require laboratory-confirmed influenza diagnoses. He noted that, historically, influenza-like illness metrics have included a range of upper respiratory infections, and he sought clarification that the current approach is based specifically on confirmed influenza cases rather than an aggregate of viral respiratory illnesses.

Dr. Dugan confirmed that all current estimates of the influenza burden are based on laboratory-confirmed cases of influenza.

Dr. Malone acknowledged the 250 pediatric deaths as a relatively modest number and asked whether there is a calculated number needed to treat (NNT) to prevent a death in the pediatric population.

Dr. Reed, an epidemiologist in the Influenza Division, responded that the number needed to treat to prevent a pediatric death has been calculated in the past, although not recently. She noted that the team can work on updating that estimate and follow up.

Dr. Malone stated that the committee would likely appreciate future reports that include NNT estimates for major endpoints related to vaccine products. He then raised a question about the sharp decline in influenza activity during the 2020–2021 season, followed by an apparent increase in influenza severity in subsequent years. He asked whether the CDC has any

hypotheses to explain the sudden decrease in influenza burden during the early years of the COVID-19 pandemic.

Dr. Dugan responded that the COVID-19 pandemic significantly changed general behaviors, including reduced travel and interpersonal contact, which led to decreased transmission not only of influenza but also of other seasonal respiratory viruses. She noted that it is difficult to attribute the decline to a single factor. As normal activities resumed, influenza, RSV, and other respiratory viruses began circulating again. She emphasized that these viruses now co-circulate and are closely monitored to understand their patterns of transmission better. However, she added that respiratory viruses remain highly unpredictable, and each influenza season tends to be unique in its characteristics and impact.

Dr. Reed agreed.

Dr. Malone noted that some members of the scientific community have raised concerns that, following the COVID-19 pandemic, changes in population-level exposure to viruses and countermeasures may be contributing to the increased severity of influenza. He acknowledged that it may be too early to conclude. Still, he encouraged the CDC to remain vigilant in considering this hypothesis and to share data that could help support or refute the possibility of a broader population-based process influencing the severity of respiratory viral illnesses.

Dr. Daskalakis thanked the Influenza Division and Dr. Dugan for the presentation and acknowledged the relevance of Dr. Malone's question. He noted that, from the CDC's surveillance perspective, this question may be better suited for researchers focused on pathogenesis and suggested that institutions such as the NIH may be better positioned to explore that area further.

Dr. Meissner commented that although influenza vaccines may have lower efficacy compared to vaccines like the measles vaccine, their public health impact remains significant due to the large number of influenza cases each year, estimated at 30 to 40 million in the United States. He emphasized that even modest vaccine effectiveness can result in substantial benefits at the population level. He then asked whether data have been collected on the percentage of influenza vaccines administered at home by individuals over 18 years of age using FluMist, and how well this option has been accepted.

Dr. Dugan noted that, based on current estimates, approximately 1 million hospitalizations would have occurred during the 2024–2025 season without influenza vaccination. This highlights the importance of vaccination in reducing disease burden. She also clarified that self-administration of FluMist is anticipated to become available for the 2025–2026 season, but it is not yet in use.

Dr. Levi emphasized the importance of continuing clinical trials to compare the efficacy of different influenza vaccines. He raised a question about how vaccine efficacy is assessed year to year and what portion of the influenza burden is truly being averted through vaccination. He noted the challenges of accurately measuring this impact. He asked CDC colleagues whether negative control approaches are being used to account for the potential influence of the healthy vaccine effect. He also expressed concern that the CDC's model for estimating averted burden appears to increase in direct proportion to the observed number of hospitalizations. He pointed

out that rising hospitalizations could be due to either a higher baseline burden or lower vaccine effectiveness, and that models should account for both factors. He asked how the CDC addresses these concerns and what steps might improve the precision of burden and efficacy estimates.

Dr. Dugan responded that the CDC regularly reviews, tests, and refines its models to improve accuracy and incorporate new data sources. She acknowledged that many factors influence both influenza burden and vaccine effectiveness, including vaccine uptake, public attitudes, timing of the season, co-circulating viruses, the predominant strain, and the antigenic relatedness between the vaccine and circulating viruses. She emphasized the complexity of these interactions and the CDC's ongoing efforts to enhance the precision and clarity of its models.

Dr. Reed confirmed that the CDC's model for estimating prevented burden includes three main components: the observed burden during the season, vaccine coverage, and vaccine effectiveness, which is measured annually through vaccine effectiveness studies. She explained that in seasons with higher influenza activity, even a vaccine with the same level of effectiveness can result in a greater number of averted outcomes due to the increased risk and incidence in the population.

Dr. Levi emphasized the importance of recognizing potential endogeneity in burden estimates, noting that the observed burden may be influenced by vaccine efficacy itself. He suggested that additional efforts are needed to refine the models, as current estimates may be too coarse to accurately monitor key issues over time. He emphasized the need for more precise methods to evaluate vaccine efficacy and enhance the public health response to a serious illness, such as influenza.

Dr. Dugan shared that, overall, they regularly evaluate, test, and stress-test their models and explore new data types to gain greater clarity and granularity. She noted that when considering the overall burden, multiple factors can influence vaccine effectiveness, including vaccine uptake, attitudes toward vaccination, seasonal timing, co-circulating viruses, predominant virus strains, and antigenic relatedness between the vaccine and circulating viruses. She emphasized that there is significant complexity involved in assessing all these factors comprehensively.

Dr. Reed added that, as mentioned, the models estimating the burden consider several factors: the observed disease burden, which varies each season; vaccine coverage for that specific season; and the vaccine's measured effectiveness from annual studies. She explained that in seasons with higher influenza activity, even if vaccine effectiveness remains the same, the vaccine may have a larger overall impact by preventing more outcomes, due to increased influenza incidence and greater risk to the population.

Dr. Goldman emphasized that 250,000 pediatric deaths is not a small number, especially when considering the personal impact on families affected by a vaccine-preventable illness. He suggested that, in addition to modeling the health impact of influenza, it would be valuable to include studies on the financial burden of the disease and the benefits of vaccination. This includes the cost of hospitalizations, the strain on clinics and urgent care centers, lost income,

and the caregiving burden on families. He also highlighted the broader public health benefit of vaccinating younger individuals who care for elderly populations. Dr. Goldman encouraged the committee to consider economic modeling studies to fully capture the value of influenza vaccination in reducing both disease burden and financial strain on the health care system.

Dr. Dugan clarified that 250 influenza-associated pediatric deaths have been reported for the 2024–2025 season. She emphasized that the number is 250 and not a larger figure.

Lyn Redwood, RN, MSN, presented on thimerosal in vaccines and noted the presentation was given as a private citizen, not on behalf of any federal agency. The recognition of mercury exposure in infants and children from vaccines followed the passage of the FDA Modernization Act of 1997, which required the FDA to identify drugs and foods containing intentionally introduced mercury compounds. This review revealed that several pediatric vaccines in multi-dose vials, including inactivated influenza, DTaP, Hib, hepatitis B, and certain immunoglobulin therapies such as hepatitis B immune globulin, contained thimerosal.

In July 1999, the Public Health Service and the American Academy of Pediatrics issued a joint statement calling for the immediate reduction and eventual elimination of the mercury-based preservative thimerosal from infant vaccines. This recommendation was based on findings that infants and children receiving these vaccines could be exposed to mercury levels exceeding federal safety guidelines. Due to potential risks, the Public Health Service, AAP, and vaccine manufacturers agreed that thimerosal-containing vaccines should be removed as soon as possible.

In October 2001, the Institute of Medicine's Immunization Safety Review Committee released a report on thimerosal-containing vaccines and neurodevelopmental disorders. The committee supported earlier calls to remove thimerosal from childhood vaccines and noted that some non-routine vaccines, such as DT, TT, influenza, and pneumococcal, still contained it. They also expressed concern about remaining supplies of thimerosal-containing Hib, hepatitis B, and DTaP vaccines. The committee recommended using thimerosal-free versions and urged further removal of thimerosal from vaccines given to infants, children, and pregnant women. These recommendations were not implemented.

The FDA reviewed the use of thimerosal in vaccines between 1997 and 1999 and found that no clinical studies had formally evaluated its safety before its initial marketing in the 1930s. The only study identified was a 1931 paper in which thimerosal was used to treat meningitis. The study lacked clinical assessments and laboratory data and was not designed to evaluate toxicity. The treating clinician questioned its effectiveness, stating that the benefits had not been definitively proven. In 1930, industry scientists recommended further toxicity testing, but there is no evidence that these studies were conducted. The FDA allowed continued use of thimerosal without requiring formal animal safety data.

Thimerosal was introduced as a vaccine preservative in the 1930s, following its development and patenting in 1927 and its marketing by Eli Lilly under the trade name Merthiolate in 1928. Following a deadly incident in Australia where 12 children died from staphylococcal contamination in a diphtheria vaccine, the FDA began requiring preservatives in all multi-dose vaccines. Thimerosal was used during manufacturing and packaging to prevent bacterial and fungal contamination and became widely used in vaccines and other medical products by the 1930s.

Starting in the late 1970s, scientists began raising concerns about the effectiveness of thimerosal, with several articles arguing it was ineffective. In response, the FDA convened a panel of experts to evaluate its use in over-the-counter products. The panel found that

thimerosal was 35.3 times more toxic to embryonic chick heart tissue than to Staphylococcus aureus and was no more effective than water in protecting mice from fatal streptococcal infections. In 1982, the FDA published the panel's findings in the Federal Register, concluding thimerosal was not safe for topical use due to its potential for cell damage and that its antimicrobial action could be reversed. In April 1998, the FDA issued a final rule stating that thimerosal in over-the-counter products is not generally recognized as safe or effective.

Thimerosal has not been shown to prevent all bacterial contamination in vaccines. This is supported by reported clusters of group A streptococcus infections linked to multi-dose DPT vials that became contaminated after they were opened. Thimerosal was present at acceptable levels in unopened vials from the same lots. The authors concluded that preservatives in multi-dose vials do not prevent short-term bacterial contamination, and that the most feasible and cost-effective method of prevention is strict adherence to sterile technique when administering vaccines from these vials.

A 2023 in vitro study on the cytotoxic effects and antimicrobial activity of thimerosal confirmed findings from earlier research. The study found that effective antimicrobial activity required a concentration of 100 micrograms per milliliter, but cell viability was lost at concentrations as low as 4.6 to 6 micrograms per milliliter. The authors concluded that thimerosal was 333 times more toxic to human and animal cells than to bacterial or fungal cells. They called for further research to determine safer concentrations for use in biopharmaceuticals. Although earlier studies led to thimerosal not being recognized as safe and effective in over-the-counter products, these concerns remain relevant today.

In 1987, the Commission of the European Communities launched a research project on ten known or suspected spindle poisons. Thimerosal was found to significantly interfere with microtubule polymerization, disrupting the spindle machinery responsible for accurate chromosome separation during cell division. This disruption suggests a direct mutagenic potential, as it can lead to structural chromosomal abnormalities. These abnormalities are a well-known pathway to cancer and congenital defects. Thimerosal has shown strong mechanistic evidence of mutagenicity and developmental toxicity, even before in vitro confirmation.

California’s Proposition 65 requires the state to identify chemicals known to cause cancer, birth defects, or reproductive harm and to provide public warnings when exposure may occur. Thimerosal has been listed under Proposition 65 since 1990. In 2003, Bayer Corporation filed a petition requesting reconsideration of the classification of mercury and mercury compounds, including thimerosal, as reproductive toxicants. The California EPA denied the petition, stating that the scientific evidence supporting thimerosal’s reproductive toxicity is robust. Thimerosal breaks down into ethyl mercury in the body, and evidence includes cases of severe mental retardation and malformations in children whose mothers were exposed during pregnancy, along with animal studies showing developmental toxicity and conversion to other toxic forms of mercury.

A 2000 study published in *Pediatrics* measured blood mercury levels in preterm and full-term infants after receiving a hepatitis B vaccine containing 12.5 micrograms of ethyl mercury. The study found elevated mercury levels in all infants post-vaccination. Low-birth-weight infants had average levels of 7.36 micrograms per liter, and one infant reached 23.6 micrograms per liter, exceeding the CDC’s threshold of 10 micrograms per liter for mercury poisoning. Measurable mercury levels were present before immunization, indicating that risk assessments should also account for background exposure.

Experts have noted that there are windows of vulnerability during neurological development. These windows may vary depending on the type of outcome and may be relatively short.

Because thimerosal from vaccines has been shown to raise blood mercury levels above thresholds associated with developmental effects, there is concern that these critical periods may be affected. Even minor neurological impairments can have a substantial impact when they occur across the broader population and lifespan.

A 2005 study funded by the National Institutes of Health compared brain mercury levels in infant macaques exposed to injected ethyl mercury (thimerosal) and ingested methyl mercury in amounts modeled after vaccine exposure. The study found that ethyl mercury converted more rapidly to inorganic mercury in the brain, resulting in higher accumulation. Primates exposed to ethyl mercury retained twice as much inorganic mercury in the brain compared to those exposed to methyl mercury. Inorganic mercury was undetectable in eight out of 17 monkeys in the methyl mercury group, while the ethyl mercury group showed consistently higher levels. This is significant because once inorganic mercury enters brain tissue, it undergoes dealkylation into toxic forms, such as Hg 2 plus, which become trapped in neurons and cannot cross back through the blood-brain barrier.

A recent review summarized evidence from human case studies, animal models, and modeling assessments, estimating the half-life of inorganic mercury in the human brain to be at least 5 to 27 years. Mercury exposure during brain development can disrupt critical processes, including neuronal proliferation, migration, differentiation, synaptogenesis, and apoptosis. These disruptions can lead to long-term effects on the nervous system. The review also noted that the timing of exposure matters, with first-trimester exposure potentially causing different outcomes than exposure during the third trimester. The authors concluded that there may be no safe level of mercury exposure, particularly for unborn children.

Thimerosal is 49.6% mercury by weight. The standard concentration in flu vaccines is 0.01%, which equals 50 micrograms per 0.5 milliliter dose. This corresponds to 100 micrograms per milliliter of thimerosal and 50 micrograms of mercury. The EPA's Toxicity Characteristic Leaching Procedure (TCLP) defines hazardous waste based on the potential to leach toxic substances into groundwater. The TCLP threshold for mercury is 0.2 mg/L, or 200 micrograms per liter. Flu vaccines containing thimerosal have a mercury concentration of approximately 50,000 micrograms per liter, which is 250 times greater than the TCLP limit. As a result, these vaccines are classified as D009 hazardous waste.

Ms. Redwood referenced an image containing online information about proper disposal guidelines for the 2025 flu season. She highlighted that the final paragraph states all full or partially used multi-dose vials of seasonal flu vaccine should be disposed of as federally hazardous waste. She noted that this information does not appear to be widely shared with clinicians or known by the public.

The most vulnerable populations to mercury exposure include pregnant women, developing fetuses, and young children. A 2003 study by Stern found that cord blood mercury levels were 1.7 times higher than maternal blood at birth. Due to rapid neurodevelopment, immature detoxification pathways, and potential genetic susceptibility, the Institute of Medicine recommended in 2001 that these sensitive groups not be exposed to mercury. Older adults may also be at risk, with recent studies linking elevated mercury levels to cardiovascular disease.

Ms. Redwood summarized that mercury is the third most toxic element, following polonium and plutonium, and has no physiological role in the human body. Thimerosal was grandfathered for use without adequate safety testing and has not been recognized as safe or effective by the FDA's over-the-counter division since 1998. Evidence suggests that thimerosal is not an effective preservative at vaccine concentrations and that it can cross both the placenta and the blood-brain barrier, converting to inorganic mercury in the brain at higher levels than methylmercury. Studies have documented infant blood mercury levels exceeding CDC

thresholds for mercury chemical poisoning following exposure to thimerosal-containing vaccines.

Thimerosal is recognized as a developmental and reproductive toxicant and has been listed under California Proposition 65 since 1990. Unused doses of thimerosal-preserved flu vaccines must be disposed of as hazardous waste. While significant progress has been made in reducing its use, data from the 2019–2020 flu season show that more than 60,000 pregnant women received thimerosal-containing flu vaccines through Medicaid. Thimerosal-free vaccines are currently available, allowing for the assurance that all pregnant women, infants, and children receive only thimerosal-free options. The Institute of Medicine made this same recommendation nearly 25 years ago. Removing a known neurotoxin from use in vulnerable populations was presented as an essential step towards making America healthy again.

Dr. Kulldorff stated that while mercury is a known toxin and exposure cannot be entirely avoided, it is a cumulative issue. Individuals are already exposed to mercury from various sources, so even small additional amounts from vaccines may contribute to an overall harmful load. He emphasized the importance of minimizing cumulative mercury exposure for the sake of public health. He noted that most seasonal influenza vaccines are now available in single-dose, thimerosal-free formulations, making the continued use of thimerosal unnecessary. He added that removing mercury-containing preservatives from vaccines could also help build public confidence, comparing it to the consumer rejection of mercury in other products, such as food. Dr. Kulldorff concluded that eliminating thimerosal from seasonal influenza vaccines is both feasible and beneficial for public trust and health.

Dr. Malone added that seasonal influenza vaccination is recommended annually, which raises concerns about repeated exposure for individuals receiving doses from multi-dose vials containing thimerosal. He noted that those receiving vaccines from multi-dose vials may disproportionately come from underserved or lower-income populations, as single-dose vials are more expensive. This creates the potential for ongoing, cumulative exposure to mercury over a lifetime rather than a single instance.

Dr. Levi agreed with the previous comments and emphasized the need to move away from the perceived trade-off between using mercury-based preservatives and the risk of bacterial or fungal contamination. He stated that vaccine and drug integrity should be maintained through strong supply chain practices and proper handling. He also highlighted the potential for real-time contamination detection technologies and urged further attention to prevention and detection measures to ensure safety without relying on mercury-containing preservatives.

Dr. Kulldorff noted that most influenza vaccines used today are single-dose and do not contain thimerosal. He added that single-dose formats eliminate the risk of contamination, as each dose is used only once.

Dr. Meissner responded that the topic of thimerosal is an old issue that has already been addressed extensively. He noted that thimerosal is metabolized into ethyl mercury and thiosalicylate, not methyl mercury, which is found in fish and shellfish. Ethyl mercury is excreted from the body more quickly and is not associated with the same level of neurotoxicity. He emphasized that all vaccines routinely recommended for children, adolescents, adults, and pregnant women in the United States are available in thimerosal-free formulations. Dr. Meissner added that thimerosal remains in widespread use globally because multi-dose vials are more cost-effective, and many countries cannot afford single-dose vials. He stressed that ACIP recommendations can influence global practices, and that removing thimerosal entirely may reduce vaccine access in lower-resource settings. He concluded by noting that no studies have shown harm from thimerosal and that the FDA’s decision to reduce its use was based on

minimizing overall mercury exposure, not on evidence of toxicity. He suggested that this is not a major issue for ACIP to focus on at this time.

Ms. Redwood pointed out that while some studies, such as the Burbacher study, found that thimerosal-exposed infants had lower blood mercury levels and faster clearance, this does not necessarily mean that the mercury had exited the body. She explained that thimerosal has a higher binding affinity for tissues, particularly the brain, which is the primary organ of concern for mercury toxicity. Ethyl mercury, the breakdown product of thimerosal, has a higher blood-brain ratio than methyl mercury, allowing more to accumulate in the brain despite lower blood levels. She cited data showing that inorganic mercury accounted for about 70% of brain mercury in ethyl mercury-exposed primates, compared to 10% in those exposed to methyl mercury. She stated that these findings challenge the argument that ethyl mercury is safer than methyl mercury. In addressing global use, she reminded the committee that alternative preservatives, such as 2-phenoxyethanol, are available and approved. Given advances in vaccine technology and safety, she urged reconsideration of the continued use of thimerosal when safer options exist.

Dr. Meissner responded that ACIP bases its recommendations on scientific evidence and stated that there is no evidence showing thimerosal has caused harm. He acknowledged that other preservatives, such as benzethonium chloride and 2-phenoxyethanol, are available, with the latter currently used in the polio vaccine. However, he noted that these alternatives have not been studied as extensively as thimerosal. He cautioned against requiring significant changes from manufacturers when there is no proven risk, suggesting the issue warrants further discussion.

Dr. Pebsworth stated that, based on the precautionary principle and the known neurotoxicity of thimerosal, efforts should be made to phase out and eliminate its use. She noted that women in early pregnancy could still receive flu vaccines containing thimerosal and emphasized the importance of reducing this risk where possible.

Dr. Levi offered a different perspective on how risk should be understood. He stated that “there is no evidence of harm” can be misleading without clearly defining what constitutes harm. If the concern is cumulative mercury exposure, efforts should be made to reduce controllable sources, since some exposures cannot be avoided. He emphasized the need for a more holistic and long-term view of risk, noting that while individual exposures may appear safe, their combined impact over time may lead to harm. In his view, the evidence clearly shows that cumulative exposure can be harmful.

Dr. Kulldorff emphasized the importance of considering cumulative mercury exposure. He explained that while individual sources may appear safe on their own, combined exposure from multiple sources could pose a risk. He noted that studying each source in isolation may not reveal harm, but the total exposure could still be dangerous. Since mercury is a known toxin, he stressed the need to reduce overall exposure wherever possible, even if some sources cannot be eliminated.

Dr. Hibbeln stated that if the committee votes in favor of the proposal, it should be noted that the precautionary principle does not override the committee’s usual requirement for demonstrable evidence of harm. He emphasized that no clear evidence of harm from thimerosal has been identified, and relying on precaution alone would represent a shift in the committee’s decision-making criteria. He also noted that public fear of mercury, regardless of the actual risk, may discourage vaccination, which poses its own public health risk.

Dr. Kulldorff agreed and added that psychological factors are an important aspect of public health. He emphasized that evidence-based decision-making should also account for public perception and behavioral responses, as these are part of the overall impact.

Dr. Malone requested input from the FDA representative regarding the potential impact of removing thimerosal. He asked what fraction of influenza vaccine doses in the United States still contain thimerosal, whether thimerosal is used in any other vaccine products beyond multi-dose influenza vials, and if the FDA could provide any additional information to help inform the committee's discussion.

Dr. Hoeg, representing the FDA, reported that for the 2024–2025 season, approximately 4–5% of influenza vaccine doses were thimerosal-containing multi-dose vials. The remaining doses were single-dose preparations. Looking ahead, there does not appear to be a limitation in supply if a shift were made to using only single-dose formulations. This information was confirmed in coordination with colleagues from CBER. Dr. Hoeg also noted that, to the best of current knowledge, the influenza vaccine is the only vaccine on the childhood immunization schedule that may still contain thimerosal and be administered to children or pregnant women.

Dr. Buchanan, representing the National Association of Pediatric Nurse Practitioners, emphasized that none of the vaccines currently on the childhood or adolescent immunization schedule contain thimerosal. After a brief review of the FDA website, she found that only about three multi-dose influenza products still contain thimerosal. She noted that thimerosal was removed from most pediatric vaccines in 2001 and highlighted that current potential exposures are very limited.

Ms. Arthur, representing the Biotechnology Innovation Organization, thanked Ms. Redwood for the presentation and requested the source of the data, stating that 60,000 Medicaid patients received thimerosal-containing flu vaccines. She also asked if a previously available CDC document on thimerosal could be reposted on the meeting website to accompany the presentation.

Dr. Malone responded that, to his understanding, the CDC document referenced was not authorized by the Office of the Secretary and has since been removed. He noted that the Office of the Secretary would take note of the comment and provide direction to the CDC as appropriate.

Dr. Zahn, representing NACCHO, emphasized that over 25 years of data show no evidence of harm from thimerosal-containing vaccines. He cited large cohort studies from countries like the UK, Sweden, and Denmark that found no link between thimerosal and adverse neurological outcomes in children, even with prenatal or early childhood exposure. He noted that while thimerosal is no longer in U.S. pediatric vaccines, the global evidence supports its safety. Dr. Zahn also cautioned against amplifying concerns that may create unnecessary fear and affirmed his confidence in the safety of these vaccines.

Dr. Joseph, representing the American College of Obstetricians and Gynecologists, emphasized strong, decades-long evidence supporting the safety of thimerosal, particularly in prenatal exposure. She affirmed that thimerosal has been removed from most products and noted that extensive data show no link between prenatal thimerosal exposure and autism spectrum disorders. She highlighted the importance of influenza vaccination during pregnancy, which protects both the mother and the infant. Maternal vaccination reduces the risk of severe disease, preterm birth, and hospitalization in infants who are too young to be vaccinated, offering protection during a critical developmental window.

Dr. Jason Goldman, representing the American College of Physicians, echoed Dr. Meissner's earlier remarks and highlighted the committee's longstanding commitment to transparency and

evidence-based decision-making. He expressed concern that many statements shared during the meeting lacked scientific backing and were based on opinion rather than data. He asked whether the committee would be presented with a comprehensive scientific review conducted by CDC staff, physicians, or subject matter experts, supported by peer-reviewed literature, rather than relying solely on presentations from non-expert or lay perspectives.

Molly Howell, representing the Association of Immunization Managers, thanked the committee and raised concerns about how removing thimerosal-containing vaccines could affect pandemic preparedness. She noted that multi-dose vials, which may contain thimerosal, could be necessary in a future influenza pandemic and asked how this decision might impact response efforts. She also questioned why, if there are concerns about thimerosal, the FDA has not restricted its use in vaccines and invited federal partners to address both points.

Dr. Kulldorff clarified that the vote under consideration applies only to seasonal influenza vaccines, not pandemic vaccines, as none are currently on the market. He noted that any future decisions regarding pandemic vaccines would need to be addressed in upcoming meetings of the ACIP and CDC.

Dr. Goode, representing the American Pharmacists Association, reiterated the question raised by Dr. Goldman regarding the ACIP process. She emphasized the importance of transparency and asked whether the committee would present a full evidence-to-recommendations framework that includes an assessment of benefits and harms, population values and preferences, resource implications, equity considerations, and feasibility before proceeding with the vote.

Dr. Kulldorff responded by affirming that the committee remains committed to openness and transparency. He acknowledged the presentation by Lyn Redwood and noted her expertise in vaccines. He emphasized that the committee welcomes input from a variety of perspectives, including those without advanced medical degrees, and that it is inappropriate to dismiss a presentation solely based on a presenter’s credentials. He highlighted that earlier in the day, comments were also received from pharmaceutical representatives and reiterated that diverse viewpoints are essential to the committee’s work.

Ms. Redwood provided additional comments regarding past studies on thimerosal-containing vaccines and autism. She referenced a 2004 report that examined the link between thimerosal and autism, noting that the committee acknowledged large epidemiological studies might not detect harm in genetically vulnerable subpopulations. She also pointed out that the committee's criteria shifted from "biological plausibility" in 2001 to requiring a defined "biological mechanism" in 2004, which limited consideration of findings at the time. Ms. Redwood cited a 2005 study by Dr. Carlos Pardo that found chronic neuroinflammation in the brains of individuals with autism, a result that has since been replicated and is now considered a hallmark of the condition. She also mentioned a CDC study by Dr. Thompson, which explored early thimerosal exposure and neuropsychological outcomes in children aged 7 to 10. That study found an association with tics, which she described as potentially debilitating. She concluded by emphasizing that evidence of harm does exist and offered to provide a list of supporting studies to the committee.

During a later session, Dr. Kulldorff relayed a correction from Dr. Thompson on behalf of the CDC regarding the previously cited Medicaid data. He clarified that the figure of more than 30,000 pregnant individuals receiving thimerosal-containing flu vaccines represents an annual estimate averaged across the 2019 and 2020 calendar years, not a single flu season.

Dr. Martin Kulldorff (ACIP Chair) shared the proposed recommendations for influenza vaccines, including those containing thimerosal.

Proposed Recommendation: Influenza Vaccines for influenza vaccination for the 2025-26 season:

> ACIP reaffirms the recommendation for routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications.

Proposed Recommendation: Thimerosal-containing influenza vaccines #1

> ACIP recommends children 18 years and younger receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.

Proposed Recommendation: Thimerosal-containing influenza vaccines #2

> ACIP recommends pregnant women receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.

Proposed Recommendation: Thimerosal-containing influenza vaccines #3

> ACIP recommends all adults receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.

Dr. Levi expressed hope that collaboration with CDC colleagues could lead to improved and more reliable methods for evaluating overall flu vaccine efficacy, as well as comparing the relative effectiveness of different vaccines. He acknowledged the complexity of this task but emphasized the importance of providing the public with the most accurate scientific assessments possible.

Dr. Hibbeln noted the significant benefits of using multi-dose vaccines over single-dose vaccines. He acknowledged the availability of data supporting the use of alternative preservatives and expressed hope that the committee would consider adding to the agenda a discussion on the continued use of multi-dose vials with safer preservative options.

Dr. Malone commented on the current recommendations for seasonal influenza vaccination, which advise routine annual vaccination for all individuals aged 6 months and older who do not have contraindications. He expressed interest in a thorough evaluation by the subcommittee of the relative risks and benefits of the various influenza vaccine products currently available. Dr. Malone also noted the importance of considering the long-standing concern of immune imprinting, also known as original antigenic sin, and whether it may be relevant to routine annual influenza vaccination.

Dr. Meissner expressed concern that requiring multidose vials to be free of thimerosal could reduce access to influenza vaccines for some individuals. He acknowledged that it may be a difficult question to answer. Still, he emphasized that the risk of influenza is significantly greater than any known risk associated with thimerosal, which has not been shown to cause harm. Dr. Meissner stated that it would be difficult to justify someone missing a vaccination because the only available option contains thimerosal.

Dr. Pebsworth stated a personal belief that access to any FDA-approved and scheduled vaccines should not be restricted. The reason for abstaining from all votes was the concern over

how the voting question was written. Specifically, the question combined two separate issues: a recommendation for all adults to receive seasonal influenza vaccination, and a recommendation that such vaccines be free of thimerosal as a preservative. Dr. Pebsworth supported eliminating thimerosal but noted there was no discussion on the first part of the question. A request was made to separate future votes to allow for clearer decision-making on individual components.

Vote: Influenza Vaccines Vote

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the Influenza vaccines into the record:

> ACIP reaffirms the recommendation for routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications

Motion/Vote: Influenza Vaccines

Dr. Malone motioned to approve the recommended voting language, stating, " ACIP reaffirms the recommendation for routine annual influenza vaccination of all persons aged ≥6 months who do not have contraindications." Dr. Pagano seconded the motion. No COIs were declared. The motion carried with 6 votes in favor, 0 votes opposed, and 1 abstention. The disposition of the vote was as follows:

6 Favored: Malone, Hibbleln, Pagano, Kulldorff, Levi, Meissner
0 Opposed:
1 Abstained: Pebsworth

Vote: Thimerosal Containing Influenza Vote #1

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the Thimerosal-containing Influenza vaccines into the record:

> ACIP recommends children 18 years and younger receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.

Motion/Vote: Thimerosal Containing Influenza Vaccines

Dr. Malone motioned to approve the recommended voting language, stating, " ACIP recommends children 18 years and younger receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative." Dr. Meissner

seconded the motion. No COIs were declared. The motion carried with 5 votes in favor, 1 vote opposed, and 1 abstention. The disposition of the vote was as follows:

5 Favored: Malone, Hibbleln, Pagano, Kulldorff, Levi
1 Opposed: Meissner
1 Abstained: Pebsworth

Vote: Thimerosal Containing Influenza Vote #2

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the Thimerosal-containing Influenza vaccines into the record:

> ACIP recommends pregnant women receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.

Motion/Vote: Thimerosal Containing Influenza Vaccines

Dr. Malone motioned to approve the recommended voting language, stating, " ACIP recommends pregnant women receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative." Dr. Meissner seconded the motion. No COIs were declared. The motion carried with 5 votes in favor, 1 vote opposed, and 1 abstention. The disposition of the vote was as follows:

5 Favored: Malone, Hibbleln, Pagano, Levi, Kulldorff
1 Opposed: Meissner
1 Abstained: Pebsworth

Vote: Thimerosal Containing Influenza Vote #3

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the Thimerosal-containing Influenza vaccines into the record:

> ACIP recommends all adults receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative.

Motion/Vote: Thimerosal Containing Influenza Vaccines

Dr. Malone motioned to approve the recommended voting language, stating, " ACIP recommends all adults receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative." Dr. Meissner seconded the motion. No COIs were declared. The motion carried with 5 in favor, 1 opposed, and 1 abstention. The disposition of the vote was as follows:

5 Favored: Levi, Malone, Hibbleln, Pagano, Kulldorff
1 Opposed: Meissner
1 Abstained: Pebsworth

CHIKUNGUNYA VACCINES

Dr. Lyle Petersen (CDC/NCEZID) presented a partial EtR for the use of chikungunya vaccines among persons in U.S. territories at risk for chikungunya virus transmission. There are currently two licensed chikungunya vaccines: a live attenuated vaccine, licensed in November 2023, for individuals aged 18 years and older, and a virus-like particle vaccine, licensed in February 2025, for individuals aged 12 years and older. The Chikungunya Vaccines Work Group was established in May 2022. Since then, ACIP has approved recommendations for the use of both vaccines among travelers and laboratory workers. Most recently, the work group has been reviewing the potential use of these vaccines for persons living in U.S. states and territories at risk for local transmission. The work group completed its review of the public health problem and values domains within the Evidence to Recommendations framework. Additional components will be discussed in future meetings. The full presentation is available online.

For the public health problem domain, the work group concluded that acute chikungunya illness can be severe, particularly in vulnerable populations such as infants, the elderly, and individuals with comorbidities. Arthralgia associated with chikungunya can persist for months to years following infection. Additionally, future outbreaks are likely to evolve rapidly and could affect a substantial portion of the population, potentially overwhelming healthcare services. Finally, there are no highly effective control measures beyond vaccination. In summary, the work group determined that chikungunya virus can have a substantial impact in U.S. territories, with the public health importance primarily due to the risk of large-scale outbreaks.

For the values and preferences domain, the work group reviewed data from surveys conducted in Puerto Rico and the U.S. Virgin Islands. Most participants expressed interest in a hypothetical chikungunya vaccine, with higher interest observed in Puerto Rico. This difference might be attributable to the timing of the surveys relative to local outbreaks, differences in overall vaccine uptake, or varying attitudes toward vaccination. A common concern across both territories was the need for more information on vaccine safety. When considering whether the target population believes the benefits of vaccination outweigh potential risks, the work group

concluded that the answer is probably yes. However, they also acknowledged important uncertainty and variability in how individuals value the main outcomes.

Dr. Petersen provided a brief update on the safety of the live attenuated chikungunya vaccine in older adults. At the April 2025 ACIP meeting, the work group reported six serious adverse events in U.S. individuals aged 65 years and older that had occurred during 2024 and were submitted to the U.S. Vaccine Adverse Event Reporting System (VAERS). Following discussions at the meeting, the CDC determined that age 65 years and older should be a precaution for use of the live attenuated vaccine.

In the three weeks following that meeting, 11 additional serious adverse events were reported internationally among individuals aged 62 to 89 years, most with underlying medical conditions. These cases were largely from Réunion, an overseas department of France, where the vaccine was being used in response to a large outbreak. In response, the European Medicines Agency recommended a temporary pause in the vaccine's use for individuals aged 65 and older. Subsequently, the FDA and CDC also recommended a temporary pause in use for persons aged 60 and older to allow further investigation. The outcome of the FDA's investigation is currently pending.

ANTHRAX VACCINE

Dr. Brendan Jackson (CDC/NCEZID) introduced the Anthrax Vaccine Work Group. *Bacillus anthracis* is the causative agent of anthrax, a spore-forming bacterium that is naturally found in soil worldwide, including in certain parts of the United States. Humans are most often infected by exposure to infected animals or animal byproducts through the cutaneous, gastrointestinal, or inhalational routes. However, *B. anthracis* is also a Tier 1 select agent due to its potential and past use as a bioweapon, its high case fatality rate, and its ability to cause significant harm to public health and safety, particularly when aerosolized.

The work group proposes to review a newer vaccine called Anthrax Vaccine Adsorbed, Adjuvanted (AVAA), marketed under the trade name Cyfendus. This second-generation anthrax vaccine was licensed by the FDA in July 2023 for post-exposure prophylaxis in adults aged 18 to 65 who have been exposed to *Bacillus anthracis*. The Anthrax Vaccine Work Group plans to evaluate the safety and immunogenicity of AVAA to develop recommendations for ACIP consideration regarding its domestic use for anthrax post-exposure prophylaxis.

MMRV VACCINE

Dr. Martin Kulldorff (ACIP Chair)

Dr. Martin Kulldorff (ACIP Chair) provided updates on the MMRV vaccine. The MMRV vaccine is a single combined shot administered with one needle that protects against measles, mumps, rubella, and varicella. It was developed as an alternative to giving the MMR and varicella vaccines separately, which requires two injections: one injection for measles, mumps, and rubella, and the other for varicella. There are no known differences in efficacy between the combined MMRV vaccine and the separate MMR plus varicella vaccines.

The timeline is as follows: in 2005, the MMRV vaccine was licensed by the FDA for children aged 12 months to 12 years. In 2006, the ACIP recommended the use of the MMRV vaccine, with a preference for administering it over separate MMR and varicella vaccines.

CDC's Vaccine Safety Datalink rapid cycle analysis demonstrated the value of ongoing near real-time safety monitoring. As the new vaccine was rolled out, the CDC tracked weekly data. For the first dose administered to children aged 12 to 23 months, a signal was detected indicating an excess number of febrile seizures. This signal emerged after approximately 26,000 doses had been given.

At that time, there were 59 observed cases of febrile seizures compared to 38 expected cases, which was statistically significant and triggered a signal from the surveillance system. When a signal like this is detected, it prompts a more thorough evaluation to determine the cause, which may include data errors or other contributing factors. As a result, a more detailed investigation into febrile seizures following this vaccine was conducted.

Febrile seizures can occur at various times after vaccination, but a noticeable increase has been observed 7 to 10 days after receiving the MMRV vaccine. While a smaller increase may also occur after the MMR vaccine, the rise following MMRV is more pronounced, suggesting a higher risk.

A formal study found that the MMRV vaccine is associated with a relative risk of about two for febrile seizures compared to separate MMR and varicella vaccines. This translates to approximately four to five additional cases per 10,000 children vaccinated. While not extremely common, it is also not considered rare. The finding was statistically significant, indicating that the increased risk is unlikely due to chance. MMRV carries a higher risk of febrile seizures compared to giving the MMR and varicella vaccines separately.

This finding is consistent with the results of a study showing an increased risk of post-vaccination fever after administering the MMRV vaccine compared to administering MMR and varicella separately. These effects are observed in children who receive their first dose, typically administered between 12 and 15 months of age.

The MMRV work group was formed to examine this issue and voted on four recommendation options. The old ACIP guidance recommended both MMRV and separate MMR plus varicella vaccines, with a preference for MMRV. Following the review, the majority of the work group voted to revise the recommendation to support both options, but with a preference for administering MMR and varicella separately (MMR+V). A minority supported recommending both with equal preference, and one vote favored recommending only MMR+V.

At the June 2009 ACIP meeting, the committee voted on updated guidance for the use of the MMRV vaccine. The majority of members voted to recommend both MMRV and separate MMR plus varicella vaccines with equal preference. A minority of members supported maintaining a preference for MMR+V, due to the increased risk of febrile seizures associated with the combination MMRV vaccine.

ACIP serves as an advisory body, while the CDC ultimately issues the official vaccine recommendations. In this case, although the CDC typically follows ACIP's guidance, it made a notable adjustment. The CDC stated that either MMRV or separate MMR plus varicella vaccines may be administered at the recommended age. However, for the first dose in children aged 12 to 47 months, the CDC expressed a preference for administering MMR plus varicella separately.

Dr. Kulldorff summarized that there is no known difference in efficacy between the MMRV vaccine and the separate MMR plus varicella vaccines. However, for the first dose given to children aged 12 to 23 months, strong evidence shows a higher risk of febrile seizures following

MMRV. This equates to approximately one additional case per 2,300 doses when compared to separate administration. For the second dose, typically given at ages 4 to 6 years, no increased risk of febrile seizures has been observed.

[Clarification from Chair: The majority of pediatricians administer the MMR+V vaccines rather than the MMRV vaccine as the first dose given to one year old toddlers. To ensure the integrity and trust in the childhood vaccine schedule, it is imperative that ACIP recommendations minimize vaccine adverse reactions as much as possible.] A proposed recommendation, which may be considered for a vote at a future meeting, is that since a safer and equally effective alternative exists, the MMRV vaccine should not be administered to children under 47 months of age.

PUBLIC COMMENT

The floor was opened for public comment on June 26, 2025. The comments made during the meeting are summarized in this document. Members of the public were also invited to submit written public comments to ACIP through the Federal eRulemaking Portal under Docket Number ID CDC-2025-0024. Visit regulations.gov for access to read the comments received.

Elias Kass
Private Citizen

Dr. Elias Kass, a naturopathic physician specializing in pediatrics, provided public comment addressing vaccine hesitancy and the importance of evidence-based communication. He emphasized that relitigating settled vaccine safety issues, such as concerns about thimerosal, creates false doubt and undermines public trust. Dr. Kass warned against policy-based evidence-making, where conclusions are reached before evidence is gathered, and raised concerns about potential conflicts of interest beyond pharmaceutical ties, including financial incentives tied to supplement sales, expert testimony, or contrarian branding. He emphasized the need for accurate, contextual risk communication, noting that highlighting minor vaccine side effects without acknowledging the severe risks of vaccine-preventable diseases can mislead the public. Dr. Kass concluded by highlighting the role of public policy in shaping health outcomes and urged the committee to prioritize decisions that protect community health through scientifically sound vaccine recommendations.

Emmett Patterson
Locked Down and Out

Emmett Patterson, a public health professional specializing in health communications and outbreak response, provided public comment expressing concern about the rising rates of vaccine-preventable illnesses. Patterson highlighted the disproportionate impact of these illnesses, including long COVID, on LGBTQ communities, who experience higher rates of infection, more severe outcomes, and increased risk of disability. He stressed that COVID-19 vaccines remain the most effective protection against severe illness, disability, and death. Patterson urged ACIP to make decisions based on science, not politics, and called for the reinstatement of universal COVID-19 vaccine recommendations for all ages. He emphasized the importance of transparency, re-engagement with expert advisors, and equitable access to vaccines to ensure that no marginalized community is left behind.

Millicent Gorham

Alliance for Women's Health and Prevention

Millicent Gorham, CEO of the Alliance for Women's Health and Prevention, provided public comment expressing serious concern about the continuity and credibility of the nation's vaccine infrastructure. She warned that recent actions, including the dismissal of ACIP's previous members and the disregard of evidence supporting COVID-19 vaccination during pregnancy, threaten decades of public health progress and trust. Gorham emphasized that ACIP recommendations are essential not only for public health guidance but also for ensuring insurance coverage, which preserves access to and choice of vaccines. She cautioned that removing or weakening recommendations could lead to confusion, loss of coverage, and increased rates of preventable illness and death. Gorham urged ACIP to prioritize science, uphold the integrity of the nation's vaccine system, and protect equitable access to vaccines.

Niki Carelli
The Coalition to Stop Flu

Niki Carelli, Executive Director of the Coalition to Stop Flu, provided public comment emphasizing the critical importance of continued support for universal influenza vaccination. She described the coalition as a multi-sector federal advocacy group focused on preventing deaths from seasonal and pandemic flu, representing a wide range of public health, academic, healthcare, and industry organizations. Carelli highlighted the significant annual burden of influenza, including tens of thousands of deaths, hundreds of thousands of hospitalizations, and billions of dollars in costs. She stressed that flu vaccination is the most effective tool for reducing serious illness and complications, with decades of safety data supporting its use. Carelli noted the record number of pediatric flu deaths in the past season, with 90% of the children who died being unvaccinated, underscoring the importance of maintaining ACIP's current influenza vaccination recommendation. She concluded by urging the committee to preserve this recommendation to ensure continued insurance coverage, broad access, and life-saving protection for millions of Americans.

Ronald F. Owens, Jr.
Muzzled Truth 1

Ronald Owens, Jr., a former employee of the California Department of Public Health, provided public comments expressing strong concerns about the safety of the COVID-19 vaccine. He referenced statements made by HHS leadership in 2022 and cited personal outreach efforts to California public health officials regarding reports of adverse vaccine events. Owens stated that he retired early to share his concerns without restriction publicly and described his ongoing efforts to warn local officials and the public. He called for ACIP and federal health agencies to acknowledge and address reports of vaccine injuries, suggesting a COVID-19 vaccine injury listening tour to hear directly from affected individuals. Owens urged federal officials to inform the public about what he described as the risks of COVID-19 vaccines.

Katrin Werner-Perez
Alliance for Aging Research

Katrin Werner-Perez, Director of Health Programs at the Alliance for Aging Research, provided public comment with five key recommendations. First, she urged ACIP to vote on updated COVID-19 vaccine recommendations, emphasizing the continued risks of severe illness, hospitalization, and death, particularly among older adults and children. She expressed concern that the HHS Secretary's removal of COVID-19 vaccines from the schedule for healthy pregnant

individuals and children undermines ACIP's role and contradicts FDA guidance. Second, she recommended finalizing ACIP's April vote to expand RSV vaccine recommendations to adults aged 50 to 59, citing the high disease burden in this population. Third, she asked ACIP to reinstate the planned vote on this year's influenza vaccine strains to ensure CMS and insurance coverage. Fourth, she called for the restoration of all originally planned votes, including those for COVID-19, HPV, and influenza vaccines, as well as for the Vaccines for Children program, to ensure free vaccine access. Lastly, she opposed removing thimerosal-containing influenza vaccines, citing their safety record and critical role in settings such as nursing homes. Werner-Perez concluded by urging ACIP to prioritize scientific integrity and impartiality to protect public health.

Allison Howells
Vaccinate Your Family

Allison Howells, Communications Coordinator at Vaccinate Your Family, provided public comment emphasizing the critical role of ACIP recommendations in guiding public health education and vaccine access. She shared personal stories from families who lost loved ones to vaccine-preventable diseases, including influenza, meningococcal B, whooping cough, and COVID-19, underscoring the human cost of delayed or limited vaccine availability. Howells warned that changes to vaccine recommendations affecting insurance coverage or creating public confusion will lead to unnecessary illness, suffering, and death. She called on the HHS and CDC to ensure that ACIP members base their decisions on the whole body of credible scientific evidence, rather than personal beliefs or selective data. Howells stressed that vaccines remain one of the safest and most effective tools in public health, and she urged the committee to maintain vaccine availability, accessibility, and affordability to protect the health of all Americans.

Avraham Seff
Private Citizen

Avraham Seff provided public comment sharing a personal story about how his expressed concerns regarding the HPV vaccine during a custody dispute led to unintended legal consequences, including the severing of his relationship with his child. He emphasized that while ACIP recommendations are intended as expert guidance, they are sometimes misinterpreted or misused by courts and child protection systems as mandates, resulting in accusations of parental unfitness. Seff acknowledged the integrity and commitment of ACIP members but urged the committee to consider including a clear disclaimer stating that vaccine recommendations are not legal requirements and should not be the sole basis for determining parental fitness. He offered sample language for such a disclaimer and encouraged ACIP to address this issue with sensitivity to prevent unintended harm to families.

Dr. Paola Ballester
Johns Hopkins All Children's Hospital

Dr. Paola Ballester, a double board-certified pediatrician, pediatric hospitalist, and mother, provided public comment emphasizing the life-saving importance of vaccines. Drawing from over 15 years of experience, she shared firsthand accounts of children suffering severe outcomes from vaccine-preventable diseases, noting that these cases are now rare but typically occur in unvaccinated patients. Dr. Ballester highlighted the critical role of vaccines in preventing millions of deaths globally and warned against allowing misinformation or conspiracy theories to influence vaccine policy. She expressed concern about recent changes to ACIP

membership and the potential erosion of longstanding standards of scientific rigor and transparency. Dr. Ballester urged the committee to follow the evidence, maintain trusted immunization schedules, and ensure continued access to vaccines, stressing that reversing course would result in preventable suffering and loss of life.

Dr. Christine Martin
WakeMed Pediatrics

Dr. Christine Martin, a board-certified pediatrician with over 30 years of experience in primary care and public health, provided public comment advocating for the continued support of routine childhood vaccinations. She shared personal and professional experiences witnessing the devastating impacts of vaccine-preventable diseases, both early in her life and throughout her career, including cases of pneumococcal meningitis, congenital rubella syndrome, polio, and whooping cough. Dr. Martin highlighted the dramatic reduction of these diseases due to vaccines such as pneumococcal, Hib, meningitis, MMR, varicella, and Tdap, and emphasized the recent availability of RSV prevention tools for infants. She warned that misinformation and public fear are creating cracks in the protective barrier provided by vaccines, as reflected in the current measles outbreak. Dr. Martin urged ACIP to uphold the existing childhood vaccination schedule, emphasizing that it is based on decades of rigorous research and developed by highly qualified experts.

Dr. Elizabeth Hornbeck
AAP

Dr. Elizabeth Hornbeck, a pediatric hospitalist and mother of two, provided public comment sharing her perspective as both a clinician and parent. She described firsthand experiences caring for previously healthy children who suffered severe complications from vaccine-preventable diseases such as influenza and RSV, including lung damage and neurological devastation. Dr. Hornbeck emphasized that her decision to vaccinate her children is based on personal protection first, and public health benefit second, noting that vaccines are safe and prevent far more harm than they could ever cause. She urged ACIP to maintain the current vaccine schedule to ensure continued insurance coverage, access, and supply. Dr. Hornbeck warned that changing recommendations could weaken public health protections and leave children vulnerable to preventable illnesses, calling on the committee to make evidence-based decisions that protect the nation’s children.

Dr. Neil Patel
Practicing Pediatrician

Dr. Neil Patel, a general pediatrician and new father, provided public comment highlighting the critical role of vaccines in protecting children and families. He shared concerns voiced by parents in his practice who fear losing access to life-saving vaccines. Reflecting on his experience on the front lines during the COVID-19 pandemic, Dr. Patel emphasized the lives saved by the timely development of vaccines and praised the previous ACIP members for their contributions. He urged the committee to continue following evidence-based medicine and to ensure that vaccines remain accessible through insurance coverage and the Vaccines for Children program. Dr. Patel also expressed concern about the recent removal of a CDC document from the ACIP website that reaffirmed the safety of thimerosal-containing vaccines, stating that such actions can erode trust. He called on ACIP to protect access to vaccines and ensure that preventable diseases remain in history books, not in hospitals, schools, or homes.

Akshata Hopkins
American Academy of Pediatrics

Dr. Akshata Hopkins, a board-certified pediatric hospitalist, provided public comment emphasizing the importance of vaccines in preventing severe childhood illnesses. She shared personal clinical experiences treating children with meningitis, pertussis, and Hib infections, noting that she had not seen these cases in over a decade due to the success of vaccines. Dr. Hopkins expressed concern that many younger physicians may no longer be trained to recognize or manage these diseases, making a return of vaccine-preventable illnesses particularly dangerous. She urged ACIP to maintain evidence-based recommendations, protect public confidence in vaccines, and ensure that decisions remain guided by science rather than political influence. Dr. Hopkins stressed that weakening vaccine infrastructure or removing medical expertise from the process will create confusion, erode trust, and lead to the resurgence of preventable diseases, ultimately putting children at risk.

With no additional business to be addressed at the June 2024 ACIP meeting, the meeting was officially adjourned.

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6/13/2025 – 6/30/2029

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EXHIBIT 7

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FOR IMMEDIATE RELEASE
July 23, 2025

Contact: HHS Press Office
202-690-6343
Submit a Request for Comment

HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines

WASHINGTON, DC—JULY 23, 2025—U.S. Health and Human Services Secretary Robert F. Kennedy, Jr. took action Tuesday signing the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) recommendations to remove the mercury-based preservative thimerosal from all influenza vaccines distributed in the United States.

This move follows a 5-1 vote at the ACIP's June 25-26 meeting at CDC headquarters in Atlanta, where committee members voted that all children 18 years and younger, pregnant women, and adults receive only single-dose influenza vaccines free of mercury. Secretary Kennedy's signature formally adopts the recommendation into federal health policy, fulfilling a commitment to restore trust with Americans by removing risk while sustaining access to vaccines.

"After more than two decades of delay, this action fulfills a long-overdue promise to protect our most vulnerable populations from unnecessary mercury exposure," **Secretary Kennedy said**. "Injecting any amount of mercury into children when safe, mercury-free alternatives exist defies common sense and public health responsibility. Today, we put safety first."

The effort to remove mercury from childhood vaccines began in 1999 when the U.S. Public Health Service, the American Academy of Pediatrics (AAP), and vaccine manufacturers jointly agreed that any potential risk from mercury warranted its removal as soon as possible. This marks the final step to remove mercury from all vaccines given to Americans.

Secretary Kennedy's newly appointed ACIP members broke with long-standing inaction by voting to remove mercury entirely from all influenza vaccines, fulfilling the 1999 pledge and aligning U.S. policy with that of Europe, which phased out mercury additives years ago.

Vaccine manufacturers have confirmed they have the capacity to replace multi-dose vials containing mercury, ensuring the Vaccines for Children (VFC) program and adult vaccine supplies will remain uninterrupted.

The ACIP, composed of leading medical and public health experts, advises the CDC on vaccine safety, efficacy, and clinical necessity. This historic decision marks a critical step toward enhancing public confidence in vaccines and advancing the nation's commitment to safer immunization practices.

"With the U.S. now removing mercury from all vaccines, we urge global health authorities to follow this prudent example for the protection of children worldwide," **Secretary Kennedy added**.

Secretary Kennedy has approved all recommendations issued from the April ACIP meeting. Other recommendations from the committee's June meeting are currently under review.

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Last revised: July 28, 2025

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Related Blog Posts



Supporting Families from the Start </blog/2025/11/24/supporting-families-from-start.html>

Content created by Assistant Secretary for Public Affairs (ASPA)
Content last reviewed July 28, 2025

EXHIBIT 8

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger

UNITED STATES 2025

Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody (Nirsevimab)	RSV-mAb	Beyfortus
Vaccine	**Abbreviation(s)**	**Trade name(s)**
COVID-19 vaccine	1vCOV-mRNA	Comirnaty/Pfizer-BioNTech COVID-19 Vaccine
		Spikevax/Moderna COVID-19 Vaccine
	1vCOV-aPS	Novavax COVID-19 Vaccine
Dengue vaccine	DEN4CYD	Dengvaxia
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel Infanrix
Haemophilus influenzae type b vaccine	Hib (PRP-T)	ActHIB Hiberix
	Hib (PRP-OMP)	PedvaxHIB
Hepatitis A vaccine	HepA	Havrix Vaqta
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated: egg-based)	IIV3	Multiple
Influenza vaccine (inactivated: cell-culture)	ccIIV3	Flucelvax
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M-M-R II Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB-4C	Bexsero
	MenB-FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/ MenB-FHbp	Penbraya
Mpox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15 PCV20	Vaxneuvance Prevnar 20
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo
Rotavirus vaccine	RV1 RV5	Rotarix RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac Tdvax
Varicella vaccine	VAR	Varivax
Combination vaccines *(use combination vaccines instead of separate injections when appropriate)*		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	DTaP-IPV/Hib	Pentacel
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix Quadracel
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Revised 07/02/2025

How to use the child and adolescent immunization schedule

1. Determine recommended vaccine by age **(Table 1)**
2. Determine recommended interval for catch-up vaccination **(Table 2)**
3. Assess need for additional recommended vaccines by medical condition or other indication **(Table 3)**
4. Review vaccine types, frequencies, intervals, and considerations for special situations **(Notes)**
5. Review contraindications and precautions for vaccine types **(Appendix)**

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/hcp/imz-schedules/app.html

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html
- ACIP Shared Clinical Decision-Making Recommendations: www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/surv-manual/php/

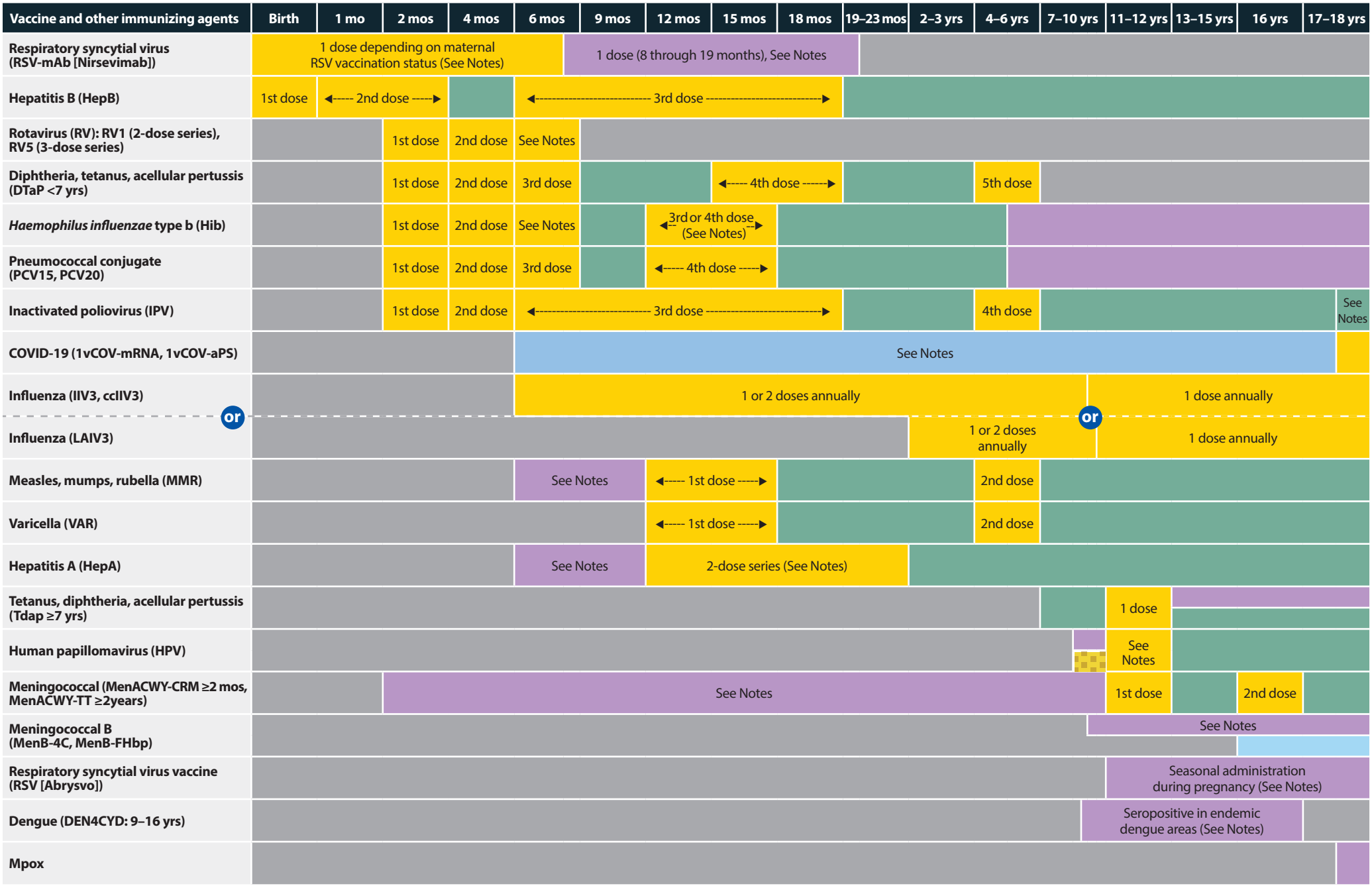
U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Scan QR code for access to online schedule

CS310020-E

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).



Range of recommended ages for all children
Range of recommended ages for catch-up vaccination
Range of recommended ages for certain high-risk groups or populations
Recommended vaccination can begin in this age group
Vaccination is based on shared clinical decision-making
No Guidance/ Not Applicable

Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2025

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the Notes that follow.**

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Children age 4 months through 6 years					
Hepatitis B	Birth	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose** minimum age for the final dose is 24 weeks		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days.	**4 weeks**	**4 weeks** maximum age for final dose is 8 months, 0 days		
Diphtheria, tetanus, and acellular pertussis	6 weeks	**4 weeks**	**4 weeks**	**6 months**	**6 months** A fifth dose is not necessary if the fourth dose was administered at age 4 years or older ***and*** at least 6 months after dose 3
Haemophilus influenzae type b	6 weeks	**No further doses needed** if first dose was administered at age 15 months or older. **4 weeks** if first dose was administered before the 1st birthday. **8 weeks (as final dose)** if first dose was administered at age 12 through 14 months.	**No further doses needed** if previous dose was administered at age 15 months or older **4 weeks** if current age is younger than 12 months ***and*** first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib, Pentacel, Hiberix), Vaxelis or unknown **8 weeks *and* age 12 through 59 months (as final dose)** if current age is younger than 12 months ***and*** first dose was administered at age 7 through 11 months; **OR** if current age is 12 through 59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose was administered at younger than 15 months; **OR** if both doses were PedvaxHIB and were administered before the 1st birthday	**8 weeks (as final dose)** This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	**No further doses needed** for healthy children if first dose was administered at age 24 months or older **4 weeks** if first dose was administered before the 1st birthday **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after	**No further doses needed** for healthy children if previous dose was administered at age 24 months or older **4 weeks** if current age is younger than 12 months ***and*** previous dose was administered at <7 months old **8 weeks (as final dose for healthy children)** if previous dose was administered between 7–11 months (wait until at least 12 months old); **OR** if current age is 12 months or older ***and*** at least 1 dose was administered before age 12 months	**8 weeks (as final dose)** This dose is only necessary for children age 12 through 59 months regardless of risk, or age 60 through 71 months with any risk, who received 3 doses before age 12 months.	
Inactivated poliovirus	6 weeks	**4 weeks**	**4 weeks** if current age is <4 years **6 months (as final dose)** if current age is 4 years or older	**6 months (minimum age 4 years for final dose)**	
Measles, mumps, rubella	12 months	**4 weeks**			
Varicella	12 months	**3 months**			
Hepatitis A	12 months	**6 months**			
Meningococcal ACWY	2 months MenACWY-CRM 2 years MenACWY-TT	**8 weeks**	See Notes	See Notes	
Children and adolescents age 7 through 18 years					
Meningococcal ACWY	Not applicable (N/A)	**8 weeks**			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	**4 weeks**	**4 weeks** if first dose of DTaP/DT was administered before the 1st birthday **6 months (as final dose)** if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday	**6 months** if first dose of DTaP/DT was administered before the 1st birthday	
Human papillomavirus	9 years	**Routine dosing intervals are recommended.**			
Hepatitis A	N/A	**6 months**			
Hepatitis B	N/A	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose**		
Inactivated poliovirus	N/A	**4 weeks**	**6 months** A fourth dose is not necessary if the third dose was administered at age 4 years or older ***and*** at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years **OR** if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	**4 weeks**			
Varicella	N/A	**3 months** if younger than age 13 years. **4 weeks** if age 13 years or older			
Dengue	9 years	**6 months**	6 months		

Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2025

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions are often not mutually exclusive. If multiple conditions are present, refer to guidance in all relevant columns. See Notes for medical conditions not listed.

Vaccine and other immunizing agents	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count[a]		CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Heart disease or chronic lung disease	Kidney failure, End-stage renal disease or on dialysis	Chronic liver disease	Diabetes
			<15% or <200/mm³	≥15% and ≥200/mm³						
RSV-mAb (nirsevimab)		2nd RSV season		1 dose depending on maternal RSV vaccination status (See Notes)			2nd RSV season for chronic lung disease (See Notes)	1 dose depending on maternal RSV vaccination status (See Notes)		
Hepatitis B										
Rotavirus		SCID[b]								
DTaP/Tdap	DTaP Tdap: 1 dose each pregnancy									
Hib		HSCT: 3 doses	See Notes			See Notes				
Pneumococcal										
IPV										
COVID-19		See Notes		See Notes						
Influenza inactivated		Solid organ transplant: 18yrs (See Notes)								
LAIV3							Asthma, wheezing: 2–4 years[c]			
MMR	*									
VAR	*									
Hepatitis A										
HPV	*	3-dose series (See Notes)								
MenACWY										
MenB										
RSV (Abrysvo)	Seasonal administration (See Notes)									
Dengue										
Mpox	See Notes									

Recommended for all age-eligible children who lack documentation of a complete vaccination series

Not recommended for all children, but recommended for some children based on increased risk for or severe outcomes from disease

Vaccination is based on shared clinical decision-making

Recommended for all age-eligible children, and additional doses may be necessary based on medical condition or other indications. See Notes.

Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction

Contraindicated or not recommended
*Vaccinate after pregnancy, if indicated

No Guidance/ Not Applicable

a. For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

b. Severe Combined Immunodeficiency

c. LAIV3 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

Notes

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule, 2025.

Additional information

- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3-2, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Barnett ED, Lynfield Ruth, Sawyer MH, eds. *Red Book: 2021–2024 Report of the Committee on Infectious Diseases*. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021:72–86).
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the child and adolescent vaccine schedule are covered by VICP except dengue, PPSV23, RSV, Mpox and COVID-19 vaccines. Mpox and COVID-19 vaccines are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID-19 vaccination

(minimum age: 6 months [Moderna and Pfizer-BioNTech COVID-19 vaccines], 12 years [Novavax COVID-19 Vaccine])

Shared clinical decision-making

Ages 6 month –17 years who are NOT moderately or severely immunocompromised.

Shared clinical decision-making vaccinations are individually based and informed by a decision process between the health care provider and the patient or parent/guardian. Where the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances. www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

Age 6 months–4 years

All vaccine doses should be from the same manufacturer.

- **Unvaccinated:**
  - 2 doses 2024–25 Moderna at 0, 4–8 weeks
  - 3 doses 2024–25 Pfizer-BioNTech at 0, 3–8, and at least 8 weeks after dose 2
- **Incomplete initial vaccination series before 2024–25 vaccine with:**
  - **1 dose Moderna:** complete initial series with 1 dose 2024–25 Moderna 4–8 weeks after most recent dose
  - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech 8 weeks apart (administer dose 1 3–8 weeks after most recent dose).
  - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 8 weeks after the most recent dose.
- **Completed initial vaccination series before 2024–25 vaccine with:**
  - **2 or more doses Moderna:** 1 dose 2024–25 Moderna at least 8 weeks after the most recent dose.
  - **3 or more doses Pfizer-BioNTech:** 1 dose 2024–25 Pfizer-BioNTech at least 8 weeks after the most recent dose.

Age 5–11 years

- **Unvaccinated:** 1 dose 2024–25 Moderna or Pfizer-BioNTech
- **Previously vaccinated before 2024–25 vaccine with 1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Pfizer-BioNTech at least 8 weeks after the most recent dose.

Age 12–17 years

- **Unvaccinated:**
  - 1 dose 2024–25 Moderna or Pfizer-BioNTech
  - 2 doses 2024–25 Novavax at 0, 3–8 weeks
- **Previously vaccinated before 2024–25 vaccine with:**
  - **1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
  - **1 dose Novavax:** 1 dose 2024–25 Novavax 3–8 weeks after most recent dose. If more than 8 weeks after most recent dose, administer 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.
  - **2 or more doses Novavax:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.

Routine vaccination

Age 18 years who are NOT moderately or severely immunocompromised

- **Unvaccinated:**
  - 1 dose 2024–25 Moderna or Pfizer-BioNTech
  - 2 doses 2024–25 Novavax at 0, 3–8 weeks
  - Previously vaccinated before 2024–25 vaccine with:
  - **1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
  - **1 dose Novavax:** 1 dose 2024–25 Novavax 3–8 weeks after most recent dose. If more than 8 weeks after most recent dose, administer 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.
  - **2 or more doses Novavax:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.

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COVID-19 vaccination - continued

Special situations

Persons who ARE moderately or severely immunocompromised.

Age 6 months–4 years

Use vaccine from the same manufacturer for all doses (initial vaccination series and additional doses*).

- **Unvaccinated:**
  - 4 doses (**3-dose initial series 2024–25 Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna 6 months later [minimum interval 2 months]).May administer additional doses.*
  - 4 doses (**3-dose initial series 2024–25 Pfizer-BioNTech** at 0, 3 weeks, and at least 8 weeks after dose 2, followed by 1 dose 2024–25 Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
- **Incomplete initial 3-dose vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna 6 months later (minimum interval 2 months). May administer additional doses of Moderna.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna 6 months later (minimum interval 2 months). May administer additional doses of Moderna.*
  - **Previous vaccination with Pfizer-BioNTech**
    - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 8 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Pfizer-BioNTech.*
    - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 8 weeks after most recent dose, followed by 1 dose 2024–25 Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Pfizer-BioNTech.*
- **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**
  - **3 or more doses Moderna:** 2 doses 2024–25 Moderna 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna.*
  - **3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Pfizer-BioNTech.*

Age 5–11 years

Use vaccine from the same manufacturer for all doses in the initial vaccination series.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series 2024–25 Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
  - 4 doses (**3-dose initial series 2024–25 Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
- **Incomplete initial 3-dose vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
  - **Previous vaccination with Pfizer-BioNTech**
    - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
    - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
- **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**
  - **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Pfizer-BioNTech.*

Age 12–17 years

Use vaccine from the same manufacturer for all doses in the initial vaccination series.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - 4 doses (**3-dose initial series Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - 3 doses (**2-dose initial series Novavax** at 0, 3 weeks, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **Incomplete initial vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

Notes Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

COVID-19 vaccination - continued

- **Previous vaccination with Pfizer-BioNTech**
  - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **Previous vaccination with Novavax**
  - **1 dose Novavax:** complete initial series with 1 dose 2024–25 Novavax at least 3 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

• **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**

- **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **2 or more doses Novavax:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

Age 18 years who ARE moderately or severely immunocompromised

Use vaccine from the same manufacturer for all doses in the initial vaccination series.

• **Unvaccinated:**

- 4 doses (**3-dose initial series Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- 4 doses (**3-dose initial series Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- 3 doses (**2-dose initial series Novavax** at 0, 3 weeks, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

• **Incomplete initial vaccination series before 2024–25 vaccine:**

- **Previous vaccination with Moderna**
  - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **Previous vaccination with Pfizer-BioNTech**
  - 1 dose Pfizer-BioNTech: complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - 2 doses Pfizer-BioNTech: complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **Previous vaccination with Novavax**
  - **1 dose Novavax:** complete initial series with 1 dose 2024–25 Novavax at least 3 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

• **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**

- **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **2 or more doses Novavax:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

***Additional doses of 2024–25 COVID-19 vaccine for moderately or severely immunocompromised:** based on shared clinical decision-making and administered at least 2 months after the most recent dose. For description of moderate and severe immunocompromising conditions and treatment, see www.cdc.gov/covid/hcp/vaccine-considerations/immunocompromised.html#cdc_cg_special_populations_section_3-description-of-moderate-and-severe-immunocompromising-conditions-and-treatment

Unvaccinated persons have never received any COVID-19 vaccine doses. There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available. Administer an age-appropriate COVID-19 vaccine product for each dose.

For information about transition from age 4 years to age 5 years or age 11 years to age 12 years during COVID-19 vaccination series, see Tables 1 and 2 at www.cdc.gov/covid/hcp/vaccine-considerations/index.html

For information about interchangeability of COVID-19 vaccines, see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability.

Current COVID-19 schedule and dosage formulation available at www.cdc.gov/covidschedule. For more information on Emergency Use Authorization (EUA) indications for COVID-19 vaccines, see www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covid19euas

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Dengue vaccination (minimum age: 9 years)

Routine vaccination

- Age 9–16 years living in areas with endemic dengue **AND** have laboratory confirmation of previous dengue infection
  - 3-dose series administered at 0, 6, and 12 months
- Endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau. For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm?s_cid=rr7006a1_w and www.cdc.gov/dengue/index.html
- Dengue vaccine should not be administered to children traveling to or visiting endemic dengue areas.

Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

Routine vaccination

- 5-dose series (3-dose primary series at age 2, 4, and 6 months, followed by booster doses at ages 15–18 months and 4–6 years)
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

Special situations

- **Children younger than age 7 years with a contraindication specific to the pertussis component of DTaP:** May administer Td for all recommended remaining doses in place of DTaP. Encephalopathy within 7 days of vaccination when not attributable to another identifiable cause is the only contraindication specific to the pertussis component of DTaP. For additional information, see www.cdc.gov/pertussis/hcp/vaccine-recommendations/td-offlabel.html.
- **Wound management in children younger than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine:** For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm.

Haemophilus influenzae type b vaccination (minimum age: 6 weeks)

Routine vaccination

- **ActHIB, Hiberix, Pentacel, or Vaxelis:** 4-dose series (3-dose primary series at age 2, 4, and 6 months, followed by a booster dose* at age 12–15 months)
  - *Vaxelis is not recommended for use as a booster dose. A different Hib-containing vaccine should be used for the booster dose.
- **PedvaxHIB:** 3-dose series (2-dose primary series at age 2 and 4 months, followed by a booster dose at age 12–15 months)
- **American Indian and Alaska Native infants:** Vaxelis and PedvaxHIB preferred over other Hib vaccines for the primary series.

Catch-up vaccination

- **Dose 1 at age 7–11 months:** Administer dose 2 at least 4 weeks later and dose 3 (final dose) at age12–15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at age 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- **Dose 1 before age 12 months and dose 2 before age 15 months:** Administer dose 3 (final dose) at least 8 weeks after dose 2.
- **2 doses of PedvaxHIB before age 12 months:** Administer dose 3 (final dose) at age12–59 months and at least 8 weeks after dose 2.
- **1 dose administered at age 15 months or older:** No further doses needed
- **Unvaccinated at age 15–59 months:** Administer 1 dose.
- **Previously unvaccinated children age 60 months or older who are not considered high risk:** Catch-up vaccination not required.

For other catch-up guidance, see Table 2. Vaxelis can be used for catch-up vaccination in children younger than age 5 years. Follow the catch-up schedule even if Vaxelis is used for one or more doses. For detailed information on use of Vaxelis see www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm.

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Special situations

- **Chemotherapy or radiation treatment:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.
- **Hematopoietic stem cell transplant (HSCT):**
  - 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant, regardless of Hib vaccination history
- **Anatomic or functional asplenia (including sickle cell disease):**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated* persons age 5 years or older
  - 1 dose
- **Elective splenectomy:**
  Unvaccinated* persons age 15 months or older
  - 1 dose (preferably at least 14 days before procedure)
- **HIV infection:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated* persons age 5–18 years
  - 1 dose
- **Immunoglobulin deficiency, early component complement deficiency, or early component complement inhibitor use:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

Unvaccinated* = Less than routine series (through age 14 months) **or no doses (age 15 months or older)*

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Hepatitis A vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination
- **2-dose series** (minimum interval: 6 months) at age 12–23 months

Catch-up vaccination
- **Unvaccinated persons through age 18 years should complete a 2-dose series** (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents age 18 years or older may receive HepA-HepB (Twinrix) as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

International travel
- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (www.cdc.gov/travel/):
  - **Infants age 6–11 months**: 1 dose before departure; revaccinate with 2 doses (separated by at least 6 months) between age 12–23 months.
  - **Unvaccinated age 12 months or older**: Administer dose 1 as soon as travel is considered.

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Hepatitis B vaccination
(minimum age: birth)

Routine vaccination
- **Mother is HBsAg-negative**
  - 3-dose series at age 0, 1–2, 6–18 months **(use monovalent HepB vaccine for doses administered before age 6 weeks)**
    - Birth weight ≥2,000 grams: 1 dose within 24 hours of birth if medically stable
    - Birth weight <2,000 grams: 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2,000 grams)
  - Infants who did not receive a birth dose should begin the series as soon as possible (see Table 2 for minimum intervals).
  - Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the birth dose.
  - **Minimum intervals (see Table 2):** when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations.
  - **Final (3rd or 4th) dose:** age 6–18 months **(minimum age 24 weeks)**
- **Mother is HBsAg-positive**
  - **Birth dose (monovalent HepB vaccine only):** administer **HepB vaccine** and **hepatitis B immune globulin (HBIG)** in separate limbs within 12 hours of birth, regardless of birth weight.
  - **Birth weight <2000 grams:** administer 3 additional doses of HepB vaccine beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**.
  - Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.
- **Mother is HBsAg-unknown**

  If other evidence suggestive of maternal hepatitis B infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to have chronic hepatitis B infection), manage infant as if mother is HBsAg-positive.
  - **Birth dose (monovalent HepB vaccine only):**
    - Birth weight ≥2,000 grams: administer **HepB vaccine** within 12 hours of birth. Determine mother's HBsAg status as soon as possible. If mother is determined to be HBsAg-positive, administer **HBIG** as soon as possible (in separate limb), but no later than 7 days of age.
    - Birth weight <2,000 grams: administer **HepB vaccine** and **HBIG** (in separate limbs) within 12 hours of birth. Administer 3 additional doses of **HepB vaccine** beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**.
  - If mother is determined to be HBsAg-positive or if status remains unknown, test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.

Catch-up vaccination
- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months. See Table 2 for minimum intervals.
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation **Recombivax HB** only).
- Adolescents age 18 years may receive:
  - **Heplisav-B:** 2-dose series at least 4 weeks apart
  - **PreHevbrio*:** 3-dose series at 0, 1, and 6 months
  - **HepA-HepB (Twinrix):** 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

Special situations
- Revaccination is generally not recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- **Post-vaccination serology testing and revaccination** (if anti-HBs <10mIU/mL) is recommended for certain populations, including:
  - Infants born to HBsAg-positive mothers
  - Persons who are predialysis or on maintenance dialysis
  - Other immunocompromised persons
  - For detailed revaccination recommendations, see www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm.

***Note:** PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant women.

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Human papillomavirus vaccination
(minimum age: 9 years)

Routine and catch-up vaccination

- HPV vaccination routinely recommended at **age 11–12 years (can start at age 9 years)** and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated.
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9–14 years at initial vaccination**: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - **Age 15 years or older at initial vaccination**: 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 12 weeks; dose 1 to dose 3 = 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series **of any valency** has been completed using recommended dosing intervals.

Special situations

- **Immunocompromising conditions, including HIV infection:** 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
- **History of sexual abuse or assault:** Start at age 9 years
- **Pregnancy:** Pregnancy testing not needed before vaccination; HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant

Influenza vaccination
(minimum age: 6 months [IIV3], 2 years [LAIV3],18 years [recombinant influenza vaccine, RIV3])

Routine vaccination

- Use any influenza vaccine appropriate for age and health status annually:
  - **Age 6 months–8 years** who have received fewer than 2 influenza vaccine doses before July 1, 2024, or whose influenza vaccination history is unknown: 2 doses, separated by at least 4 weeks. Administer dose 2 even if the child turns 9 years between receipt of dose 1 and dose 2.
  - **Age 6 months–8 years** who have received at least 2 influenza vaccine doses before July 1, 2024: 1 dose.
  - **Age 9 years or older:** 1 dose
  - **Age 18 years solid organ transplant recipients receiving immunosuppressive medications:** high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines are acceptable options. No preference over other age-appropriate IIV3 or RIV3.
- For the 2024–25 season, see www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm.
- For the 2025–26 season, see the 2025–26 ACIP influenza vaccine recommendations.

Special situations

- **Close contacts (e.g., household contacts) of severely immunosuppressed persons who require a protected environment:** should not receive LAIV3. If LAIV3 is given, they should avoid contact with, or caring for such immunosuppressed persons for 7 days after vaccination.

Note: Persons with an egg allergy can receive any influenza vaccine (egg-based or non-egg based) appropriate for age and health status.

Measles, mumps, and rubella vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination

- 2-dose series at age 12–15 months, age 4–6 years
- MMR or MMRV* may be administered

Note: For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV* may be used if parents or caregivers express a preference.

Catch-up vaccination

- **Unvaccinated children and adolescents:** 2-dose series at least 4 weeks apart*
- The maximum age for use of MMRV* is 12 years.

Special situations

- **International travel**
  - **Infants age 6–11 months:** 1 dose before departure; revaccinate with 2-dose series at age 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.*
  - **Children age 12 months or older:**
    - Unvaccinated: 2-dose series (separated by at least 4 weeks*) before departure
    - Previously received 1 dose: administer dose 2 at least 4 weeks after dose 1*
- In mumps outbreak settings, for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm

***Note:** If MMRV is used, the minimum interval between MMRV doses is 3 months.

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Meningococcal serogroup A,C,W,Y vaccination
(minimum age: 2 months [MenACWY-CRM, Menveo], 2 years [MenACWY-TT, MenQuadfi]), 10 years [MenACWY-TT/MenB-FHbp, Penbraya])

Routine vaccination
- 2-dose series at age 11–12 years; 16 years

Catch-up vaccination
- **Age 13–15 years:** 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- **Age 16–18 years:** 1 dose

Special situations
Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

- **Menveo***
  - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
  - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
  - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- **MenQuadfi**
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

Travel to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj (www.cdc.gov/travel/)**:**

- **Children younger than age 24 months:**
  - **Menveo* (age 2–23 months)**
    - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
    - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
    - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
- **Children age 2 years or older:** 1 dose Menveo* or MenQuadfi

First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits: 1 dose Menveo* or MenQuadfi

Adolescent vaccination of children who received MenACWY prior to age 10 years:

- **Children for whom boosters are recommended because of an ongoing increased risk of meningococcal disease** (e.g., those with complement component deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk.
- **Children for whom boosters are not recommended** (e.g., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

**Menveo has two formulations: lyophilized and liquid. The liquid formulation should not be used before age 10 years. See www.cdc.gov/vaccines/vpd/mening/downloads/menveo-single-vial-presentation.pdf.*

Note: For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Children age 10 years or older may receive a single dose of Penbraya as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day (see "Meningococcal serogroup B vaccination" section below for more information).

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Meningococcal serogroup B vaccination
(minimum age: 10 years [MenB-4C, Bexsero; MenB-FHbp, Trumenba; MenACWY-TT/MenB-FHbp, Penbraya])

Shared clinical decision-making
- **Adolescents not at increased risk age 16–23 years (preferred age 16–18 years)* based on shared clinical decision-making.**
  - **Bexsero or Trumenba (use same brand for all doses):** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

*To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision-making for MenB, see www.cdc.gov/vaccines/hcp/admin/downloads/isd-job-aid-scdm-mening-b-shared-clinical-decision-making.pdf

Special situations
Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use.

- **Bexsero or Trumenba (use same brand for all doses including booster doses)** 3-dose series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3)

For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Children age 10 years or older may receive a dose of Penbraya (MenACWY–TT/MenB–FHbp) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. For age-eligible children not at increased risk, if Penbraya is used for dose 1 MenB, MenB-FHbp (Trumenba) should be administered for dose 2 MenB. For age-eligible children at increased risk of meningococcal disease, Penbraya may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day **and** at least 6 months have elapsed since most recent Penbraya dose.

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Mpox vaccination
(minimum age: 18 years [Jynneos])

Special situations

- **Age 18 years and at risk for mpox infection:** complete 2-dose series, 28 days apart.

  Risk factors for mpox infection include:
  - Gay, bisexual, or other MSM, or a person who has sex with gay, bisexual, or other MSM who in the past 6 months have had one of the following:
    - A new diagnosis of at least 1 sexually transmitted disease
    - More than 1 sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
  - Persons who are sexual partners of the persons described above
  - Persons who anticipate experiencing any of the situations described above
- **Pregnancy:** There is currently no ACIP recommendation for Jynneos use in pregnancy due to lack of safety data in pregnant women. Pregnant women with any risk factor described above may receive Jynneos.

For detailed information, see www.cdc.gov/mpox/hcp/vaccine-considerations/vaccination-overview.html

Pneumococcal vaccination
(minimum age: 6 weeks [PCV15], [PCV 20]; 2 years [PPSV23])

Routine vaccination with PCV

- 4-dose series at 2, 4, 6, 12–15 months

Catch-up vaccination with PCV

- Healthy children ages 2–4 years with any incomplete* PCV series: 1 dose PCV
- For other catch-up guidance, see Table 2.

Note: For children **without** risk conditions, PCV20 is not indicated if they have received 4 doses of PCV13 or PCV15 or another age appropriate complete PCV series.

Special situations

Children and adolescents with cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; or diabetes mellitus:

Age 2–5 years

- Any incomplete* PCV series with:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23.
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 administer at least 8 weeks after the most recent PCV dose.

Age 6–18 years

- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.**
- Received PCV before age 6 years but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: 1 dose PCV20 or 1 dose PPSV23 administer at least 8 weeks after the most recent PCV dose.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: no further doses of any PCV or PPSV23 indicated.

Children and adolescents on maintenance dialysis, or with immunocompromising conditions such as nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; or sickle cell disease or other hemoglobinopathies:

Age 2–5 years

- Any incomplete* PCV series:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.

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Pneumococcal vaccination - continued

Age 6–18 years

- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or 1 dose of PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.**
- Received PCV before age 6 years but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no additional dose of PCV or PPSV23
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer either PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose and at least 5 years after dose 1 PPSV23.

Pregnancy: no recommendation for PCV or PPSV23 due to limited data. Summary of existing data on pneumococcal vaccination during pregnancy can be found at www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm

For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app, which can be downloaded here: wcms-wp.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html

**Incomplete series* = Not having received all doses in either the recommended series or an age-appropriate catch-up series. See Table 2 in ACIP pneumococcal recommendations at stacks.cdc.gov/view/cdc/133252

***When both PCV15 and PPSV23 are indicated, administer all doses of PCV15 first. PCV15 and PPSV23 should not be administered during the same visit.*

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Poliovirus vaccination (minimum age: 6 weeks)

Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended on or after age 4 years and at least 6 months after the previous dose.

Catch-up vaccination

- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- **Adolescents age 18 years known or suspected to be unvaccinated or incompletely vaccinated:** administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.* Unless there are specific reasons to believe they were not vaccinated, most persons aged 18 years or older born and raised in the United States can assume they were vaccinated against polio as children.

Series containing oral poliovirus vaccine (OPV), either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s_%20cid=mm6601a6_w.
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements.
  - Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
  - Doses of OPV administered on or after April 1, 2016, should not be counted.
  - For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w.
- For other catch-up guidance, see Table 2.

Special situations

- **Adolescents aged 18 years at increased risk of exposure to poliovirus and completed primary series*:** may administer one lifetime IPV booster

***Note:** Complete primary series consist of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

For detailed information, see: www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

Respiratory syncytial virus immunization (minimum age: birth [Nirsevimab, RSV-mAb, Beyfortus])

Routine immunization

- **Infants born October – March in most of the continental United States***
  - Mother did not receive RSV vaccine or mother's RSV vaccination status is unknown or mother received RSV vaccine in previous pregnancy: administer 1 dose nirsevimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **less than 14 days** prior to delivery: administer 1 dose nirsevimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **at least 14 days** prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html)
- **Infants born April–September in most of the continental United States***
  - Mother did not receive RSV vaccine or mother's RSV vaccination status is unknown or mother received RSV vaccine in previous pregnancy: administer 1 dose nirsevimab shortly before start of RSV season.*
  - Mother received RSV vaccine **less than 14 days** prior to delivery: administer 1 dose nirsevimab shortly before start of RSV season.*
  - Mother received RSV vaccine **at least 14 days** prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html)

Infants with prolonged birth hospitalization** (e.g., for prematurity) discharged October through March should be immunized shortly before or promptly after discharge.

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Notes

Special situations

- **Ages 8–19 months with chronic lung disease of prematurity requiring medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season; severe immunocompromise; cystic fibrosis with either weight for length <10th percentile or manifestation of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable)**:**
  - 1 dose nirsevimab shortly before start of second RSV season*
- **Ages 8–19 months who are American Indian or Alaska Native:** 1 dose nirsevimab shortly before start of second RSV season*
- **Age-eligible and undergoing cardiac surgery with cardiopulmonary bypass**:** 1 additional dose of nirsevimab after surgery. See www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

***Note:** While the timing of the onset and duration of RSV season may vary, administration of nirsevimab is recommended October through March in most of the continental United States (optimally October through November or within 1 week of birth). Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdiction with tropical climate) should follow guidance from public health authorities (e.g., CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

****Note:** Nirsevimab can be administered to children who are eligible to receive palivizumab. Children who have received nirsevimab should not receive palivizumab for the same RSV season.

For further guidance, see www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm and www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html

Respiratory syncytial virus vaccination (RSV [Abrysvo])

Routine vaccination

- **Pregnant at 32 weeks 0 days through 36 weeks and 6 days gestation from September through January in most of the continental United States*:** 1 dose Abrysvo. Administer RSV vaccine regardless of previous RSV infection.
  - Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab (RSV monoclonal antibody) is recommended to prevent severe respiratory syncytial virus disease in infants.
- **All other pregnant women:** RSV vaccine not recommended
- **Subsequent pregnancies:** additional doses not recommended. No data are available to inform whether additional doses are needed in subsequent pregnancies. Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab.

***Note:** Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climate) should follow guidance from public health authorities (e.g., CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

Rotavirus vaccination (minimum age: 6 weeks)

Routine vaccination

- **Rotarix:** 2-dose series at age 2 and 4 months
- **RotaTeq:** 3-dose series at age 2, 4, and 6 months
- If any dose in the series is either **RotaTeq** or unknown, default to 3-dose series.

Catch-up vaccination

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

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Tetanus, diphtheria, and pertussis (Tdap) vaccination (minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

Routine vaccination

- **Age 11–12 years:** 1 dose Tdap (adolescent booster)
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36

Note: Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

Catch-up vaccination

- **Age 13–18 years who have not received Tdap:** 1 dose Tdap (adolescent booster)
- **Age 7–18 years not fully vaccinated* with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- **Tdap administered at age 7–10 years:**
  - **Age 7–9 years** who receive Tdap should receive the adolescent Tdap booster dose at age 11–12 years
  - **Age 10 years** who receive Tdap do not need the adolescent Tdap booster dose at age 11–12 years
- **DTaP inadvertently administered on or after age 7 years**:
  - **Age 7–9 years**: DTaP may count as part of catch-up series. Administer adolescent Tdap booster dose at age 11–12 years.
  - **Age 10–18 years**: Count dose of DTaP as the adolescent Tdap booster dose.
- For other catch-up guidance, see Table 2.

Special situations

- **Wound management** in persons age 7 years or older with history of 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons age 11 years or older who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant adolescent, use Tdap.
- For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm.

**Fully vaccinated* = 5 valid doses of DTaP or 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

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Varicella vaccination
(minimum age: 12 months)

Routine vaccination

- 2-dose series at age 12–15 months, 4–6 years
- VAR or MMRV may be administered*
- Dose 2 may be administered as early as 3 months after dose 1 (a dose inadvertently administered after at least 4 weeks may be counted as valid).

*__Note__: For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

Catch-up vaccination

- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have a 2-dose series:
  - **Age 7–12 years**: Routine interval: 3 months (a dose inadvertently administered after at least 4 weeks may be counted as valid)
  - **Age 13 years and older**: Routine interval: 4–8 weeks (minimum interval: 4 weeks)
  - The maximum age for use of *MMRV* is 12 years.

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Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

Guide to Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4-1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024–25 Influenza Season | MMWR (cdc.gov), *and* Contraindications and Precautions for COVID-19 Vaccination

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
COVID-19 mRNA vaccines [Pfizer-BioNTech, Moderna]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine[3]	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID-19 vaccine[3]; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
COVID-19 protein subunit vaccine [Novavax]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a Novavax COVID-19 vaccine[3]	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of Novavax COVID-19 vaccine[3]; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of a Novavax COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg)	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable (ccIIV3) [Flucelvax]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[4] of ccIIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV3) [Flublok]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[4] of RIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV3) [Flumist]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg) • Children age 2–4 years with a history of asthma or wheezing • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear or any other cranial CSF leak • Children and adolescents receiving aspirin or salicylate-containing medications • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons age 5 years old or older • Persons with underlying medical conditions other than those listed under contraindications that might predispose to complications after wild-type influenza virus infection, e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus) • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should **NOT** be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
3. See package inserts and FDA EUA fact sheets for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG).
4. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. See Package inserts for U.S.-licensed vaccines.

Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
Dengue (DEN4CYD)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Lack of laboratory confirmation of a previous dengue infection	• Pregnancy • HIV infection without evidence of severe immunosuppression • Moderate or severe acute illness with or without fever
Diphtheria, tetanus, pertussis (DTaP)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP	• Guillain-Barré syndrome (GBS) within 6 weeks after previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid-containing vaccine • For DTaP only: Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized • Moderate or severe acute illness with or without fever
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Younger than age 6 weeks	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • Pregnancy: PreHevbrio is not recommended due to lack of safety data in pregnant women. Use other hepatitis B vaccines if HepB is indicated[4]	• Moderate or severe acute illness with or without fever
Hepatitis A-Hepatitis B vaccine (HepA-HepB) [Twinrix]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended.*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever • For MMRV only: Personal or family (i.e., sibling or parent) history of seizures of any etiology • If using MMRV, see Varicella/MMRV for additional precautions
Meningococcal ACWY (MenACWY) MenACWY-CRM [Menveo] MenACWY-TT [MenQuadfi]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Men ACWY-CRM only: severe allergic reaction to any diphtheria toxoid— or CRM197—containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	• For MenACWY-CRM only: Preterm birth if younger than age 9 months • Moderate or severe acute illness with or without fever
Meningococcal B (MenB) MenB-4C [Bexsero] MenB-FHbp [Trumenba]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY-TT/MenB-FHbp) [Penbraya]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction to a tetanus toxoid-containing vaccine	• Moderate or severe acute illness, with or without fever
Mpox [Jynneos]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness, with or without fever
Pneumococcal conjugate (PCV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria-toxoid-containing vaccine or its component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
RSV monoclonal antibody (RSV-mAb)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[5]	• Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Rotavirus (RV) RV1 [Rotarix] RV5 [RotaTeq]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe combined immunodeficiency (SCID) • History of intussusception	• Altered immunocompetence other than SCID • Chronic gastrointestinal disease • RV1 only: Spina bifida or bladder exstrophy • Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid–containing vaccine • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized • Moderate or severe acute illness with or without fever
Varicella (VAR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever • If using MMRV, see MMR/MMRV for additional precautions

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.
4. For information on the pregnancy exposure registry for persons who were inadvertently vaccinated with PreHevbrio while pregnant, please visit www.prehevbrio.com/#safety.
5. Full prescribing information for BEYFORTUS (nirsevimab-alip) www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf.

Addendum

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

In addition to the recommendations presented in the previous sections of this immunization schedule, CDC has approved the following ACIP recommendations since October 24, 2024.

Vaccines	Recommendations	Effective Date of Recommendation[†]
Meningococcal (MenACWY-CRM/MenB-4C, Penmenvy)	ACIP recommends GSK's MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit* *(1) healthy persons aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccine and (2) persons aged ≥10 years who are at increased risk for meningococcal disease (e.g., because of persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia).	June 25, 2025

Note: As of May 29, 2025, the schedule incorporates the HHS directive regarding COVID-19 vaccine recommendations. (Changes were made to tables and notes for COVID-19 vaccines in pregnant women and children/adolescents ages 6 months through 17 years who are not moderately or severely immunocompromised.)

[†]The effective date is the date when the recommendation was adopted and became official.

EXHIBIT 9

Recommended Adult Immunization Schedule
for ages 19 years or older

UNITED STATES
2025

Vaccines in the Adult Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
COVID–19 vaccine	1vCOV–mRNA	Comirnaty/Pfizer–BioNTech COVID–19 Vaccine Spikevax/Moderna COVID–19 Vaccine
	1vCOV–aPS	Novavax COVID–19 Vaccine
Haemophilus influenzae type b vaccine	Hib	ActHIB, Hiberix, PedvaxHIB
Hepatitis A vaccine	HepA	Havrix, Vaqta
Hepatitis A and hepatitis B vaccine	HepA–HepB	Twinrix
Hepatitis B vaccine	HepB	Engerix–B, Heplisav–B, PreHevbrio, Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated, egg-based)	IIV3	Multiple
	aIIV3	Fluad
	HD–IIV3	Fluzone High–Dose
Influenza vaccine (inactivated, cell–culture)	ccIIV3	Flucelvax
Influenza vaccine (recombinant)	RIV3	Flublok
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M–M–R II, Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY–CRM	Menveo
	MenACWY–TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB–4C	Bexsero
	MenB–FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY–TT/ MenB–FHbp	Penbraya
Mpox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance
	PCV20	Prevnar 20
	PCV21	Capvaxive
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo, Arexvy, mResvia
Tetanus and diphtheria vaccine	Td	Tenivac
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel, Boostrix
Varicella vaccine	VAR	Varivax
Zoster vaccine, recombinant	RZV	Shingrix

*Administer recommended vaccines if vaccination history is incomplete or unknown.
Do not restart or add doses to vaccine series if there are extended intervals between doses.
The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

Revised 07/02/2025

How to use the adult immunization schedule

1 Determine recommended vaccinations by age **(Table 1)**

2 Assess need for additional recommended vaccinations by medical condition or other indication **(Table 2)**

3 Review vaccine types, dosing frequencies and intervals, and considerations for special situations **(Notes)**

4 Review contraindications and precautions for vaccine types **(Appendix)**

Report

- Suspected cases of reportable vaccine–preventable diseases or outbreaks to the local or state health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc–info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/hcp/imz-schedules/app.html.

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/acip-recs/hcp/vaccine-specific/
- ACIP Shared Clinical Decision–Making Recommendations: www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
- *General Best Practice Guidelines for Immunization* www.cdc.gov/vaccines/hcp/acip–recs/general–recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine–Preventable Diseases (including case identification and outbreak response): www.cdc.gov/surv-manual/php/index.html

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Scan QR code for access to online schedule

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2025

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID–19	1 or more doses of 2024–2025 vaccine (See Notes)			2 or more doses of 2024-2025 vaccine (See Notes)
Influenza inactivated (IIV3, ccIIV3) **Influenza recombinant** (RIV3)	1 dose annually			1 dose annually (HD–IIV3, RIV3, or aIIV3 preferred)
Influenza inactivated (aIIV3; HD–IIV3) **Influenza recombinant** (RIV3)	Solid organ transplant (See Notes)			
Influenza live, attenuated (LAIV3)	1 dose annually			
Respiratory syncytial virus (RSV)	Seasonal administration during pregnancy (See Notes)		60 through 74 years (See Notes)	≥75 years
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (See Notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For health care personnel (See Notes)
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (See Notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27 through 45 years		
Pneumococcal (PCV15, PCV20, PCV21, PPSV23)			See Notes	See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication (See Notes for booster recommendations)			
Meningococcal B (MenB)	19 through 23 years	2 or 3 doses depending on vaccine and indication (See Notes for booster recommendations)		
***Haemophilus influenzae* type b** (Hib)	1 or 3 doses depending on indication			
Mpox	2 doses			
Inactivated poliovirus (IPV)	Complete 3-dose series if incompletely vaccinated. Self–report of previous doses acceptable (See Notes)			

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity

Recommended vaccination for adults with an additional risk factor or another indication

Recommended vaccination based on shared clinical decision–making

No Guidance/ Not Applicable

Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2025

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions or indications are often not mutually exclusive. If multiple medical conditions or indications are present, refer to guidance in all relevant columns. See Notes for medical conditions or indications not listed.

VACCINE	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count		Men who have sex with men	Asplenia, complement deficiency	Heart or lung disease	Kidney failure, End–stage renal disease or on dialysis	Chronic liver disease; alcoholism[a]	Diabetes	Health care Personnel[b]
			<15% or <200/mm³	≥15% and ≥200/mm³							
COVID–19		See Notes									
Influenza inactivated Influenza recombinant		Solid organ transplant (See Notes)	1 dose annually								
LAIV3					1 dose annually if age 19–49 years		1 dose annually if age 19–49 years				
RSV	Seasonal administration (See Notes)	See Notes				See Notes			Liver disease (See Notes)	See Notes	
Tdap or Td	Tdap: 1 dose each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	*										
VAR	*			See Notes							
RZV		See Notes									
HPV	*	3-dose series if indicated									
Pneumococcal											
HepA											
Hep B	See Notes									Age ≥ 60 years	
MenACWY											
MenB											
Hib		HSCT: 3 doses[c]				Asplenia: 1 dose					
Mpox	See Notes				See Notes						See Notes
IPV		Complete 3-dose series if incompletely vaccinated. Self–report of previous doses acceptable (See Notes)									

- Recommended for all adults who lack documentation of vaccination, **OR** lack evidence of immunity
- Not recommended for all adults, but recommended for some adults based on either age **OR** increased risk for or severe outcomes from disease
- Recommended vaccination based on shared clinical decision–making
- Recommended for all adults, and additional doses may be necessary based on medical condition or other indications. See Notes.
- Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended *Vaccinate after pregnancy, if indicated
- No Guidance/ Not Applicable

a. Precaution for LAIV3 does not apply to alcoholism.

b. See Notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations.

c. Hematopoietic stem cell transplant.

Notes

For vaccination recommendations for persons ages 18 years or younger, see the Recommended Child and Adolescent Immunization Schedule, 2025: www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

Additional Information

- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3–2, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip–recs/general–recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8–1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip–recs/general–recs/immunocompetence.html
- For information about vaccination in the setting of a vaccine–preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no–fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the adult immunization schedule except PPSV23, RSV, RZV, Mpox, and COVID–19 vaccines are covered by the National Vaccine Injury Compensation Program (VICP). Mpox and COVID–19 vaccines are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID–19 vaccination

Routine vaccination

Age 19–64 years (not pregnant)

- **Unvaccinated:**
  - 1 dose 2024–25 Moderna or Pfizer-BioNTech
  - 2 doses 2024–25 Novavax at 0, 3–8 weeks
- **Previously vaccinated before 2024–25 vaccine with:**
  - **1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
  - **1 dose Novavax:** 1 dose 2024–25 Novavax 3–8 weeks after most recent dose. If more than 8 weeks after most recent dose, administer 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.
  - **2 or more doses Novavax:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
  - **1 or more doses Janssen:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.

Age 65 years and older

- **Unvaccinated:** follow recommendations above for unvaccinated persons ages 19–64 years **and** administer dose 2 of 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).
- **Previously vaccinated before 2024–25 vaccine:** follow recommendations above for previously vaccinated persons ages 19–64 years **and** administer dose 2 of 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months).

Special situations

Persons who are moderately or severely immunocompromised. Use vaccine from the same manufacturer for all doses in the initial vaccination series.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series 2024–25 Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
  - 4 doses (**3-dose initial series 2024–25 Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
  - 3 doses (**2-dose initial series 2024–25 Novavax** at 0, 3 weeks, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
- **Incomplete initial vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*

Notes

COVID-19 vaccination - continued

- **Previous vaccination with Pfizer-BioNTech**
  - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*
  - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*
- **Previous vaccination with Novavax**
  - **1 dose Novavax:** complete initial series with 1 dose 2024–25 Novavax at least 3 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses.*

- **Completed the initial vaccination series before 2024–25 vaccine with:**
  - **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses.*
  - **2 or more doses Novavax:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses.*

***Additional doses of 2024–25 COVID-19 vaccine for moderately or severely immunocompromised:** based on shared clinical decision-making and administered at least 2 months after the most recent dose (see Table 2 at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02.). For description of moderate and severe immunocompromising conditions and treatment, see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromising-conditions-treatment.

Unvaccinated persons have never received any COVID-19 vaccine doses. There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available. Administer an age-appropriate COVID-19 vaccine product for each dose.

For information about interchangeability of COVID-19 vaccines, see wcms-wp.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability.

Current COVID-19 schedule and dosage formulation available at www.cdc.gov/covidschedule. For more information on Emergency Use Authorization (EUA) indications for COVID-19 vaccines, see www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

Haemophilus influenzae type b vaccination

Special situations

- **Anatomical or functional asplenia (including sickle cell disease):** 1 dose if previously did not receive Hib vaccine
  - **Elective splenectomy:** 1 dose preferably at least 14 days before splenectomy
- **Hematopoietic stem cell transplant (HSCT):** 3-dose series 4 weeks apart starting 6–12 months after successful transplant, regardless of Hib vaccination history

Hepatitis A vaccination

Routine vaccination

- **Any person who is not fully vaccinated and requests vaccination** (identification of risk factor not required): complete 2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA–HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 5 months])

Special situations

- **Any person who is not fully vaccinated and who is at risk for hepatitis A virus infection or severe disease from hepatitis A virus infection:** complete 2-dose series HepA or 3-dose series HepA–HepB as above. Risk factors include:
  - **Chronic liver disease** including persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.
  - **HIV infection**
  - **Men who have sex with men**
  - **Injection or noninjection drug use**
  - **Persons experiencing homelessness**
  - **Work with hepatitis A virus** in research laboratory or with nonhuman primates with hepatitis A virus infection
  - **Travel in countries with high or intermediate endemic hepatitis A:** HepA–HepB (Twinrix) may be administered on an accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months.
  - **Close, personal contact with international adoptee** (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A: dose 1 as soon as adoption is planned; preferably at least 2 weeks before adoptee's arrival.

Notes

Hepatitis A vaccination - continued

- **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy
- **Settings for exposure,** including health care setting serving persons who use injection or noninjection drugs, or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

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Hepatitis B vaccination

Routine vaccination

- **Age 19 through 59 years:** complete a 2- or 3- or 4-dose series
  - 2-dose series only applies when 2 doses of Heplisav–B are used at least 4 weeks apart
  - 3-dose series Engerix–B, PreHevbrio*, or Recombivax HB at 0, 1, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 8 weeks; dose 1 to dose 3 = 16 weeks)
  - 3-dose series HepA–HepB (Twinrix) at 0, 1, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 5 months)
  - 4-dose series HepA–HepB (Twinrix) accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months

***Note:** PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant women.

- **Age 60 years or older without** known risk factors for hepatitis B virus infection **may** receive a HepB vaccine series.
- **Age 60 years or older with** known risk factors for hepatitis B virus infection **should** receive a HepB vaccine series.
- **Any adult age 60 years of age or older** who requests HepB vaccination **should** receive a HepB vaccine series.
  - **Risk factors for hepatitis B virus infection include:**
    - **Chronic liver disease** including persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.
    - **HIV infection**
    - **Sexual exposure risk** e.g., sex partners of hepatitis B surface antigen (HBsAg)–positive persons, sexually active persons not in mutually monogamous relationships, persons seeking evaluation or treatment for a sexually transmitted infection, men who have sex with men
    - **Current or recent injection drug use**
    - **Percutaneous or mucosal risk for exposure to blood** e.g., household contacts of HBsAg–positive persons, residents and staff of facilities for developmentally disabled persons, health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood–contaminated body fluids, persons on maintenance dialysis (including in–center or home hemodialysis and peritoneal dialysis), persons who are predialysis, and patients with diabetes**
    - **Incarceration**
    - **Travel in countries with high or intermediate endemic hepatitis B**

****Age 60 years or older with diabetes:** Based on shared clinical decision making, 2-, 3-, or 4-dose series as above.

Special situations

- **Patients on dialysis:** complete a 3- or 4-dose series
  - 3-dose series Recombivax HB at 0, 1, 6 months (Note: Use Dialysis Formulation 1 mL = 40 mcg)
  - 4-dose series Engerix–B at 0, 1, 2, and 6 months (Note: Use 2 mL dose instead of the normal adult dose of 1 mL)
- **Age 20 years or older with an immunocompromising condition:** complete a 2- or 3- or 4-dose series.
  - 3-dose series Recombivax HB at 0,1, 6 months (Note: Use Dialysis Formulation 1ml = 40 mcg)
  - 4-dose series Engerix–B at 0,1,2, and 6 months (Note: Use 2mL dose instead of the normal adult dose of 1mL)
  - 2-doses series Heplisav–B at 0, 1 months
  - 3-dose series PreHevbrio* at 0,1, 6 months

Notes

Human papillomavirus vaccination

Routine vaccination

- **All persons through age 26 years:** complete 2– or 3-dose series depending on age at initial vaccination or condition.
  - **Age 9–14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart:** 1 additional dose
  - **Age 9–14 years at initial vaccination and received 2 doses at least 5 months apart:** HPV vaccination series complete, no additional dose needed
  - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 12 weeks; dose 1 to dose 3 = 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series of any valency has been completed using the recommended dosing intervals.

Shared clinical decision–making

- **Adults age 27–45 years:** Based on shared clinical decision–making, complete a 2-dose series (if initiated age 9–14 years) or 3-dose series (if initiated ≥15 years).

For additional information on shared clinical decision–making for HPV; see www.cdc.gov/vaccines/hcp/admin/downloads/isd–job–aid–scdm–hpv–shared–clinical–decision–making–hpv.pdf

Special situations

- **Age ranges recommended above for routine and catch–up vaccination or shared clinical decision–making also apply in special situations**
  - **Immunocompromising conditions, including HIV infection**: complete 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
  - **Pregnancy**: Pregnancy testing is not needed before vaccination. HPV vaccination is not recommended until after pregnancy. No intervention needed if inadvertently vaccinated while pregnant.

Influenza vaccination

Routine vaccination

- **Age 19 years or older:** 1 dose any influenza vaccine appropriate for age and health status annually
  - **Solid organ transplant recipients aged 19 through 64 years receiving immunosuppressive medications:** HD–IIV3 and aIIV3 are acceptable options. No preference over other age–appropriate IIV3 or RIV3.
  - **Age 65 years or older:** Any one of HD-IIV3, RIV3, or aIIV3 is preferred. If none of these three vaccines is available, then any other age–appropriate influenza vaccine should be used.
- For the 2024–25 season, see www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm
- For the 2025–26 season, see the 2025–26 ACIP influenza vaccine recommendations.

Special situations

- **Close contacts (e.g., caregivers, healthcare workers) of severely immunosuppressed persons who require a protected environment:** should not receive LAIV3. If LAIV3 is given, they should avoid contact with/caring for such immunosuppressed persons for 7 days after vaccination.

Note: Persons with an egg allergy can receive any influenza vaccine (egg-based or non–egg based) appropriate for age and health status.

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Measles, mumps, and rubella vaccination

Routine vaccination

- **No evidence of immunity to measles, mumps, or rubella:** 1 dose
  - **Evidence of immunity:** Born before 1957 (except for health care personnel, see below), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)

Special situations

- **Pregnancy with no evidence of immunity to rubella:** MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility): 1 dose
- **Nonpregnant women of childbearing age with no evidence of immunity to rubella:** 1 dose
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm³ for at least 6 months and no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart; MMR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm³
- **Severe immunocompromising conditions:** MMR contraindicated
- **Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons with no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR
- **In mumps outbreak settings,** for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm

Notes

Measles, mumps, and rubella vaccination - continued

- **Health care personnel:**
  - **Born before 1957 with no evidence of immunity to measles, mumps, or rubella:** Consider 2-dose series at least 4 weeks apart for protection against measles or mumps or 1 dose for protection against rubella.
  - **Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart for protection against measles or mumps or at least 1 dose for protection against rubella.

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Meningococcal vaccination

Special situations for MenACWY

- **Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:** 2-dose primary series Menveo or MenQuadfi at least 8 weeks apart; 1 booster dose 5 years after primary series and every 5 years if risk remains
- **Travel in countries with hyperendemic or epidemic meningococcal disease, or for microbiologists routinely exposed to *Neisseria meningitidis*:** 1 dose Menveo or MenQuadfi; 1 booster dose 5 years after primary series and every 5 years if risk remains
- **First–year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:** 1 dose Menveo or MenQuadfi

For MenACWY recommendations **in outbreak setting** (e.g., in community or organizational settings, or among men who have sex with men) and **additional meningococcal vaccination** information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm

Shared clinical decision–making for MenB

- **Adolescents and young adults age 16–23 years (age 16–18 years preferred)* not at increased risk for meningococcal disease:** based on shared clinical decision–making
  - **Bexsero or Trumenba (use same brand for all doses):** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

*To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision–making for MenB, see www.cdc.gov/vaccines/hcp/admin/downloads/isd–job–aid–scdm–mening–b–shared–clinical–decision–making.pdf

Special situations for MenB

- **Anatomical or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, or microbiologists routinely exposed to *Neisseria meningitidis*.**
  - **Bexsero or Trumenba (use same brand for all doses including booster doses):** 3-dose primary series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3).
  - **Booster doses:** 1 booster dose one year after primary series and every 2–3 years if risk remains
- **Pregnancy:** Delay MenB until after pregnancy due to lack of safety data in pregnant women. May administer if at increased risk and vaccination benefits outweigh potential risks.

For MenB recommendations **in outbreak setting** (e.g., in community or organizational settings, or among men who have sex with men) and **additional meningococcal vaccination** information, see ww.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Adults may receive a single dose of Penbraya (MenACWY–TT/MenB–FHbp) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. For adults not at increased risk, if Penbraya is used for dose 1 MenB, then MenB–FHbp (Trumenba) should be administered for dose 2 MenB. For adults at increased risk of meningococcal disease, Penbraya may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day **and** at least 6 months have elapsed since most recent Penbraya dose.

Notes

Mpox vaccination

Special situations

- **Any person at risk for mpox infection:** complete 2-dose series, 28 days apart.

  Risk factors for mpox infection include:
  - Persons who are gay or bisexual, and other MSM, transgender or nonbinary people who in the past 6 months have had:
    - A new diagnosis of at least 1 sexually transmitted disease
    - More than 1 sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
  - Persons who are sexual partners of the persons described above
  - Persons who anticipate experiencing any of the situations described above
- **Pregnancy:** There is currently no ACIP recommendation for Jynneos use in pregnancy due to lack of safety data in pregnant women. Pregnant women with any risk factor described above may receive Jynneos.
- **Health care personnel:** Vaccination to protect against occupational risk in healthcare settings is not routinely recommended.

  For detailed information, see www.cdc.gov/mpox/hcp/vaccine-considerations/vaccination-overview.html.

Pneumococcal vaccination

Routine vaccination

- **Age 50 years or older who have:**
  - **Not previously received a dose of PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21
    - If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose
  - **Previously received only PPSV23:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21, at least 1 year after the last PPSV23 dose.
    - If PCV15 is used, no additional PPSV23 doses are recommended.
  - **Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older:** 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.
  - **Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older:** Based on shared clinical decision–making, 1 dose of PCV20 or 1 dose of PCV21 at least 5 years after the last pneumococcal vaccine dose.

Special situations

- **Age 19–49 years with certain underlying medical conditions or other risk factors** who have:**
  - **Not previously received a PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21
    - If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose
  - **Previously received only PPSV23:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21, at least 1 year after the last PPSV23 dose.
    - If PCV15 is used, no additional PPSV23 doses are recommended.
  - **Previously received PCV13 and 1 dose of PPSV23:**
    - Cochlear implant, cerebrospinal fluid leak, or an immunocompromising condition*: 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.
    - Alcoholism, chronic heart/liver/lung disease, cigarette smoking, or diabetes mellitus: no additional PCV or PPSV23 doses recommended at this time. Review pneumococcal recommendations when age 50 years or older.

Adults aged 19 years and older who have received PCV20 or PCV21: no additional pneumococcal vaccine dose recommended.

Pregnancy: no recommendation for PCV or PPSV23 due to limited data. Summary of existing data on pneumococcal vaccination during pregnancy can be found at www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm.

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Notes

Pneumococcal vaccination - continued

PPSV23 not available: adults aged 19 years or older who received PCV15 but have not yet completed PPSV23 series, can complete the series with either 1 dose of PCV20 or 1 dose of PCV21 if they no longer have access to PPSV23.

For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app which can be downloaded here: www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html.

***Note:** Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiencies, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.

****Note:** Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV infection, Hodgkin disease, immunodeficiencies, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, or sickle cell disease or other hemoglobinopathies.

Poliovirus vaccination

Routine vaccination

- **Adults known or suspected to be unvaccinated or incompletely vaccinated:** administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.* Unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children.

Special situations

- **Adults at increased risk for exposure to poliovirus who completed primary series*:** may administer one lifetime IPV booster.

***Note:** Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

For detailed information, see www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

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Respiratory syncytial virus vaccination

Routine vaccination

- **Pregnant women of any age:**
  - **Pregnant at 32 weeks 0 days through 36 weeks and 6 days gestation from September through January in most of the continental United States*:** 1 dose **Abrysvo**. Administer RSV vaccine regardless of previous RSV infection.
  - Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab (RSV monoclonal antibody) is recommended to prevent severe respiratory syncytial virus disease in infants.
  - **All other pregnant women:** RSV vaccine not recommended
  - **Subsequent pregnancies:** additional doses not recommended. No data are available to inform whether additional doses are needed in subsequent pregnancies. Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab.

***Note:** Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climate) should follow guidance from public health authorities on timing of administration. Refer to the 2025 Child and Adolescent Immunization Schedule for considerations regarding nirsevimab administration to infants.

Age 75 years or older

- **Unvaccinated:** 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended
- **Previously vaccinated:** additional doses not recommended. No data are available to inform whether additional doses are needed.

Notes

Respiratory syncytial virus vaccination - continued

Special situations

- **Age 60–74 years:**
  - **Unvaccinated and at increased risk of severe RSV disease**:** 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended.
  - **Previously vaccinated:** additional doses not recommended. No data are available to inform whether additional doses are needed.

Persons 60 years and older can get RSV vaccine at any time but it is best to administer in late summer and early fall before RSV spreads in communities—ideally August through October in most of continental United States. For further guidance, see www.cdc.gov/mmwr/volumes/73/wr/mm7332e1.htm.

****Note: *People can self–attest to the presence of a risk factor.* The following medical and other conditions increase the risk of severe RSV disease:**

- Chronic cardiovascular disease e.g., heart failure, coronary artery disease, congenital heart disease. Excludes isolated hypertension.
- Chronic lung or respiratory disease e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, cystic fibrosis
- End stage renal disease or dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end–organ damage
- Diabetes mellitus requiring treatment with insulin or sodium–glucose cotransporter 2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness e.g., post–stroke dysphagia, amyotrophic lateral sclerosis, muscular dystrophy. Excludes history of stroke without impaired airway clearance.
- Chronic liver disease e.g., cirrhosis
- Chronic hematologic conditions e.g., sickle cell disease, thalassemia
- Severe obesity (body mass index ≥ 40 kg/m2)
- Moderate or severe immune compromise
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk of severe disease due to viral respiratory infection e.g., frailty, concern for presence of undiagnosed chronic medical conditions, residence in a remote or rural community where escalation of medical care is challenging.

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Tetanus, diphtheria, and pertussis vaccination

Routine vaccination

- **Completed primary series and received at least 1 dose Tdap at age 10 years or older:** Td or Tdap every 10 years thereafter
- **Completed primary series and did NOT receive Tdap at age 10 years or older:** 1 dose Tdap, then Td or Tdap every 10 years thereafter
- **Unvaccinated or incomplete primary vaccination series for tetanus, diphtheria, or pertussis:** administer remaining doses (1, 2, or 3 doses) to complete 3-dose primary series. 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks later, and a third dose of Td or Tdap 6–12 months later (Tdap is preferred as first dose and can be substituted for any Td dose), then Td or Tdap every 10 years thereafter.

Special situations

- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- **Wound management:** Persons with 3 or more doses of tetanus–toxoid–containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus–toxoid–containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus–toxoid–containing vaccine. Tdap is preferred for persons who have not previously received Tdap or whose Tdap history is unknown. If a tetanus–toxoid–containing vaccine is indicated for a pregnant woman, use Tdap. For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm

Notes

Varicella vaccination

Routine vaccination

- **No evidence of immunity to varicella:** 2-dose series 4–8 weeks apart if previously did not receive varicella–containing vaccine (VAR or MMRV [measles–mumps–rubella–varicella vaccine] for children); if previously received 1 dose varicella–containing vaccine, 1 dose at least 4 weeks after first dose.
  - **Evidence of immunity:** U.S.–born before 1980 (except for pregnant women and health care personnel [see below]), documentation of 2 doses varicella–containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease.

Special situations

- **Pregnancy with no evidence of immunity to varicella:** VAR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose if previously received 1 dose varicella–containing vaccine or dose 1 of 2-dose series (dose 2: 4–8 weeks later) if previously did not receive any varicella–containing vaccine, regardless of whether U.S.–born before 1980.
- **Health care personnel with no evidence of immunity to varicella:** 1 dose if previously received 1 dose varicella–containing vaccine; 2-dose series 4–8 weeks apart if previously did not receive any varicella–containing vaccine, regardless of whether U.S.–born before 1980.
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm^3 with no evidence of immunity:** Vaccination may be considered (2 doses 3 months apart); VAR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm^3.
- **Severe immunocompromising conditions:** VAR contraindicated

Zoster vaccination

Routine vaccination

- **Age 50 years or older*:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of zoster vaccine live (ZVL, Zostavax) vaccination.

***Note:** Serologic evidence of prior varicella is not necessary for zoster vaccination. However, if serologic evidence of varicella susceptibility becomes available, providers should follow ACIP guidelines for varicella vaccination first. RZV is not indicated for the prevention of varicella, and there are limited data on the use of RZV in persons without a history of varicella or varicella vaccination.

Special situations

- **Pregnancy:** There is currently no ACIP recommendation for RZV use in pregnancy. Consider delaying RZV until after pregnancy.
- **Immunocompromising conditions (including persons with HIV regardless of CD4 count)**:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon). For detailed information, see www.cdc.gov/shingles/hcp/vaccine–considerations/immunocompromised–adults.html

****Note:** If there is no documented history of varicella, varicella vaccination, or herpes zoster, providers should refer to the clinical considerations for use of RZV in immunocompromised adults aged ≥19 years and the ACIP varicella vaccine recommendations for further guidance: www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

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Appendix

Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4–1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024–25 Influenza Season | MMWR (cdc.gov), *and* Contraindications and Precautions for COVID–19 Vaccination

Vaccines and Other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
COVID–19 mRNA vaccines [Pfizer–BioNTech, Moderna]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID–19 vaccine[3]	• Diagnosed non–severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID–19 vaccine[3]; or non–severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID–19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID–19 vaccine • Multisystem inflammatory syndrome in children (MIS–C) or multisystem inflammatory syndrome in adults (MIS–A) • Moderate or severe acute illness, with or without fever
COVID–19 protein subunit vaccine [Novavax]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a Novavax COVID–19 vaccine[3]	• Diagnosed non–severe allergy (e.g., urticaria beyond the injection site) to a component of Novavax COVID–19 vaccine[3]; or non–severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of a Novavax COVID–19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID–19 vaccine • Multisystem inflammatory syndrome in children (MIS–C) or multisystem inflammatory syndrome in adults (MIS–A) • Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg)	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture–based inactivated injectable (ccIIV3) [Flucelvax]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[4] of ccIIV3	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV3) [Flublok]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[4] of RIV3	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV3) [Flumist]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg) • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear, or any other cranial CSF leak • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days.	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons aged 5 years or older • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild–type influenza virus infection [e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)] • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
3. See package inserts and FDA EUA fact sheets for a full list of vaccine ingredients. mRNA COVID–19 vaccines contain polyethylene glycol (PEG).
4. Vaccination providers should check FDA–approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. See Package inserts for U.S.–licensed vaccines.

Appendix

Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Vaccine	Contraindicated or Not Recommended[1]	Precautions[2]
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • Pregnancy: PreHevbrio is not recommended due to lack of safety data in pregnant women. Use other hepatitis B vaccines if HepB is indicated[4]	• Moderate or severe acute illness with or without fever
Hepatitis A–Hepatitis B vaccine (HepA–HepB) [Twinrix]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long–term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody–containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon–gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever
Meningococcal ACWY (MenACWY) (MenACWY–CRM) [Menveo] (MenACWY–TT) [MenQuadfi]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For MenACWY–CRM only: severe allergic reaction to any diphtheria toxoid– or CRM197–containing vaccine • For MenACWY–TT only: severe allergic reaction to a tetanus toxoid–containing vaccine	• Moderate or severe acute illness with or without fever
Meningococcal B (MenB) MenB–4C [Bexsero] MenB–FHbp [Trumenba]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB–4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY–TT/MenB–FHbp) [Penbraya]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction to a tetanus toxoid–containing vaccine	• Moderate or severe acute illness, with or without fever
Mpox [Jynneos]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness, with or without fever
Pneumococcal conjugate (PCV15, PCV20, PCV21)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria–toxoid–containing vaccine or to its vaccine component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (e.g., anaphylaxis) to a vaccine component	• Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus–toxoid–containing vaccine • History of Arthus–type hypersensitivity reactions after a previous dose of diphtheria–toxoid containing or tetanus–toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus–toxoid–containing vaccine • Moderate or severe acute illness with or without fever • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized
Varicella (VAR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long–term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody–containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin–containing products • Moderate or severe acute illness with or without fever
Zoster recombinant vaccine (RZV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever • Current episode of herpes zoster

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip–recs/general–recs/contraindications.html.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip–recs/general–recs/contraindications.html.
3. Vaccination providers should check FDA–approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.–licensed vaccines are available at www.fda.gov/vaccines–blood–biologics/approved–products/vaccines–licensed–use–united–states.
4. For information on the pregnancy exposure registry for persons who were inadvertently vaccinated with PreHevbrio while pregnant, please visit www.prehevbrio.com/#safety.

Addendum

Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

In addition to the recommendations presented in the previous sections of this immunization schedule, CDC has approved the following ACIP recommendations since October 24, 2024.

Vaccines	Recommendations	Effective Date of Recommendation[†]
Meningococcal (MenACWY-CRM/MenB-4C, Penmenvy)	ACIP recommends GSK's MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit* *(1) healthy persons aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccine and (2) persons aged ≥10 years who are at increased risk for meningococcal disease (e.g., because of persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia).	June 25, 2025
RSV (Abrysvo,Arexvy,mResvia)	ACIP recommends adults 50–59 years of age who are at increased risk of severe RSV disease[a] receive a single dose of RSV vaccine.[b,c] a. CDC will publish Clinical Considerations that describe chronic medical conditions and other risk factors for severe RSV disease for use in this risk-based recommendation. b. At this time, RSV vaccination is recommended as a single dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose. c. RSV vaccine can be administered with any product licensed in this age group.	June 25, 2025

Note: As of May 29, 2025, the schedule incorporates the HHS directive regarding COVID-19 vaccine recommendations. (Changes were made to tables and notes for COVID-19 vaccines in pregnant women.)

[†]The effective date is the date when the recommendation was adopted and became official.

EXHIBIT 10

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Agenda

Centers for Disease Control and Prevention
Atlanta, GA

Thursday, September 18, 2025

10:00 AM	**Welcome and Roll Call**	Dr. Martin Kulldorff (ACIP Chair) Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
10:30 AM	**Update on Work Groups**	Dr. Martin Kulldorff (ACIP Chair)
10:40 AM	**Measles, Mumps, Rubella, and Varicella (MMRV) Vaccines**	
	Introduction	Dr. Martin Kulldorff (ACIP Chair)
	Background on MMRV	Dr. Arjun Srinivasan (CDC/NCIRD)
	Presentation on febrile seizure following MMRV vaccine	Dr. John Su (CDC/NCEZID)
	MMRV Vaccine Manufacturer Statements	TBD
	Proposed recommendations and discussion	Dr. Martin Kulldorff (ACIP Chair)
	VFC presentation	Dr. Jeanne Santoli (CDC/NCIRD)
12:35 PM	***Lunch***	
1:05 PM	**Hepatitis B Vaccine**	
	Introduction	Dr. Martin Kulldorff (ACIP Chair)
	Presentation on Hepatitis B Birth Dose Vaccination	Dr. Adam Langer (CDC/NCHHSTP)
	Hep B vaccine safety updates	Dr. John Su (CDC/NCEZID)
	Hep B Vaccine Manufacturer Statements	TBD
	Proposed recommendations and discussion	Dr. Martin Kulldorff (ACIP Chair)
	VFC presentation	Dr. Jeanne Santoli (CDC/NCIRD)
3:55 PM	***Break***	
4:10 PM	**Agency Updates**	CDC, CMS, FDA, HRSA, IHS, NIH
4:30 PM	Public Comment	
5:00 PM	**Votes**	
	MMRV vaccines	Dr. Martin Kulldorff (ACIP Chair)
	MMRV vaccines - VFC	Dr. Jeanne Santoli (CDC/NCIRD)
5:30 PM	**Adjourn**	

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Agenda

Friday, September 19, 2025

8:30 AM	**Welcome and Roll Call**	Dr. Martin Kulldorff (ACIP Chair) Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
8:40 AM	**Votes**	
	Hepatitis B vaccines	Dr. Martin Kulldorff (ACIP Chair)
	Hepatitis B vaccines – VFC	Dr. Jeanne Santoli (CDC/NCIRD)
9:00 AM	**Agency Updates**	CDC, CMS, FDA, HRSA, IHS, NIH
9:10 AM	**COVID-19 Vaccines**	
	Introduction	Dr. Retsef Levi (ACIP WG Chair)
	COVID-19 epidemiology update	Dr. Arjun Srinivasan (CDC/NCIRD)
	Updates to 2024-2025 COVID-19 Implementation Considerations	Dr. Arjun Srinivasan (CDC/NCIRD)
	COVID-19 vaccine effectiveness update	Dr. Arjun Srinivasan (CDC/NCIRD)
	COVID-19 vaccine safety update	Dr. John Su (CDC/NCEZID)
10:10 AM	***Break***	
10:15 AM	**COVID-19 Vaccines (continued)**	
	Workgroup Safety Uncertainties of mRNA COVID Vaccines	Dr. Wafik El-Deiry & Dr. Charlotte Kuperwasser (COVID-19 Workgroup Member)
	Genomics of Vaccine-Induced Myocarditis	Dr. Bruce Carleton (COVID-19 Workgroup Member)
	Economic analysis of COVID-19 vaccination	Dr. Arjun Srinivasan (CDC/NCIRD) on behalf of the University of Michigan
	COVID-19 Vaccine Manufacturer Statements	TBD
11:25 AM	***Lunch***	
11:45 AM	**COVID-19 Vaccines (continued)**	
	COVID-19 Discussion Framing	Dr. Retsef Levi (ACIP WG Chair)
	Presentation on additional workgroup considerations in COVID-19 vaccination Policy and practice	Dr. Stanley Perlman, Dr. Henry Bernstein, Dr. Mitchell Miglis (COVID-19 Workgroup Members)
	Proposed recommendations and discussion	Dr. Retsef Levi (ACIP WG Chair)
1:45 PM	***Break***	
1:50 PM	Public Comment	
2:20 PM	**Votes**	
	COVID-19 Vaccines	Dr. Retsef Levi (ACIP WG Chair)
3:00 PM	**Adjourn**	

Acronyms

CDC Centers for Disease Control and Prevention

CMS Centers for Medicare & Medicaid Services

COVID-19 Coronavirus disease 2019

FDA Food and Drug Administration

HRSA Health Resources and Services Administration

IHS Indian Health Service

MMRV Measles, Mumps, Rubella, Varicella Vaccine

NCIRD National Center for Immunization & Respiratory Diseases

NCEZID National Center for Emerging and Zoonotic Diseases

NCHHSTP National Center for HIV, Viral Hepatitis, STD, and Tuberculosis Prevention

NIH National Institutes of Health

VFC Vaccines for Children

EXHIBIT 11

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

SEPTEMBER 18-19, 2025
MEETING SUMMARY

Trade names are used for identification purposes only and do not indicate endorsement.

THURSDAY: SEPTEMBER 18, 2025

WELCOME AND ROLL CALL

Call to Order/Roll Call

Dr. Mina Zadeh, ACIP Executive Secretary, CDC, convened the meeting at 10:00 a.m. on September 18, 2025, and welcomed participants to the September 18–19 session of the Advisory Committee on Immunization Practices (ACIP). She provided general logistical information and noted that presentation slides were available on the ACIP website. Dr. Zadeh reviewed the public comment process, explaining that two oral comment sessions were scheduled, with 19 speakers selected in advance through a blinded lottery, and that written comments were accepted through regulations.gov (Docket No. CDC-2025-0454). She reaffirmed ACIP's commitment to transparency and reviewed conflict of interest policies, noting that members must disclose relevant conflicts and may receive limited waivers for activities that enhance expertise but may not vote on related matters.

Dr. Zadeh then conducted the roll call and introduced five new ACIP members appointed for the September 2025 meeting: Dr. Catherine M. Stein, Dr. Evelyn Griffin, Dr. Hilary Blackburn, Dr. Kirk Milhoan, and Dr. Raymond Pollak. A complete list of Members, Ex Officio members, and Liaison Representatives is provided in the appendices at the end of this summary document. While no conflicts of interest were identified for the first day of the meeting, Dr. Robert Malone abstained from the MMRV votes due to existing legal agreements.

UPDATE ON WORK GROUPS

Dr. Kulldorff provided an update on the current work groups, noting that several are actively engaged in ongoing scientific discussions and analyses, with some scheduled to present their deliberations during this session. He announced the formation of two new work groups: one focused on vaccines in pregnant women and another on the childhood and adolescent vaccine schedule.

He explained that most existing work groups focus on individual vaccines or related vaccine groups. The new group will examine interaction effects and optimal sequencing within the broader vaccine schedule. Dr. Kulldorff emphasized the importance of careful consideration when evaluating vaccines during pregnancy due to potential risks, such as birth defects. He concluded by noting that findings from these new work groups will be presented at future ACIP meetings.

MEASLES, MUMPS, RUBELLA, AND VARICELLA (MMRV) VACCINE

Introduction

Dr. Martin Kulldorff (ACIP Chair)

Dr. Martin Kulldorff, Chair of the ACIP, opened the session by introducing the MMRV (measles, mumps, rubella, varicella) vaccine. He noted that the vaccine combines protection against four diseases in a single injection, developed to replace two separate shots (MMR and varicella), thereby reducing the number of needles children receive.

Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

Background on MMRV

Dr. Arjun Srinivasan (CDC/NCIRD)

Dr. Arjun Srinivasan (CDC/NCIRD) provided background information on the measles, mumps, rubella, and varicella (MMRV) vaccine. He reviewed the significant health burden of these diseases in the United States (U.S.) before vaccine introduction. During the 1964 to 1965 rubella epidemic, approximately 11,000 pregnant women lost their babies, 2,100 newborns died, and 20,000 were born with congenital rubella syndrome, which can cause deafness, heart defects, and developmental delays. Before the measles vaccine, an estimated 48,000 hospitalizations and 400 to 500 deaths occurred each year due to measles. Mumps was the leading cause of viral encephalitis and sudden-onset deafness before the introduction of vaccination. In the early 1990s, varicella caused between 10,500 and 13,500 hospitalizations annually, along with 100 to 150 deaths.

The introduction of vaccines to protect against these diseases, in the form of monovalent vaccines and combination vaccines such as MMR (measles, mumps, rubella) and MMRV (measles, mumps, rubella, varicella), coupled with achieving and maintaining coverage rates above 90%, led to dramatic reductions in disease burden in the U.S. These efforts resulted in the elimination of endemic measles in 2000, elimination of endemic rubella in 2004, a 99% decline in mump cases by the early 2000s, and a 97% decline in varicella incidence by 2019.

In the U.S., two options are available for measles, mumps, rubella, and varicella vaccination: the combination MMRV vaccine or MMR plus varicella vaccine. The routine schedule consists of two doses, administered at 12–15 months and 4–6 years. The MMRV vaccine available in the US, ProQuad, manufactured by Merck, was licensed by the FDA in September 2005 based on the non-inferior immunogenicity of its components compared with the simultaneous administration of the MMR and varicella vaccines. Efficacy of the individual components had already been established in clinical studies of the monovalent vaccines. At the time of MMRV licensure, disease burden in the U.S. was too low to perform efficacy-based clinical trials for the MMRV vaccine, so immunobridging trials were used to support approval. [Of note, immunobridging trials is an established approach for the development of vaccines.]

Immunogenicity after the first dose of MMRV was compared with that of MMR plus varicella vaccine in children aged 12–23 months in four randomized clinical trials. A total of 5,446 children received MMRV and 238 received MMR plus varicella at separate injection sites. In these studies, seroconversion rates and geometric mean titers were similar between groups and met the pre-established criteria for non-inferiority. Immunogenicity after the second dose in children aged 4–6 years was assessed in one randomized clinical trial, where 399 children received MMRV, 205 received MMR plus placebo, and 195 received MMR plus varicella. The findings also met the pre-established criteria for non-inferiority. As noted in the 2008 and 2009 reviews by the ACIP Vaccine Work Group, safety after MMRV was compared with MMR plus varicella. Based on the demonstrated non-inferior immunogenicity, vaccine effectiveness was assumed to be equal.

Upon licensure in September 2005 for children aged 12 months through 12 years, MMRV was preferred over the separate administration of MMR and varicella vaccines, consistent with the ACIP's preference at the time for combination vaccines. In February 2008, preliminary post-licensure safety findings from two studies identified an increased risk of febrile seizures after the first dose of MMRV, leading ACIP to remove its preference for MMRV over separate administration of MMR and varicella for both the first and second doses. After further review of safety data, consideration of the benefits of one fewer injection with MMRV, analysis of febrile

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seizure epidemiology, input from parents and providers, and consultation with ethics experts, the ACIP issued updated recommendations in June 2009.

These recommendations remain current and state that for the first dose of measles, mumps, rubella, and varicella vaccination at age 12–47 months, either MMR plus varicella or MMRV may be used. Providers who consider administering MMRV should discuss the benefits and risks of both options with parents and caregivers. At the time of publication, CDC implementation guidance recommended that, unless a parent or caregiver specifically preferred MMRV, the first dose in this age group should be administered as separate MMR and varicella vaccines. For the first dose at age 48 months or older and for the second dose at any age through 12 years, MMRV is generally preferred over separate administration of MMR and varicella vaccines.

No post-licensure vaccine effectiveness estimates are available for MMRV used in the U.S., as measles and rubella have been eliminated, and mumps and varicella remain at very low levels. There are not enough cases or outbreaks among children in the U.S. to assess vaccine effectiveness. However, those vaccinated with either MMRV or MMR plus varicella continue to have very low rates of measles, mumps, rubella, and varicella. To date, CDC has received no reports suggesting lower effectiveness of MMRV compared with the separate component vaccines, consistent with the immunogenicity results observed in clinical trials.

In terms of utilization, MMRV accounts for 15% of first-dose measles, mumps, rubella, and varicella vaccination among children aged 19–35 months. In most states, the use of MMRV for the first dose ranges from about 10% to under 20%, based on the first and third quartiles. Among children aged 4–6 years, MMRV accounts for 75% of second-dose vaccination.

Dr. Srinivasan concluded that the MMRV vaccine is one of two options for vaccination of U.S. children against measles, mumps, rubella, and varicella. As ACIP assessed in 2008 and 2009, given the balance of risks and benefits of a first dose of MMRV compared with a first dose of MMR plus varicella, and the importance of individual values and preferences in weighing these risks and benefits, maximizing choice remains an important ethical principle. Decisions should be made on a case-by-case basis by providers, parents, or caregivers. The two vaccination options, MMRV or separate injections of MMR and varicella, are considered equivalent in terms of protection. Under current recommendations, most MMRV use in the U.S. is among children aged 4–6 years for the second dose. Overall, vaccination for measles, mumps, rubella, and varicella has resulted in a reduction of at least 97% in all four diseases compared to the pre-vaccine era.

Discussion

Dr. Milhoan requested clarification on the adjuvant content, specifically comparing the amount in the MMRV vaccine with that of administering MMR and varicella separately, and whether the adjuvant is similar or different between these options.
Dr. Oliver, NCIRD SME, clarified that neither the MMRV vaccine nor the separately administered MMR plus varicella vaccines contain an adjuvant.

Dr. Hibbeln inquired about the overall risk-benefit balance, noting that the benefits were described extensively and that febrile seizures were identified as a potential risk. He requested an assessment of the magnitude of harm from febrile seizures and other side effects in relation to the benefits at both the individual and population levels.

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Dr. Srinivasan stated that Dr. Su would present the risk profile in the following presentation.

Dr. Malone disclosed that, due to his prior service as an expert witness in litigation involving vaccines, which granted him access to internal manufacturer communications under a legal agreement, he is bound not to conduct research on or offer opinions about these products. He clarified that he will not vote on this topic and has no opinion to provide due to the pre-existing legal agreement.

Dr. Pebsworth requested clarification on the varicella antigen amount in the two vaccination options: MMRV versus separate MMR plus varicella, and whether the amounts differ.

Dr. Marin, NCIRD SME, clarified that the measles, mumps, and rubella components are the same in MMR and MMRV. The varicella component in MMRV utilizes the same virus strain as the single-antigen varicella vaccine, but at a higher potency, approximately 3.99 log10 PFU, compared to about 3.13 log10 PFU in the single-antigen product, or roughly sevenfold higher. The viruses themselves are identical across products; the difference is potency.

Dr. Levi asked whether there is a biological or clinical rationale for the higher varicella antigen amount in MMRV compared with separate administration of MMR plus varicella, and why more is needed when included in the combination vaccine.

Dr. Marin explained that initial manufacturer trials using the same varicella potency as the single-antigen vaccine within MMRV produced a suboptimal immunologic response to the varicella component. Manufacturers then tested higher varicella potencies and selected the current formulation as the best balance of immunogenicity and adverse events. Evidence reviewed in 2008–2009 suggested potential interference between the measles and varicella viruses when combined in the same vaccine, resulting in a stronger measles response (with more fever and a measles-like rash) and a weaker varicella response than with a single-antigen varicella vaccine. Increasing the varicella potency in MMRV was intended to achieve an immune response comparable to that of the single-antigen varicella vaccine.

Dr. Levi asked whether there is a clearly understood biological mechanism that explains why different vaccine formulations and combinations produce different immune responses, beyond the outcomes observed.

Dr. Kulldorff shared that the manufacturer will provide more information on this topic later in the meeting.

Dr. Blackburn requested clarification on immunogenicity following the first dose of the MMR vaccine. She noted that most children develop protective antibodies after the initial dose and asked for the scientific basis for recommending a routine second dose. She wondered whether the second dose primarily addresses primary vaccine failure, waning immunity, or both, and whether antibody titers could be used to verify response after the first dose, rather than universally administering a second dose.

Dr. Oliver stated that antibody titers are one component of the protective response and are higher after two doses. She noted that the second dose, particularly for measles, helps identify and protect children who did not mount a protective response to the first dose, addressing primary vaccine failure. Two doses are recommended because this schedule has been used in many efficacy studies and provides additional overall protection.

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Dr. Blackburn requested percentages.

Dr. Oliver referenced slide 15 in the presentation, which showed seropositivity rates, percent fold rise in antibody titers, and geometric mean titers across multiple doses for ProQuad (MMRV), with MMR plus Varivax shown at the bottom of each group as the separate-vaccine comparator.

Dr. Milhoan inquired whether data are available on the serologic response after the primary first dose, noting that the presented results reflect responses after the second dose, and requested seroconversion or seropositivity data following the first dose.

Dr. Oliver shared that the data can be found on slide 13.

Dr. Meissner emphasized that while recent attention has focused on measles vaccination, rubella vaccination is equally critical. He noted that the last rubella pandemic in the U.S. occurred in 1964–1965, resulting in approximately 11,000 fetal deaths and 20,000 infants born with congenital rubella syndrome, a severe condition associated with congenital heart disease, developmental delay, and eye problems. He added that in 1969, Dr. Stanley Plotkin and colleagues at the Wistar Institute developed the rubella vaccine, which has been highly effective. In recent years, the U.S. has typically seen fewer than five cases of congenital rubella annually, primarily among women born in countries without rubella vaccination programs. He underscored the importance of ensuring every child is vaccinated against measles, mumps, rubella, and varicella.

Dr. Meissner thanked the chair and expressed appreciation for the participation of professional societies focused on infectious diseases and vaccines. He stated that the American Academy of Pediatrics' non-participation in these discussions is a mistake and expressed concern that continued absence could diminish the Academy's influence.

Febrile Seizures following Measles, Mumps, Rubella, and Varicella (MMRV) vaccine
Dr. John Su (CDC/NCEZID)

Dr. John Su (CDC/NCEZID) presented on febrile seizures following Measles, Mumps, Rubella, and Varicella (MMRV) vaccine. The ACIP chair requested that the Immunization Safety Office present an analysis of febrile seizures following the administration of MMRV compared with the simultaneous administration of separate MMR and varicella vaccines, with results stratified by two age groups: 1–2 and 4–6 years. The presentation should draw on data from randomized clinical trials and from the Vaccine Safety Datalink (VSD) project.

Dr. Su recapped that MMRV was licensed in the U.S. in 2005. Interim recommendations in 2008 removed the preferential recommendation for MMRV, and updated recommendations were issued in June 2009. Between February 2008 and June 2009, the MMRV Vaccine Safety Work Group reviewed multiple data sources, including two post-licensure studies from Merck and analyses from the Vaccine Safety Datalink (VSD). In brief, the 2009 updates stated that unless a parent or caregiver prefers MMRV, the first dose for children aged 12–47 months should be administered as separate MMR and varicella vaccines, while MMRV remains generally preferred for the second dose. Additional details can be found in the May 2010 issue of the MMWR Recommendations and Reports.

Background on the MMRV vaccine and febrile seizures was provided. Combination vaccines, like MMRV, reduce the number of injections a child receives and can improve vaccine

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compliance and coverage. MMRV is licensed for children aged 12 months–12 years. The routine schedule recommends two doses: the first at 12–15 months of age and the second at 4–6 years of age. ProQuad is the MMRV product licensed for use in the U.S.

Febrile seizures are seizures that occur in children who have a fever. By age 5 years, 2–4% of children have had at least one. They occur primarily between 6 months and 5 years of age, with a peak between 14 and 18 months of age. Although distressing, most febrile seizures are short (less than 15 minutes) and resolve without complications. They most commonly accompany fevers from routine childhood illnesses such as middle ear infections, viral upper respiratory infections, and roseola. Still, they can occur with any condition that causes fever, including those that follow vaccination. A family history of febrile seizures increases risk.

Pre-licensure studies of MMRV among children aged 12–23 months found that fever and measles-like rash were reported significantly more often during the 0–42 days after vaccination in children who received a first dose of MMRV than in those who received separate first doses of MMR and varicella at the same visit. Fever occurred in 21.5% of MMRV recipients versus 14.9% of recipients of separate MMR and varicella (risk difference 6.6%; 95% CI, 4.6%–8.5%). Considering these findings, CDC and Merck initiated post-licensure studies to evaluate whether an increased risk of febrile seizures might be associated with the first dose of MMRV.

Analyses of postvaccination intervals from a Vaccine Safety Datalink (VSD) study and a Merck-sponsored study, conducted primarily among children aged 12–23 months, used different populations and methods. Yet, both found significant associations in the first two weeks after vaccination. The VSD study, after medical record review, confirmed an increased risk of febrile seizures during days 7–10 after MMRV compared with MMR plus varicella, with an attributable risk of 4.3 per 10,000 doses and a relative risk of 2.0 (95% CI, 1.4–2.9). The Merck-sponsored study also observed an increased risk during days 5–12 after MMRV, with an attributable risk of 1.3 per 10,000 doses administered during 0–30 days postvaccination; the relative risk was 1.1 with a non-significant confidence interval.

An analysis of VSD outpatient visits for fever among children aged 12–23 months from 2000 to 2008 revealed that fever visits increased after any measles-containing vaccine during days 7–10 postvaccination, with the greatest increase following MMRV. Temporal scan statistics identified significant clustering on days 7–10 for all measles-containing vaccines ($p < 0.001$), while no temporal clustering of fever visits was observed after varicella vaccination alone.

An analysis of the number of seizures after vaccination among children aged 12–23 months (2000–2008) revealed peaks on days 7–10 following any measles-containing vaccine, with the highest counts occurring after MMRV vaccination. Temporal scan statistics indicated significant clustering on days 8–10 after MMRV (relative risk 7.6; p=0.001), days 7–10 after MMR plus varicella given at the same visit (relative risk 4.0; p=0.001), and days 7–11 after MMR alone (relative risk 3.7; p=0.001). No seizure peak or significant temporal clustering was observed after varicella vaccination alone.

A review of the biomedical literature on post-licensure febrile seizures following MMR or varicella vaccination identified one study showing a significant increase in febrile seizures during days 8–14 after MMR compared with unvaccinated children, corresponding to approximately one additional febrile seizure per 3,000–4,000 children vaccinated. No increased risk of febrile seizure was observed among children aged 12–23 months after varicella vaccination during the 0–30 days postvaccination.

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A 2015 systematic review and meta-analysis assessed the risk of febrile seizures following MMRV vaccination, including studies that used Priorix Tetra (MMRV) or ProQuad (MMRV). The analysis included both clinical trials and post-marketing observations, with some studies enrolling children as young as 9 months. Clinical trial data showed no significant differences in febrile seizure incidence between MMRV and MMR, with or without varicella, after any dose across multiple risk windows. Additionally, concomitant administration of MMRV with other pediatric vaccines was not a significant predictor of febrile seizures. In post-marketing analyses, an approximate twofold increase in risk of seizure or febrile seizure was observed during days 7–10 or 5–12 after MMRV vaccination in children aged 10–24 months.

A 2021 Cochrane review examined the use of MMRV in children, including five cohort studies, four of which evaluated first-dose vaccination only. Overall, there was a significant increase in febrile seizure risk among children receiving MMRV compared with separate MMR and varicella during the 0–42 days postvaccination and during days 7–10. In brand-stratified analyses, a cohort study of Priorix Tetra reported non-significant findings for febrile seizure risk compared with separate MMR and varicella vaccines, including in post hoc analyses. The four other cohort studies, which evaluated ProQuad, showed a significantly increased risk during the 0–42-day and 7–10-day postvaccination windows.

Dr. Su summarized that post-licensure studies assessed febrile seizures in children aged 12–23 months who received a first dose of MMRV compared with children who received a first dose of MMR and varicella at the same visit. Despite differences in methods, populations of children, and MMRV formulations, the findings were consistent across all studies. Studies identified an increased risk of febrile seizures during the 1–2 weeks after the first dose of MMRV compared with the first dose of MMR plus varicella; outside that period, risks were similar between the two options.

MMRV is licensed as a two-dose series, with the routine second dose at ages 4–6 years. The risk of febrile seizures is lower in children aged 4–6 years than in those aged 12–15 months. In Merck pre-licensure trials, fever rates were lower after a second dose of MMRV in children aged 15–31 months than after the first dose. Among children aged 4–6 years, fever rates were similar after receiving a second dose of MMRV and after receiving a second dose of MMR plus varicella, both administered at the same visit.

Merck-sponsored studies among children aged 4–6 years observed no febrile seizures in either of the comparison arms. In a VSD post-licensure study, very few seizures were identified by ICD-9 codes after measles-containing vaccines, with no significant differences during days 7–10 or 0–42 after MMRV, MMR plus varicella, or MMR alone. However, rates were numerically higher after MMRV. Electronic medical record review of the four events coded as seizures, 7–10 days after MMRV, found two afebrile seizures, one indeterminate event, and one confirmed febrile seizure. The resulting occurrence of febrile seizure 7–10 days after a second dose of MMRV was 1 per 86,750 doses (about 1.2 per 100,000), with the upper 95% confidence limit corresponding to no more than 1 per 15,570 doses (about 6.4 per 100,000). Similarly, for MMR plus varicella given the same day, the upper 95% confidence limit corresponded to no more than one febrile seizure per 18,282 doses.

The systematic review published in 2015 examined febrile seizure incidence and risk after the second MMRV dose. Pre-licensure data showed no statistically significant differences between children who received MMRV alone and those who received MMRV with one or more other pediatric vaccines at the same visit. Likewise, there were no significant differences between children who received MMRV plus other pediatric vaccines and those who received other

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pediatric vaccines without MMRV. The systematic review also summarized a post-licensure VSD study concluding that, among children aged 4–6 years, neither MMRV nor same-day separate MMR and varicella vaccination was associated with an increased risk of febrile seizures.

Dr. Su summarized that among children aged 4–6 years, the data do not suggest an increased risk of febrile seizures after a second dose of MMRV compared with a second dose of MMR plus varicella given at the same visit. In conclusion, there is a small increased risk of febrile seizures after the first dose of measles-containing vaccines (MMR and MMRV), with the risk slightly higher after MMRV. Studies have shown a small increased risk during days 5–12 after the first MMR dose; no increased risk has been observed after the varicella vaccine alone. There is no increased risk of febrile seizures after MMRV in children aged 4–6 years.

Discussion

Dr. Kulldorff asked whether vaccine coverage rates are influenced more by the reduced number of injections with combination vaccines or by concerns arising from adverse reactions that may spread through families and communities. He requested studies that quantify both effects and indicate which has the greater impact on coverage.

Dr. Srinivasan acknowledged the question, noted that subject matter experts could better address the effects of vaccine coverage, and requested the backup slide on the parent and provider survey to inform the discussion.

Dr. Oliver reported that the National Immunization Survey Child COVID module, published in 2024, asked parents to consider routine childhood vaccines (measles, polio, tetanus) and indicate overall hesitancy. Only 14% of parents of children aged 6 months–4 years expressed hesitancy toward these routine vaccines.

Dr. Kulldorff asked whether the 14% hesitancy figure referred specifically to parents whose child had experienced a febrile seizure or to the broader survey population.

Dr. Oliver clarified that the 2024 National Immunization Survey Child COVID module was a random-digit-dial survey of the general parent population, not specifically parents of children who had experienced febrile seizures.

Dr. Kulldorff asked how a febrile seizure attributed to MMRV, compared with MMR plus varicella, affects parents' willingness to continue vaccinating the child, vaccinate younger siblings, and recommend vaccination within their social circles. He asked whether such events reduce coverage and whether any studies quantify these effects relative to the coverage gains from fewer injections with combination vaccines, and which effect is larger.

Dr. Oliver referenced background slide 27 from the MMRV presentation and noted that there are no survey data specifically of parents whose children previously had febrile seizures. She explained that during the 2008–2009 Work Group discussions, a parent survey of mothers found that approximately 33% would be resistant to MMRV, about 25% were neutral, and around 40% would accept it. She emphasized that the most effective conversations about vaccination risks and side effects occur between the pediatrician and the parent, and that parents should be offered a choice between MMRV and separate MMR plus varicella. The CDC recommends that pediatricians include these risks in counseling and help families weigh the benefits and risks for the specific child and situation.

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Dr. Kulldorff acknowledged that there are no data available and that it is difficult to quantify how much vaccine hesitancy might increase because of additional febrile seizures.

Dr. Meissner noted that the discussion mirrors debate from about 15 years ago and was one of the few times the ACIP and the American Academy of Pediatrics (AAP) diverged, with the AAP not expressing a preference for the 12–15 months dose, while the ACIP allowed the use of separate MMR plus varicella. He added that a busy pediatric practice might see about one additional febrile seizure after MMRV at 12–15 months compared with separate vaccines. He asked Drs. Su and Oliver to confirm that febrile seizures after MMR alone at 12–15 months occur at roughly 1 per 3,000 doses and that MMRV increases the risk about twofold.

Dr. Su confirmed that prior studies show an additional risk of about one febrile seizure per 3,000–4,000 children after MMR and that a twofold increase in risk with MMRV compared with separate MMR plus varicella is correct.
Dr. Meissner asked to confirm that more than 95% of febrile seizures occur before age 4, with only a small percentage occurring after age four from any cause.

Dr. Su noted that febrile seizures after age five are rare.

Dr. Levi proposed that existing records could quantify downstream effects of febrile seizures on vaccine uptake, since diagnoses identify which children experienced a seizure and immunization records show subsequent vaccinations. He cautioned that the lower observed risk after the second dose might reflect selection bias if children who reacted strongly to the first dose delayed or skipped the second dose. He also questioned the field's limited mechanistic understanding, noting that a higher varicella antigen dose in MMRV may provoke a stronger immune response in some children. He asked whether children who experience febrile seizures have been evaluated for distinctive immune responses or biomarkers to clarify the underlying mechanisms, emphasizing that safety assessment should extend beyond symptoms to a biological explanation.

Dr. Pollak echoed concerns about limited mechanistic understanding and noted that very young children may have heightened IL-1–mediated fever responses. He asked whether cytokine levels were measured in febrile children and whether cytokine gene polymorphisms or other genetic predispositions were assessed. He cautioned that second-dose findings may reflect selection bias if pediatricians avoid revaccinating children with a history of febrile seizures. He recommended that guidance address how to manage vaccination schedules for children who have had prior febrile seizures.

Dr. Kulldorff agreed with the point that existing medical and immunization records could quantify whether a febrile seizure affects subsequent vaccination for the child and younger siblings. He added that he was not aware of any analysis that has examined this to date, though the data likely exist to do so.

Dr. Milhoan emphasized that febrile seizures are diagnosed retrospectively and that, for families, a 15-minute seizure feels incredibly long. He noted that in his practice, families who have experienced a febrile seizure are often hesitant to proceed with the next vaccine, and he shares their caution. He asked whether fever from natural viral illness shares the exact mechanisms as vaccine-associated fever, highlighted that rising temperature lowers the seizure threshold in all people, and questioned whether the measles vaccine further lowers that threshold. He observed increased vaccine hesitancy among families and emphasized the

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importance of clearly communicating the risks and benefits of vaccination. He also asked whether there are long-term follow-up data on children who experienced a febrile seizure after the first dose.

Dr. Su stated that the request was to present data on the risk of febrile seizures and that he would need to review data regarding longer-term outcomes.

Dr. Stein asked how risks are communicated to parents and guardians in practice, noting that some evidence predated the guidelines and additional data have been published since. She wondered how parental choice is incorporated into those discussions.

Dr. Marin explained that one-pagers were developed to support risk communication: a provider one-pager in table format outlining risks, benefits, and their implications, and a parent one-pager noting the increased risk of febrile seizures with MMRV compared to MMR plus varicella. These materials were designed to help pediatricians discuss options in clear, understandable terms.

Dr. Oliver added that usage data indicate about 85% of children receive separate MMR plus varicella at the first visit, while roughly 15% receive MMRV. She noted this distribution likely reflects discussions between pediatricians and parents about risks and benefits.

Dr. Griffin inquired whether manufacturers or other groups are conducting studies on the educational performance of children following febrile seizures.

An NCIRD SME shared that the group is not currently doing any long-term studies on the topic.

Dr. Griffin noted that, since the product has been licensed since 2005, it would be helpful to reassure parents that studies on children's educational outcomes after febrile seizures have been conducted. She also asked whether any studies were tested against a trustworthy saline placebo.

Dr. Su said a follow-up would be necessary to answer the question definitively. Most available studies compare MMRV with MMR plus varicella.

Dr. Griffin argued that comparing MMRV with separate MMR plus varicella introduces confounding and makes risk interpretation difficult. She noted the usual rationale that vaccine versus saline placebo trials are considered unethical once a vaccine is deemed safe and effective. Still, she contended that, given current levels of parental non-vaccination by informed choice, an actual placebo-controlled study could be ethical. She suggested inviting parents who have already chosen not to vaccinate their children to participate, to enable a clearer assessment of the risks.

Dr. Marin explained that a placebo study would require a randomized controlled trial. Selecting only parents who avoid vaccination would introduce confounding, as their children may differ systematically (for example, prior adverse events). Participants cannot be chosen based on willingness to forgo vaccination; they must consent to random assignment to either the vaccine or control group.

Dr. Oliver added that in a randomized controlled trial, participants must have an equal likelihood of receiving either a placebo or a vaccine, and families must consent to the randomization process. Given the currently elevated measles activity, asking parents to accept a chance of a

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placebo, and therefore no protection against measles, mumps, rubella, or varicella, would be concerning.

Dr. Griffin thanked Dr. Oliver for her response and shared that, in today's environment, many parents are asking for more studies. She suggested that the public would welcome observational studies comparing vaccinated and unvaccinated children.

Dr. Kulldorff suggested that ethical randomized trials could be conducted by varying the timing of vaccination rather than withholding it, noting that countries recommend MMR at different ages. For example, children could be randomized to receive MMR at 12 months versus 18 months, allowing randomized designs without denying vaccination.

Dr. Blackburn asked why trials were designed with MMR and varicella given on the same day, noting that simultaneous administration might produce adverse event rates similar to MMRV. She suggested that separating MMR and varicella by at least 28 days could better distinguish differences in adverse reactions. She asked whether this approach had been considered, given that typical pediatric visits occur at 12, 15, 18, and 24 months of age.

Dr. Marin explained that trials were designed to compare MMRV with the same-day administration of separate MMR plus varicella, because MMRV is intended to replace two injections with one. The primary question was whether a single injection would provide comparable immunogenicity and an acceptable adverse event profile relative to administering both vaccines at the same visit. While some studies included arms with MMR alone or varicella alone, most focused on the two practical options parents and providers face. Spacing MMR and varicella across separate visits (for example, at 12 and 15 months) would not answer the substitution question because children would still receive two injections.

Dr. Pebsworth inquired whether the MMR/MMRV Vaccine Information Statement states that a prior febrile seizure or any post-vaccination seizure constitutes a contraindication, noting that this relates to informed consent. She also referenced VSD findings that included both febrile and afebrile seizures and questioned whether the lack of statistical significance for second-dose events at ages 4–6 years might reflect selection bias. Additionally, she asked whether the assumption that febrile seizures are largely benign is clinically justified and whether a history of febrile seizures should be considered a contraindication to receiving the vaccine again.

Dr. Oliver noted that the MMRV Vaccine Information Statement advises parents to consult their health care provider if the child has a history of seizures or if a parent or sibling has a seizure history. She added that the FDA sets contraindications.

Dr. Marin added that the MMRV Vaccine Information Statement includes language under "Risks of a vaccine reaction", noting that seizures, often associated with fever, can occur after MMRV. The risk is higher with MMRV than with separate MMR and varicella when given as a first dose. The VIS advises that a health care provider can recommend the appropriate vaccines.

Dr. Meissner stated that febrile seizures occur in 3–5% of children, are familiar to pediatricians, and have an excellent prognosis. He emphasized that while the episodes are frightening for families, they are not associated with impaired neurocognitive development, school problems, or long-term performance issues. He noted that the practical question is whether to use MMRV or separate MMR plus varicella doses. Combination vaccines can improve completion rates by reducing the number of injections, whereas separating doses may reduce compliance. The argument against using MMRV at 12–15 months is a slight increase in febrile seizure risk. He

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supported the current ACIP wording, which allows parents to choose based on their preferences: those concerned about febrile seizures may select separate MMR and varicella vaccines. In contrast, those prioritizing fewer injections may choose MMRV. He added that about 85% of children currently receive separate MMR and varicella at the first visit and concluded that the existing guidance is appropriate.

Dr. Levi expressed unease about assumptions underlying current interpretations. He cautioned that febrile seizures after viral infection may differ biologically from those observed after vaccination and that measurement alone may obscure important mechanistic differences. He urged agencies to investigate mechanisms, including biomarkers, and to follow children who experience seizures over the long term. He noted that higher antigen content may be associated with more events and recommended that safety assessments extend beyond 30–40 days.

Dr. Meissner thanked Dr. Levi and responded that febrile seizures are well-defined: they occur in children, usually under 5 years (often under 4), are generalized rather than focal, last less than 15 minutes (typically a few minutes), and do not recur within 24 hours. He noted that most febrile seizures are not associated with vaccination and that the prognosis is excellent apart from the emotional impact on families. Given the limited resources and extensive pediatric experience with these events, he questioned whether investing heavily in additional studies on vaccine-associated febrile seizures would be the most effective use of effort.

Dr. Milhoan cautioned that heavy reliance on ICD codes can be problematic. As a practicing physician, he noted that selecting precise codes is often time-consuming and prohibitive, and retrospective analyses should account for this limitation. He emphasized the importance of “clean” data, suggesting a clear distinction between ICD-coded febrile seizures temporally related to vaccination and those not associated with vaccination. He urged researchers who use ICD-based datasets to acknowledge that these codes are imperfect and may not fully capture clinical reality.

Dr. Pebsworth thanked Dr. Meissner for his comments and clinical perspective; however, she noted a 2023 study on long-term neurodevelopmental outcomes of febrile seizures reporting clinical and animal evidence of potential adverse effects, including attention deficit hyperactivity disorder, increased susceptibility to epilepsy, hippocampal sclerosis, and cognitive decline in adulthood, while mechanisms remain unclear. She recommended adding this topic to a future agenda for safety review.

Rick Haupt, a Merck representative, noted that as a pediatrician, he witnessed fatal pneumococcal, Hib, and varicella infections before they became vaccine-preventable and emphasized the importance of not returning to that era. He stated that ProQuad (MMRV) has been rigorously evaluated in clinical trials and post-licensure studies, with findings shared with regulators, public health agencies, and medical societies, and published in journals. He reiterated that a slight increase in febrile seizures after the first dose was first reported in a 2009 observational study with Kaiser and has informed current recommendations: MMRV is preferred for the second dose, while separate MMR plus varicella is preferred for the first, with provider or family choice allowing MMRV; about 15% choose MMRV at the first visit. He stressed evidence and consensus that combination vaccines improve series completion and on-time vaccination. He cited recent CDC data showing kindergarten coverage below the 95% threshold needed for measles herd immunity. He cautioned that policies that reduce clarity or consistency around MMRV could further erode public confidence. Addressing antigen content, he explained that only the varicella antigen is higher in MMRV (the MMR antigens remain unchanged), which was

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necessary to demonstrate a non-inferior immune response compared with separate MMR plus varicella, likely due to local antigen interference in the combination product.

Dr. Kulldorff offered a correction, noting that the initial identification of an excess risk of febrile seizures with MMRV compared with MMR was made at CDC using the Vaccine Safety Datalink's rapid cycle analysis. He said the signal was detected after approximately 25,000 doses and highlighted the strong work of the CDC and the VSD in monitoring vaccine safety.

Dr. Hibbeln cautioned that the small risk of febrile seizures—likely without long-term consequence—must be weighed against the danger of vaccination coverage falling below 90%, which could lead to devastating outcomes such as fetal loss, neonatal death, and congenital rubella syndrome. He stressed avoiding actions that might drive nonvaccinating through fear or oversimplified "for or against" views of vaccines. He emphasized that any major change to long-standing guidance should have a powerful, clearly articulated rationale.

Proposed recommendations and discussion
Dr. Martin Kulldorff (ACIP Chair)

Dr. Martin Kulldorff, Chair of the ACIP, presented the proposed recommendations from the MMRV Vaccine Work Group.

Proposed Recommendation:

> The pediatric vaccine schedule should be updated to reflect the following change:
> -For measles, mumps, rubella and varicella vaccines given before age 4 years, the combined MMRV vaccine is not recommended.
> -Children in this age group should receive separate measles, mumps, and rubella vaccine and varicella vaccine (MMR+V).

Discussion

Dr. Stein asked how the proposed recommendation differs from current guidance, noting that the 2009 recommendation appears to call for two separate shots for the first dose.

Dr. Kulldorff outlined two differences. First, the proposal states that both options are acceptable, with a preference for MMR plus varicella for doses administered between 12 and 47 months of age. Second, for children who receive a "second" dose before age 4 (for example, after an early outbreak dose at 7 months followed by a dose at 12–15 months), that dose would be treated as a pre-4-year dose so that the preference would be separate MMR plus varicella rather than MMRV.

Dr. Levi stated that if adherence were guaranteed to be the same, separate MMR plus varicella doses would be preferable, given the added adverse events with MMRV and the lower antigen exposure with separate vaccines. He questioned whether separating the first-dose vaccines meaningfully reduces adherence, suggesting that safer profiles likely increase trust and adherence. In the absence of strong evidence either way, he favored the option that appears safer.

Dr. Pebsworth sought confirmation that at the first visit (12–15 months), approximately 85% of vaccinations are administered as separate MMR plus varicella and about 15% as MMRV.

Dr. Kulldorff confirmed that at the first visit (12–15 months), about 85% of vaccinations are administered as separate MMR plus varicella, and roughly 15% as MMRV. He commended

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pediatricians and nurses for prioritizing the option associated with fewer febrile seizures and shared a brief personal example illustrating providers' awareness of the rationale.

Dr. Meissner shared two points. First, an MMR dose given before 12 months is intended for infants traveling to measles-endemic areas and does not count toward the routine two-dose series; those children still need doses at 12–15 months and 4–6 years. He also clarified that MMRV is licensed only for ages 12 months through 12 years. Second, he cautioned against removing parental choice for the first dose, noting that while about 85% currently receive separate MMR and varicella, some parents prefer a single visit with MMRV, and that option should remain available.

Dr. Goldman inquired whether a fully vetted Evidence to Recommendations (EtR) presentation would be provided, addressing harms, benefits, acceptability, and feasibility, with input from practicing clinicians and liaisons. He argued the proposed recommendation could confuse the public, does not reflect real-world clinician experience with vaccine hesitancy, and might enable insurers and the Vaccines for Children program to decline coverage. He added that the change would remove parental choice for informed decision-making with their physicians. He urged the committee not to change recommendations and, if proceeding, to use the established EtR process with transparent data to support debate and discussion.

Dr. Hopkins agreed with Dr. Goldman.

Dr. Middleman endorsed Dr. Goldman's comments and emphasized the need to present all available evidence in a single, coherent, and scientifically vetted format, so that providers and patients can understand the full scope of information. She emphasized the importance of focusing on what the evidence reveals rather than beliefs unsupported by evidence.

Dr. Kulldorff thanked Dr. Srinivasan and Dr. Su for their excellent and informative presentations.

Dr. Levi requested clarification on what information had not been discussed or considered, noting that prior comments had implied missing data. He asked whether anyone is disputing the evidence of increased febrile seizures after MMRV, and what additional data they believe should be reviewed.

Dr. Goldman argued that the discussion was not thoroughly vetted and relied too narrowly on selected data points without incorporating real-world clinical experience. He noted that liaison members have been removed from work groups, reducing subject matter expertise and the patient voice. He emphasized that a complete assessment should address implementation, acceptability, feasibility, equity, and the balance of harms and benefits, and urged inclusion of physicians' practical experience with patients.

Dr. Middleman echoed Dr. Goldman's comments and requested that all available evidence be presented together, encompassing the full extent of scientific literature rather than only the few studies discussed.

Dr. Levi responded that he trusts the CDC staff to have presented all relevant data and noted that several colleagues are pediatricians with experience in patient care. He invited anyone who believes information is missing to specify it so the committee can consider it.

Dr. Hopkins appreciated the CDC data, describing it as thorough and informative, but noted that equity considerations and the practical implications for patients and practicing physicians had not been adequately addressed. He stated that without a full Evidence to Recommendations (EtR) review of these elements, the committee lacks a complete basis for decision-making.

Dr. Goldman agreed with Dr. Hopkins.

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Dr. Jshlay emphasized practical considerations at the 12-month visit, noting that children may receive multiple vaccines and some parents prefer fewer injections. She estimated that up to 7 vaccines can be given at a single visit and underscored the need for informed consent and alignment with parental preferences when scheduling and selecting vaccines.

Dr. Stein noted that the Vaccine Information Statement indicates an increased risk of fever and seizures after the combined MMRV shot compared with separate MMR and varicella shots. She asked how this risk is communicated to parents in practice and whether clinic time pressures, such as busy patient flow, ever limit the ability to provide clear informed consent. She invited input from medical professionals on how these discussions are handled.

Dr. Milhoan suggested asking parents directly about the adequacy of risk and benefit discussions rather than relying solely on clinicians' perspectives. He noted that in busy practices, informed consent is often incomplete across various medicines and vaccines, with rare but serious risks not always being thoroughly reviewed. He said that many parents felt they were given little information and concluded that current practices may not fully meet the standard for informed consent.

VFC Resolution Update: MMRV Vaccine
Jeanne Santoli (CDC/NCIRD)

Jeanne Santoli (CDC/NCIRD) presented the VFC resolution update with all revisions from the previously approved resolution shown in red. The purpose of the update is to provide revised guidance on the use of the combined measles, mumps, rubella, and varicella (MMRV) vaccine. The resolution includes three components: MMR, varicella, and the combined MMRV. No changes were made to the MMR or varicella components; eligibility, recommended schedules, dosage intervals, contraindications, and precautions remain the same. The changes apply only to the combined MMRV component and clarify eligible groups, recommended schedule, dosage, and contraindications to align with the proposed recommendations under discussion today by the ACIP.

Discussion

Dr. Kulldorff noted that, as is standard procedure, two votes will be conducted. The first will address the recommendation, followed by a separate vote on the VFC resolution. He added that this approach is consistent with the process used during the June meeting.

Dr. Griffin echoed comments from Dr. Milhoan, noting from her personal experience as a mother that vaccine information statements were not always consistently explained when her children received immunizations, with the expectation that parents would read the handout independently. She added that many of her patients and non-physician acquaintances had reported similar experiences, although she acknowledged that this was anecdotal. Dr. Griffin emphasized the value of having additional data for committee review and clarified her earlier comments regarding randomized controlled trials, acknowledging the ethical limitations of such studies. She concluded by stressing the importance of considering a broader range of studies and raw data, as well as individual experiences that collectively inform the balance of vaccine benefits and risks.

Dr. Jshlay shared that at the Public Health Institute of Denver Health, her large-scale immunization program provides the VFC and VIS forms before vaccination and reviews them with patients to ensure informed decision-making. She emphasized that providing the VIS before vaccination is a requirement and noted that local public health agencies across the country follow this same practice. She added that, although she could not comment on anecdotal reports, her clinic strives to uphold this standard.

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Dr. Middleman emphasized the importance of grounding public health recommendations in a comprehensive body of data rather than anecdotal evidence. She noted that while physicians focus on individual patients, public health decisions must consider the health of the entire population. She highlighted the breadth of studies that inform the evidence-to-recommendation process and stressed the need to evaluate all elements of public health, including disease impact, risks and benefits, feasibility, acceptability, cost-benefit ratio, and equity. Dr. Middleman questioned the urgency of deciding at this meeting and urged the committee to follow a methodical evidence-to-recommendation process to ensure scientific rigor and maintain public confidence.

Dr. Kulldorff apologized for sharing an anecdote about his twins' vaccinations but noted that the committee had engaged in a strong, science-based discussion. He commended the CDC colleagues for their presentations and highlighted the quality of the debate on various aspects of the vaccines.

Dr. Pebsworth acknowledged that at the 12–14-month visit, many vaccines are administered and noted that approximately 85% of pediatricians and parents currently choose MMR plus varicella separately. She then raised a technical question regarding the language of the posted vote, which states "recommends." She sought clarification on whether this language would prohibit the use of the FDA-licensed MMRV vaccine for certain patients, emphasizing the importance of preserving provider discretion to administer licensed products.

Dr. Kulldorff clarified that the committee's role is to make recommendations, while the FDA determines which vaccines can or cannot be used. He noted that committee votes may have consequences for insurance coverage, including through CMS, but emphasized that the authority to approve vaccine use rests with the FDA.

Dr. Srinivasan suggested that it would be helpful for a VFC representative to comment on how ACIP recommendations affect the Vaccines for Children program, given that the program funds many pediatric vaccines.

Dr. Santoli explained that if a vaccine is designated as "not recommended," it will not be covered under the VFC program for children. She noted that while there are ways to address individual-based decisions that allow for coverage, the current resolution under consideration would mean that VFC would not cover the vaccine even if a parent and physician chose it.

Dr. Johnson added that a "not recommended" designation could also affect coverage under Medicaid and the Children's Health Insurance Program, as well as individual and group insurance markets. She noted that this could impact overall coverage and potentially result in out-of-pocket costs, such as co-pays.

Dr. Kulldorff clarified that the coverage discussion pertains specifically to the MMRV vaccine. He emphasized that coverage for the MMR and varicella vaccines will remain unchanged, with both continuing to be fully covered.

Dr. Johnson confirmed.

Dr. Hibbeln requested clarification that under the proposed change, administration of the MMRV vaccine before four years of age would be considered "not recommended," and therefore would not be covered for payment.

Dr. Santoli clarified that, under the Vaccines for Children program, the MMRV vaccine would not be covered for children under the age of four.

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Dr. Hibbeln expressed concern that under the proposed change, parents would lose the option to choose the MMRV vaccine for their child unless they were willing to pay out of pocket. He noted that if parents preferred a single vaccination rather than multiple shots, this option would effectively be taken away despite their understanding of the risks and benefits.

Dr. Santoli confirmed that VFC would not cover the vaccine for those children.

Vote: MMRV Vaccines Vote
Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for MMRV vaccines into the record:

> The pediatric vaccine schedule should be updated to reflect the following change:
> -For measles, mumps, rubella and varicella vaccines given before age 4 years, the combined MMRV vaccine is not recommended.
> -Children in this age group should receive separate measles, mumps, and rubella vaccine and varicella vaccine (MMR+V).

Motion/Vote: MMRV Vaccines

Dr. Levi motioned to approve the recommended voting language, stating,
"The pediatric vaccine schedule should be updated to reflect the following change:
-For measles, mumps, rubella and varicella vaccines given before age 4 years, the combined MMRV vaccine is not recommended.
-Children in this age group should receive separate measles, mumps, and rubella vaccine and varicella vaccine (MMR+V)."
Dr. Pagano seconded the motion. No COIs were declared. The motion carried with 8 votes in favor, 3 votes opposed, and 1 abstention. The disposition of the vote was as follows:

8 Favored: Pagano, Milhoan, Stein, Griffin, Pollak, Pebsworth, Levi, Kulldorff
3 Opposed: Blackburn, Hibbeln, Meissner
1 Abstained: Malone

Discussion

Dr. Santoli requested clarification on the wording used during the vote discussion, noting that she had heard the term "compensate" and wanted to ensure it was understood correctly. She explained that a yes vote would align the VFC resolution with the recommendation vote that had already passed, meaning the combination vaccine would not be covered in VFC for children under four years of age. A 'no' vote would maintain the current VFC coverage as it stands today, which includes the combination vaccine for children aged 12 months through 12 years. She acknowledged that timing issues had prevented the full written materials from being available before the meeting, as the resolution had to be made late the previous evening to align with the committee's proposed language.

A CMS representative confirmed that the same coverage decision would apply to Medicaid, CHIP, and the individual and small group markets, clarifying that the combined vaccine for children under four years would not be covered if the resolution were to pass.

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Dr. Meissner expressed confusion, asking what would happen if the committee voted no, and emphasized the need for clarity.

Dr. Santoli reiterated that a no vote would maintain VFC coverage unchanged, meaning the combination vaccine would remain covered; however, CMS and VFC could ultimately have different coverage policies, potentially creating confusion.

Dr. Malone commented that it was difficult for the committee to vote without a written text of the resolution, even though the presentation was clear, and suggested that complete written information be provided in the future.

Dr. Pagano sought clarification on whether a recommendation automatically leads to reimbursement.

Dr. Levi stated that his understanding was that there are two parallel decisions: the recommendation and the resolution. If no new approval is granted, the previous decision remains in effect.

Dr. Pagano noted that this process seemed convoluted, as the committee was being asked to vote no to maintain coverage.

Dr. Milhoan requested clarification on the relationship between the VFC and CMS programs. Dr. Santoli explained that VFC covers Medicaid, uninsured children, American Indian and Alaska Native children, and underinsured children served in federally qualified health centers, while CHIP is administered separately under CMS.

A CMS representative confirmed that CHIP and the individual markets are not directly affected by this vote but rather by the broader ACIP recommendation.

While there was a VFC vote on the initial day of the meeting, with the results of 1 in favor, 8 opposed, and 3 abstained, the committee decided to reconsider the vote due to not fully understanding the implications. Dialogue to follow:

Dr. Kulldorff noted that most members were still new to ACIP and might not yet grasp specific technical issues. He explained that after the meeting, a member had raised concerns about the second vote taken on the VFC resolution regarding the MMRV vaccine and whether the committee had fully understood the implications. He stated that VFC votes are typically aligned to ensure equal coverage and access for all children, and that some consideration had been given to resolving the conflicting votes.

Dr. Pebsworth moved to reconsider the VFC resolution on MMRV that had been voted on the previous day.

Dr. Griffin seconded the motion.

Dr. Kulldorff explained that the committee would first vote on whether to reconsider the matter. If that vote passed, the resolution itself would then be voted on a second time. He asked members to state their names, declare any conflicts of interest, and indicate their votes. Results to follow:

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Vote: To Reconsider the original MMRV Vaccines- VFC Vote

Motion/Vote: MMRV Vaccines

Dr. Pebsworth motioned to reconsider the VFC resolution vote voted on September 18, 2025. Dr. Griffin seconded the motion. No COIs were declared. The motion carried with 10 votes in favor, 0 votes opposed, and 2 abstentions. The disposition of the vote was as follows:

10 Favored: Levi, Pebsworth, Hibbeln, Pollak, Griffin, Stein, Blackburn, Milhoan, Pagano, Kulldorff
0 Opposed:
2 Abstained: Malone, Meissner

Discussion

Dr. Goldman, representing the American College of Physicians, expressed concern about the vote taken the previous day because the committee had two conflicting votes on the same resolution, with the second primarily affecting children from lower socioeconomic backgrounds. He questioned whether the outcome of the first vote implied that children from lower socioeconomic groups should only receive what the committee had described as a harmful vaccine, or whether the second vote revealed that there was no evidence of harm from MMRV and that the risk was not a concern. He argued that the second vote should be considered valid for the entire population, as it indicated that there was insufficient data to support claims of harm.

Dr. Levi stated that the chair had already explained there was an error in the interpretation of the votes and suggested that the committee focus its time on scientific debate rather than pursuing discussion without merit.

Dr. Hibbeln stated that the committee had acknowledged the wording of the second vote was confusing and imprecise. He remarked that, considering the extensive work by CDC and the committee, the confusion was mainly due to wording and expressed appreciation for the more precise phrasing now provided.

Dr. Kulldorff emphasized that the vote's outcome ensures every child, including those in the Vaccines for Children program, will have access to vaccination against measles, mumps, rubella (also known as German measles), and varicella (chickenpox). He stated that this guarantees all children will be able to receive protection against these four critical diseases.

Vote: MMRV Vaccines- VFC Vote

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for MMRV vaccines into the record:

Approve the updated Vaccines for Children (VFC) resolution for prevention of measles, mumps, rubella and varicella.

Motion/Vote: MMRV Vaccines

Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

Dr. Levi motioned to approve the recommended voting language to approve the updated Vaccines for Children (VFC) resolution for prevention of measles, mumps, rubella and varicella. Dr. Pebsworth seconded the motion. No COIs were declared. The motion carried with 9 votes in favor, 0 votes opposed, and 3 abstentions. The disposition of the vote was as follows:

9 Favored: Levi, Pebsworth, Hibbeln, Pollak, Griffin, Stein, Milhoan, Pagano, Kulldorff

0 Opposed:

3 Abstained: Blackburn, Malone, Meissner

HEPATITIS B VACCINES

Introduction
Dr. Martin Kulldorff (ACIP Chair)

ACIP Chair Dr. Martin Kulldorff opened the session by introducing the Hepatitis B Vaccine. He explained that the focus of the discussion today was very specific: to evaluate only the birth dose of the hepatitis B vaccine given within 24 hours of birth, and only for infants whose mothers have tested negative for hepatitis B. He clarified that no changes are being considered for infants born to mothers who test positive or whose status is unknown.

Hepatitis B Birth Dose Vaccination
Dr. Adam Langer (CDC/NCHHSTP)

Dr. Adam Langer (CDC/NCHHSTP) presented on Hepatitis B birth dose vaccination. Hepatitis B virus (HBV) infection causes hepatitis B, which affected an estimated 254 million people worldwide in 2022. While some infections clear naturally, many progress to chronic hepatitis B, an incurable condition that can lead to severe liver disease, liver cancer, and death.

HBV can be transmitted from mother to child (perinatal transmission) as well as through household or community exposure. [hepatitis B is easily transmitted through relatively casual contact; sexual contact or sharing of needles is not required to transmit the virus to others.] Without intervention, up to 85% of infants born to HBV-infected mothers will become infected. Risk of developing chronic infection is highest in children: about 90% of infants perinatally infected develop chronic hepatitis B, and roughly 25% infected in childhood die prematurely from related complications. [Likelihood of chronic infection increases inversely with age, so the youngest children (i.e., newborns and infants) are at greatest risk.]

In the U.S., an estimated 2.4 million people are living with hepatitis B, about half unaware of their infection. Roughly 70% of those with chronic hepatitis B were born in countries with intermediate to high prevalence, often infected at birth or early childhood. [Chronic hepatitis B is incurable and can ultimately be fatal, so immunization against hepatitis B is lifesaving, and the earlier in life the vaccination series is started, the more lives that will be saved and severe chronic illness that will be prevented.]

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Vaccination programs have reduced hepatitis B among U.S. children, but most reported cases now occur among unvaccinated adults. In 2023, about 14,400 acute cases were estimated, with the highest rates in adults aged 40–59 years.

Chronic hepatitis B carries significant healthcare costs. Analysis of claims data from 2004 to 2015 showed annual per-patient costs (adjusted to 2015 dollars) ranging from approximately $94,000 for less severe disease to roughly $325,000 for those requiring a liver transplant. Overall, more than $1 billion is spent annually on hepatitis B-related hospitalizations in the U.S.

Two products prevent perinatal hepatitis B virus (HBV) infection: the hepatitis B vaccine, which provides long-term protection and is used for both pre- and post-exposure prophylaxis, and hepatitis B immune globulin (HBIG), which offers temporary protection in specific post-exposure settings.

When used together, vaccination and HBIG prevent about 94% of mother-to-child transmissions. The hepatitis B vaccine is the cornerstone of prevention, with effectiveness increasing the sooner the birth dose is given after delivery.

The hepatitis B vaccine, available in the U.S. for more than 40 years, was the first vaccine to prevent infection with a cancer-causing virus. Two single-antigen recombinant vaccines are FDA-approved for use from birth: Recombivax HB (1986) and Engerix-B (1989). [These vaccines were tested using placebo-controlled randomized trials prior to licensure in the United States, so there is no need to do additional placebo-controlled studies now.] Extensive research and reviews by the Institute of Medicine and WHO confirm the vaccine's safety and effectiveness. [The vaccine has been routinely given to all newborns in the United States since 1991, and very few serious adverse effects of the vaccine have been identified over the 34 years that this vaccine has been in routine use. The worst reported adverse effect, anaphylaxis, is literally a one in a million occurrence, and this extremely rare reaction can be addressed with immediate treatment and causes no long-term injury to the vaccinated person.]

Full hepatitis B protection requires a multi-dose series, typically three doses. Protective antibody responses are seen in 25% of infants after the first dose, 63% after the second dose, and 98% after the full three-dose series. Immunity can last for decades; one Alaska-based study showed that more than 90% of individuals retained protection over 30 years after vaccination. [The sooner the vaccination series is started, the sooner that the child is protected.]

Since 1988, universal screening for hepatitis B surface antigen (HBsAg) has been recommended for pregnant women, with additional testing for at-risk women later in pregnancy or at delivery. Vaccination at birth has been recommended since 1984 for infants of women testing positive, with the timing specified as within 12 hours of birth starting in 1988. HBIG administration has also been recommended within 12 hours for infants of HBsAg-positive women since 1984, and since 2018 for infants under 2,000 grams born to women with unknown results.

In 1991, the U.S. adopted universal infant hepatitis B vaccination. Guidance on the timing of the birth dose has evolved from "before hospital discharge but no later than 2 months" (1991), to "administered in the birth hospital" (2005), to "within 24 hours of birth" (2018).

The universal hepatitis B birth dose provides a critical safety net for infants who may have unrecognized HBV exposure during pregnancy or early childhood, which can lead to severe outcomes. Gaps in post-exposure prophylaxis occur due to lack of prenatal care, missed

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screening, or administrative errors. One reported case involved a mother with a positive test result that was miscommunicated, resulting in her infant not receiving prophylaxis and later dying from fulminant hepatitis. Between 1999 and 2002, more than 500 similar transmission events were documented when prophylaxis was not administered.

In the U.S., 12–16% of pregnant women receive inadequate or no prenatal care, and a similar percentage are never tested for hepatitis B. The national perinatal hepatitis B prevention program identifies less than half of infants born to HBsAg-positive mothers annually, underscoring the importance of universal birth dose vaccination.

The birth dose also protects against household or community transmission. HBV can survive for over seven days on surfaces, and even microscopic amounts of blood or body fluid are sufficient to transmit the infection. Unvaccinated infants are at risk if they live with or are cared for by individuals with chronic HBV, many of whom are unaware of their infection. Studies before widespread use of the birth dose showed 7–11% of U.S.-born children of immigrant mothers with no HBV evidence tested positive, pointing to community exposure. [Even for infants born to mothers known to be HBsAg-negative, the birth dose and subsequent doses provide crucial protection against household and community (e.g., daycare) exposures that could occur as soon as the infant leaves the hospital.]

Initiating the hepatitis B series on the first day of life offers early protection and benefits infants of both positive and negative mothers. It poses no increased risk of adverse events compared to later vaccination.

Over three decades of data-driven, evidence-based hepatitis B vaccination recommendations for newborns and infants have led to significant reductions in U.S. acute hepatitis B cases. Following the 1991 recommendation for universal infant vaccination (within 12 hours for infants of mothers with unknown status), the number of reported acute cases fell by 69%, from 18,003 in 1991 to 5,494 in 2005. Following the 2005 guidance to administer the first dose before hospital discharge, later updated in 2018 to within 24 hours of life, cases dropped an additional 60% to 2,214 in 2023. However, after adjusting for underreporting, the estimated actual number of 2023 cases was 14,400.

Rescinding the universal birth dose recommendation poses risks, including more perinatal HBV transmission, increased lifetime risk of severe liver disease, added administrative complexity, gaps in care, reduced vaccine series completion, and higher lifetime healthcare costs. Harms would fall disproportionately on uninsured or low-engagement patients. The only potential benefit is a reduction in already rare adverse events; serious events, such as anaphylaxis, occur at a rate of 1.1 per 1 million doses.

CDC was asked to address four specific questions related to the hepatitis B birth dose. The first two questions, reviewed in this session, concern hepatitis B vaccination recommendations in developed countries: specifically, the recommended age of the first dose for infants born to test-positive mothers and for all other infants, and the prevalence of hepatitis B infection among pregnant women. The remaining two questions will be addressed later by colleagues from the Immunization Safety Office.

Countries differ in their approaches to the birth dose. Some recommend a universal birth dose for all infants regardless of maternal status, others recommend it only for infants of HBV-positive mothers, some provide a universal birth dose in limited regions, and some have no recommendation at all. Currently, 43 countries do not have a birth dose policy; however, with

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Gavi support beginning in 2024, many of these countries are either introducing the birth dose or have expressed plans to do so within the next three to five years.

Among the 38 countries reviewed by ACIP, 36, including the U.S., recommend a birth dose within 24 hours along with HBIG for infants born to HBV-positive mothers. The only exceptions are Ireland and Denmark, though both generally provide the vaccine within 24 hours. For infants born to test-negative mothers, eight countries provide a universal birth dose within 24 hours. Of the 38 countries, 26% limit the birth dose to infants of HBV-positive mothers but still recommend routine infant vaccination later. Canada's policies differ by province. Only four countries, Denmark, Finland, Iceland, and New Zealand, limit the birth dose to infants of HBV-positive mothers and do not offer universal infant vaccination.

The most recent prevalence data from 2023 or the past 10 years for hepatitis B among pregnant women were available in 20 of the 38 countries. Nine reported prevalence below 0.5% and all used selective birth dose policies. Eight countries reported prevalence between 0.5% and 0.9%, while three reported prevalence greater than 2%. No U.S. prevalence data have been available in the past 10 years. Only six of the 38 countries maintain national registries to track HBV prevalence in pregnant women, while the other 32, including the U.S., do not collect this data regularly.

Screening data were available in 19 of the 37 comparator countries. Several countries met the 2030 global target of screening 90% or more of pregnant women. In the U.S., an estimated 14% of pregnant women are not screened, placing the U.S. below the target. The U.S. is one of five countries not meeting the goal and one of only three without universal healthcare coverage. Unlike the U.S., most countries provide universal health coverage, ensuring access to prenatal care and vaccination, which supports higher screening rates and timely prophylaxis. This difference highlights the importance of the universal birth dose in the U.S. as a safety net for infants born to mothers with unknown HBV status. Notably, no country has reverted from universal to selective birth dose, and several are moving toward universal adoption.
The second question requested a systematic review of randomized trials on administering the hepatitis B vaccine within 24 hours of birth. The updated review screened 1,390 studies in addition to 833 from the existing review. Seventeen studies met the inclusion criteria, including seven from the earlier review and 10 from the update.

The risk of bias assessment revealed a high overall risk, primarily due to unclear methods of randomization and limited reporting on whether investigators were blinded to the outcomes, which could impact the results. The 17 studies were grouped by intervention type, including efficacy, timing of vaccination, product or formulation differences, dose and schedule, and HBIG co-intervention. Outcomes of interest included protection, efficacy, and safety.

Efficacy trials demonstrated high levels of protection among infants born to HBV-positive mothers. Birth dose vaccination alone reduced transmission by up to 94% and combining the vaccine with HBIG reduced transmission by up to 99%. Adverse events were few and generally mild, such as low-grade fever.

A timing study among infants of HBV-negative mothers compared vaccination at birth, 2 months, or 6 months, with a control group starting at 18 months. All timing groups showed high levels of protection (91%) with no significant safety differences.

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Several product and formulation trials comparing different hepatitis B vaccines found them to be non-inferior. Across studies, high levels of seroprotection and equivalent efficacy in preventing perinatal transmission were observed, with few reported adverse events.

Dose and schedule trials showed strong seroprotection in both HBV-positive and HBV-negative infants. One study reported 96% seroprotection in the intervention arm compared to 0% seroprotection in the comparator arm with no birth dose. Efficacy was consistently high across groups, and safety profiles were similar, with very few local or systemic adverse events.

The updated systematic review did not identify any new placebo-controlled trials assessing efficacy, which is unsurprising since the vaccine's efficacy was established in the 1980s, and withholding it would be considered unethical. There was limited reporting for pre-term, low birthweight, and extremely low birthweight infants, and no morbidity or mortality outcomes were reported. The studies were heterogeneous, and many were conducted before the CONSORT statement was widely adopted, resulting in weaker reporting standards. The risk of bias was primarily associated with randomization and outcome measurement; however, even studies with a high risk of bias can provide helpful information if the findings are consistent and the effects are significant.

Dr. Langer concluded that the body of evidence from both the existing and updated systematic reviews supports the birth dose as safe, effective, and capable of inducing strong seroprotection in infants born to mothers who are both test-positive and test-negative. CDC interprets these findings as continued support for the ACIP's universal birth dose recommendation, first made in 1991 and later strengthened in 2005 and 2018 as part of the national strategy for hepatitis B elimination.

Discussion

Dr. Griffin asked how many of the 17 studies included in the review had declared a conflict of interest.

Dr. Nyendak, an SME who oversaw the rapid systematic review, stated that, to her knowledge, there were no reported conflicts of interest but noted they would confirm and provide that information later.

Dr. Griffin noted that the ACIP group does not have open access to journals, and purchasing individual studies can cost $45 to $60 each, which becomes a significant barrier when reviewing hundreds of studies. In reviewing the 17 studies included in the systematic review, she found that eight declared conflicts of interest. Among the studies focused on adverse events, five of the eight had declared conflicts, while three others had unclear declarations. Several involved pharmaceutical funding, where companies both funded the study and provided the vaccine. She expressed concern about this issue and then referenced CDC data, stating that there were 912 hepatitis B-related deaths in 1991, the year the vaccine was approved, compared to 1,740 deaths in 2021. She asserted that percentage rates indicate an increasing death rate despite the adoption of the vaccine and asked what accounts for this change.

Dr. Nyendak clarified that after conferring with the systematic review team in real time, the team was aware of three studies that reported conflicts of interest and provided this as a correction to the record.

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Dr. Wester from the Division of Viral Hepatitis stated that the team would investigate the question further regarding hepatitis B death rates. She noted that, for surveillance purposes, reportable death rates come through the National Vital Statistics System and that reporting practices have evolved significantly over the decades referenced.

Dr. Levi reviewed the data by age group and noted that vaccination of infants born to HBV-positive mothers clearly reduced cases in children aged 0–19. However, he observed that after the 2005 recommendation for universal birth dose, further reductions mainly appeared in older age groups rather than in young children. He questioned whether the data demonstrate an added benefit of universal vaccination at birth for infants of test-negative mothers living in typical environments. Dr. Levi emphasized that the vaccine is critical for infants born to HBV-positive mothers and other high-risk populations but expressed uncertainty about the evidence supporting universal administration to all newborns.

Dr. Langer responded to Dr. Levi, identifying two questions: why declines are more visible in older age groups than in younger ones, and whether there are data on community and household exposures. He explained that the observed declines in older groups reflect a birth cohort effect, where individuals vaccinated as infants in the early 1990s have since aged into older cohorts. As time passes, those who benefited from early vaccination policies move into older age categories, which explains the shifts seen in the data.

Dr. Levi observed that since universal birth dose vaccination began prior to hospital discharge in 2005, infants born after that year would not yet have aged into the older cohorts where declines are being measured. He suggested that any measurable impact of the universal policy may not be evident until these cohorts are older. He noted that current data may not yet show a meaningful effect.
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Dr. Stein asked about the incidence of hepatitis B in children born to mothers confirmed as hepatitis B negative, noting this would help understand the risk. She also pointed out that only two of the reviewed clinical trials specifically stratified children born to negative mothers, and both were rated as high risk of bias. She asked how reliable the data are on hepatitis B incidence in this group.

An SME referred to slide 30, noting that in dose and schedule trials involving infants of hepatitis B surface antigen–negative mothers, efficacy was equivalent between intervention and comparator groups. The randomized efficacy literature has focused more on infants of surface antigen–positive mothers, where outcomes such as seroprotection, efficacy, and safety are more measurable and show larger effect sizes. Infections among infants of negative mothers typically result from missed or late maternal infection or early horizontal exposure from a household member or caregiver. This underscores the rationale for a universal birth dose as a safety net. Data have shown a 7–11% prevalence of infection among U.S.-born children of immigrant mothers with no evidence of maternal infection, reflecting community or household transmission as the only plausible explanation. The universal birth dose policy was adopted after risk-based strategies failed to prevent perinatal and early childhood transmission, with only 26% of acute hepatitis B cases linked to a reported risk factor, [and the universal birth dose policy has been demonstrated to be highly successful in reducing incidence of new hepatitis B infections in the United States.]

Dr. Kulldorff commented that although U.S. data on hepatitis B prevalence among pregnant women were not available, estimates based on women aged 20–40 suggest a prevalence of about 4–5% overall, with less than 0.1% among U.S.-born women. He noted that roughly 80%

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of infections are among immigrants and 20% among U.S.-born women, emphasizing that U.S. rates are very low compared to Western European countries, where only Portugal has a universal birth dose policy. He also reviewed adverse event data, noting five localized and ten systemic events among 178 vaccinated infants compared to three localized and four systemic events among unvaccinated infants. Although overlap between localized and systemic events was unclear, combining them produced a borderline statistically significant result ($p = 0.054$) with a relative risk slightly above two. Although the sample size was small, the data suggest somewhat higher adverse events for infants vaccinated at birth, which should be considered in deliberations.

Dr. Levi inquired about the duration of the clinical trials for safety monitoring and the surveillance time window for these results.

Dr. Kulldorff responded that he believed it was short-term.

Dr. Levi then asked whether the short-term safety monitoring period in the trials was only a few days, such as up to five, and clarified that if so, the data may suggest higher adverse events in the first days after vaccination but provide no information beyond that period.

An SME directed participants to slides 44 and 45, which show sample sizes and follow-up periods in months. Most safety data were collected after the first dose, with monitoring beginning at 24 hours. The follow-up periods were shown for study and ranged from five to 24 months.

Dr. Levi asked whether data from the longer follow-up periods could be used to compare adverse events overall.

SME responded that the studies reported safety outcomes for as long as each study continued.

Dr. Milhoan asked what specific signals were being tracked during follow-up, noting that if the period extended to 24 months, it would be important to know whether the criteria included hospitalizations, fevers, hepatitis, or other potential adverse reactions, especially since children would have received additional vaccines during that time.

SME explained that slide 41 of the extra slides shows the time points used in the studies. Seroprotection was reported at the first time point after the last dose in the series. Efficacy was measured at the latest available time point with the ongoing intervention, and safety was assessed at birth at the closest time point immediately after the birth dose, as requested.

Dr. Milhoan asked if it was for seroprotection rather than side effects.

SME clarified that it referred to the follow-up period.

Dr. Levi requested clarification on whether there were any follow-up reports of side effects beyond the first few days after birth.

SME responded that follow-up varied across studies and said they would provide clarification later.

Dr. Wester responded to questions about the prevalence of hepatitis B infection in the U.S. She explained that there is no disease surveillance registry to answer this directly, but NHANES data

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from 2013–2018 estimated national prevalence at 0.3%. She noted this may underrepresent populations with the highest burden. Stratification revealed a similar prevalence among males and females, as well as among reproductive-age adults (25–49 years). By country of birth, prevalence was 0.1% for U.S.-born individuals and 1.2% for non-U.S.-born individuals. A modeling study estimated that in 2015, approximately 0.5% of U.S. births were to women who were HBsAg-positive, with 40% of these women being U.S.-born and 60% non-U.S.-born. She also noted that evolving recommendations over the past three decades have had a generational impact. Finally, she clarified that the 1991 infant vaccination recommendation was intended for administration before hospital discharge. However, it allowed vaccination up to two months of age, with a preference for vaccination before discharge.

Dr. Malone asked if there were data on the number needed to treat to prevent a case of hepatitis B in a child born to an HBsAg-negative mother in the U.S. population.

Dr. Wester replied that such data are not available. She noted, however, that if delaying the first dose for infants of test-negative mothers were considered, it would be important to have modeling data to estimate potential harms from unrecognized exposures during pregnancy or early childhood.

Dr. Malone added that to assess the risk-benefit reasonably, more granular data on the number needed to treat for infants of mothers with negative test results are required, as well as a clear risk analysis of potential adverse events and their incidence rates for the vaccines.

Dr. Wester clarified that there is no data on new cases associated with delaying the birth dose recommendation to one month of age.

Dr. Kulldorff asked whether the FDA has any information on this and suggested it may be fair to say no.

Dr. Hoeg noted that the original clinical trial data from the 1980s, which appear on the product label, only included short-term follow-up of four to five days. She stated that this makes it difficult to directly compare the safety risks of giving the vaccine at birth versus later in early childhood. She asked how many of the studies presented by the CDC applied specifically to neonates and echoed earlier questions about follow-up and long-term safety data. She emphasized the need for more robust long-term data, particularly for infants of hepatitis B-negative mothers, where the risk of infection is low, to weigh risks and benefits thoroughly.

Dr. Griffin addressed Dr. Stein's earlier question about safety, noting that the CDC confirmed as early as 2020 that no cases of hepatitis B transmission had been documented in school settings, including elementary, middle, or high schools. She then referred to slide six, asking about its source and what year it was from.

Dr. Langer responded that multiple reports are stating the vaccine was safe, published in 1994, 2002–2004, 2012, and 2013.

Dr. Griffin followed up, noting that in 2012, the Institute of Medicine reviewed hepatitis B vaccine safety studies and concluded that evidence was inadequate to rule out the possibility that vaccination could lead to more than two dozen neurologic and autoimmune disorders. She asked how this statement could be reconciled with describing the vaccine as safe and effective.

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Dr. Wester added that, while the 2012 Institute of Medicine report stated there was insufficient evidence to accept or reject a causal relationship, an extensive body of literature has emerged over the past four decades. She noted that colleagues in the Immunization Safety Office would provide additional data and are better positioned to respond in detail.

Dr. Hibbeln stated that the question before the committee is whether the first dose of the hepatitis B vaccine should be delayed until one month of age for infants of hepatitis B-negative mothers. He said he was unclear if any safety or hazard data had been presented comparing vaccination before versus after one month. He asked why one month was chosen as the time point, and whether data exist showing a greater risk of adverse effects before or after that age.

Dr. Kulldorff noted that the current schedule recommends the second dose at one to two months of age, so delaying the first dose until one month would coincide with or come after the second dose. He suggested that the CDC is best suited to address the broader question of safety.

Dr. Hibbeln reiterated that the committee is being asked to vote on whether the first dose should be delayed until at least one month of age for infants of negative mothers. He wondered if data show that vaccination before one month carries a greater risk of adverse effects than after one month.

Dr. Malone added by asking whether there is data on a gradient of adverse events by age post-birth, rather than only at the one-month time point, and whether risk decreases over time. Dr. Hibbeln agreed, emphasizing that if the committee is to vote on delaying the dose to one month, data are needed comparing adverse effects before and after that time.

Dr. Malone asked whether one month represents a distinct point of higher or lower risk, or if risk changes more gradually over time, and whether data is available to clarify this.

Dr. Kulldorff suggested the committee proceed to the safety presentation to address these questions.

Dr. Pebsworth raised concern about data showing that 12–16% of women do not receive prenatal care or hepatitis B screening. She questioned whether infants are being born in the U.S. without the mother's hepatitis B status known, noting that a rapid test (stat titer) should be able to provide results within one to two hours, which has important implications for infant care. Dr. Kulldorff responded that while in principle maternal status should always be known, the standard test typically takes one to three days, so results may not be available before delivery.

Dr. Pebsworth noted reports that a stat titer can provide results in one to two hours and asked if this was accurate.

Dr. Griffin, speaking as an obstetrician-gynecologist, confirmed that the screening test can indeed be completed in under one hour, with results often available the same day. She added that in the U.S., 98–99% of women deliver in hospitals with laboratory capacity, and most receive prenatal care. While approximately 7% of women lacked prenatal care in 2023 (according to the March of Dimes), hospitals routinely test for hepatitis B surface antigen at delivery if prior results are unavailable, with results typically available within hours.

Dr. Levi asked whether informed consent discussions with mothers include the opportunity to test at delivery, assuming such talks take place as part of the decision to vaccinate the infant.

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Dr. Griffin added that women typically remain in the hospital for at least 24 hours postpartum, allowing time for confirmatory testing and administration of infant vaccinations and HBIG, if needed. She reflected that this raises an important question: are we vaccinating all newborns on day one to lower hepatitis B prevalence in high-risk populations, essentially asking babies to solve an adult problem?

Dr. Langer explained that while a rapid hepatitis B test can sometimes be completed within 30 minutes to an hour, this assumes an ideal situation. Factors such as births outside hospitals, laboratory backlogs, or the need for confirmatory testing can cause delays in results. He noted that vaccination within 12 hours can avoid these risks and ensure timely protection. He added that there are no data showing harm from vaccinating at birth compared to one month, but there are potential harms to delaying the dose, while the vaccination series would still be needed regardless.

Dr. Kulldorff clarified that initial rapid testing can identify if a mother is negative within a short time, while positive results require longer confirmatory testing.

Dr. Griffin agreed, noting that the purpose of screening is to quickly identify those at risk, which allows for counseling and informed consent. She confirmed that in practice, results are available within a few hours, certainly within the first day, while the patient is still in the hospital.

Dr. Kulldorff added that for the committee's decision, it is only necessary to know if the mother is negative. If the initial test is positive, the mother can be treated as positive without waiting for confirmation.

Dr. Griffin agreed.

Dr. Pollak noted that data suggest children not vaccinated in the perinatal period are much less likely to return for vaccination later, with a hazard ratio of three. He emphasized that this disproportionately affects single mothers, women of low socioeconomic status, persons of color, and high-risk groups such as Alaskans and First Nations. He requested data from the CDC on follow-up and vaccination completion among infants who were not vaccinated at birth, such as those weighing under 2,000 grams or those with contraindications.

Dr. Langer responded that there is an association between receiving the birth dose and completing the vaccine series on time. Infants who do not receive the birth dose are less likely to be vaccinated later.

Dr. Pagano asked whether this association is confounded by parental choice, noting that some parents may refuse the birth dose and also decline later doses.

Dr. Langer agreed that the association does not imply causation. Parents who accept the birth dose are more likely to complete the series, but the underlying factor may be parental willingness rather than the timing of the first dose.

Dr. Levi noted that Canada's provinces have a wide range of hepatitis B vaccination policies, with first doses given as early as two months or as late as 11–12 years. He asked whether outcomes differ by province and if delaying vaccination for infants of mothers with negative test results shows any impact on incidence.

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Dr. Meissner emphasized that targeting select groups for vaccination has historically been less effective than broad recommendations. He noted the difficulty of identifying and vaccinating high-risk groups such as IV drug users, sex workers, and people experiencing homelessness. He added that hepatitis B vaccination at birth, followed by the recommended series, likely provides lifelong protection, as even if antibodies wane, cellular immunity produces an anamnestic response upon exposure. He argued that no data suggest that vaccination at two or three months is safer than at birth, calling the vaccine extremely safe, with severe allergic reactions occurring in approximately one in a million doses. He questioned what would be gained by delaying the birth dose.

Dr. Hibbeln asked for clarification that hepatitis B can be transmitted to infants from sources other than the mother, noting that the virus survives on surfaces and can be spread by many people.

Dr. Levi responded that he was not aware of any documented data showing children becoming infected through such mechanisms, although he acknowledged that he could have missed relevant studies.

Dr. Langer pointed out that during his presentation, he discussed a study of U.S.-born children of immigrant mothers who tested negative at birth found that 7–11% later tested positive for hepatitis B surface antigen, proving infections occurred postnatally. These children were too young for sexual or injection drug exposures, and their mothers were confirmed negative, so transmission had to occur through casual or household contact. He added that the virus can survive on indoor surfaces for at least seven days, supporting the likelihood of community or household transmission.

Dr. Stein observed that the percentages cited for infections from non-maternal sources represent attributable risk rather than raw incidence counts. She emphasized that while still important, these numbers are not the same as direct incidence data.

Dr. Hibbeln responded that his concern was not about exact numbers but about the framing of the committee's vote, which divides infants only by maternal hepatitis B status. He argued that infections can occur from other household or community sources, and therefore, relying solely on maternal status is insufficient. He stated that the most prudent approach would be to vaccinate as many children as possible to protect them broadly.

Dr. Griffin noted that informed consent discussions and social history intake are part of medical practice, where providers assess risk factors with patients.

Dr. Hibbeln countered that if roughly half of infected people are unaware of their status, informed consent discussions cannot reliably identify risk.

Dr. Griffin replied that physicians should still ask these questions and document the responses in electronic medical records, which could eventually be analyzed using advanced tools.

Dr. Hibbeln responded that patients often cannot answer questions about their household infection status if no one in the household has been tested.

Dr. Griffin reiterated that risk assessment must start somewhere.

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Dr. Hibbeln concluded that if the goal is lifelong universal protection from a vaccine with very few side effects, then limiting the recommendation based on maternal status alone is flawed, since infection can occur from many sources throughout life.

Dr. Meissner emphasized that medicine is not precise, and the risk for hepatitis B cannot be reliably determined through questioning alone, similar to HIV. He added that maternal testing is not perfect, with potential errors in transcription, assay performance, and distinguishing between hepatitis B surface antigen and surface antibody. He concluded that no system will ever identify all hepatitis B surface antigen–positive mothers at delivery with 100% accuracy.

The ACIP chair, Dr. Kulldorff, requested a review of the 2004 study by Garly and colleagues titled *Hepatitis B vaccination associated with higher female than male mortality in Guinea-Bissau: an observational study*. The review included an assessment of non-specific effects of vaccination and findings from a rapid systematic review on mortality following hepatitis B vaccination.

Non-specific effects are defined as vaccine effects beyond protection against the target pathogen, possibly due to changes in the immune system. These differ from adverse, cross-protective, or indirect downstream effects. Clinical manifestations may include all-cause mortality, increased susceptibility to unrelated infections, or an increased risk of allergic and autoimmune diseases. Live attenuated and non-live vaccines may differ in these effects.

Garly and colleagues noted that while some studies have examined non-specific effects of vaccines on all-cause mortality, few have assessed hepatitis B vaccination specifically. Their study aimed to determine whether the hepatitis B vaccine was associated with sex-specific differences in mortality. The study was conducted within a trial of a two-dose standard measles vaccine in the Bandim Health Project surveillance system in Guinea-Bissau. Birth cohorts from March 1994 through February 2000 were included. Children born from March 1996 through February 1997 were eligible to receive a hepatitis B vaccine at 7.5, 9, and 10.5 months of age. The product used was a human plasma-derived vaccine, which is not licensed in the U.S. [This raises questions about the applicability or relevance of the Garly et al. study to current U.S. hepatitis B immunization recommendations.]

A Review of the Safety of Hepatitis B Birth Dose Vaccination

Dr. John Su (CDC/NCEZID)

Dr. John Su (CDC/NCEZID) reviewed the safety of hepatitis B birth dose vaccination. The ACIP chair requested safety data on hepatitis B administration within 24 hours of birth from the CDC's Vaccine Safety Datalink (VSD) and the FDA's Biologics Effectiveness and Safety System. The request included mild and serious adverse events, all-cause morbidity and mortality, short- and long-term safety, outcomes of predetermined concern, and data-mining results, with findings reported both combined and stratified by sex.

To address this, the CDC conducted a rapid systematic review of safety data on hepatitis B vaccination within 24 hours of birth. The key question was the safety of the vaccine when administered in the first 30 days of life. To capture a broad range of studies, the review included all vaccines administered within 30 days, not just 24 hours. The search was performed on July 31, 2025, using PICO(ST) criteria, and databases searched included Medline, EMBASE, CINAHL, and Cochrane.

Inclusion criteria were newborn infants receiving hepatitis B vaccine at 30 days or less, randomized controlled trials, observational studies, case series with 10 or more patients, and

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surveillance data. Outcomes included safety, adverse events, serious adverse events, and side effects. Exclusion criteria included non-English articles, animal studies, populations not receiving the vaccine within 30 days or less, case series with fewer than 10 patients, clinical trial protocols, conference abstracts or posters, proceedings, or journal titles beginning with a number.

The search identified 1,916 studies; after removing duplicates, 1,907 remained. Title and abstract screening excluded 1,678, and full-text review excluded another 158. Of the 71 studies left, 20 either focused on the birth dose or reported results stratified by birth dose.

Among these, five defined birth dose as administration within 24 hours of birth, including one VSD study. Four, including another VSD study, used terms such as “at birth,” “birth dose,” or “within 120 hours.” One study reported that 85% of infants received hepatitis B on the day of birth, with none vaccinated beyond 8 days. The remaining 11 studies allowed vaccination at any time in the first month of life; although included in the systematic review provided to ACIP, they were not discussed at the meeting.

Studies evaluated local reactions. One randomized trial found 7.7% of infants experienced pain with movement or pressure within 5 days of vaccination. Three studies reported pain or soreness within 4 days for fewer than 10% of infants, with few severe cases. For injection site redness, one trial reported none within 5 days, while three studies reported 8–20% within 4 days, with no severe cases. For swelling, one trial reported a 7.7% rate within 5 days, while three studies reported 0–4% within 4 days, with no severe cases. One trial that evaluated local reactions as a combined outcome found 2.8% of infants experienced a reaction within the first week.

Studies also evaluated systemic reactions. Four studies on fever after hepatitis B vaccination within 24 hours of birth reported rates ranging from 0 to 5.6% during birth hospitalization up to 21 days after birth. Among three studies where vaccination occurred within 0–5 days of birth, fever within 4 days of vaccination was reported for 0–5.9% of newborns. Few cases were severe.

For anorexia or decreased appetite, one randomized trial of vaccination within 24 hours of birth reported no cases within 5 days of vaccination. In three studies where vaccination occurred within 5 days of birth, anorexia, feeding issues, or decreased appetite within 4 days of vaccination were reported in 2.6–16.5% of newborns, with few severe cases.

For diarrhea or vomiting, one randomized trial of vaccination within 24 hours of birth reported no cases within 5 days of vaccination. Two additional studies where vaccination occurred within 5 days of birth found diarrhea or vomiting within 3 days of vaccination in 8.1–11.7% and 4.4–22.3% of infants, respectively, with no severe cases.

For irritability or fussiness, one randomized trial of vaccination within 24 hours of birth reported 11.5% of infants affected within 5 days of vaccination. Across three other studies where vaccination occurred within 5 days of birth, irritability, fussiness, or unusual crying within 4 days of vaccination was reported in 1.5–22.1% of infants. Few cases were severe.

No studies specifically evaluated sleep disturbance after vaccination within 24 hours of birth. However, three studies where vaccination occurred within 5 days of birth reported drowsiness or increased sleep within 4 days of vaccination in 5.1–32.4% of infants, and restlessness or reduced sleep within 3 days of vaccination in 16.9–31.1% of infants. Few cases were severe.

A cohort study of vaccination within 24 hours of birth found no differences in care for allergic reactions between vaccinated and unvaccinated newborns within 21 days of life. No additional studies evaluated allergic reactions in infants vaccinated within 5 days of birth.

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One study evaluated infections after hepatitis B vaccination within 24 hours of birth. In this cohort study, vaccinated newborns were less likely to be evaluated for possible sepsis and less likely to have a positive blood or cerebrospinal fluid culture. No studies assessed infections among newborns vaccinated within 5 days of birth.

Two studies examined other adverse events. In one cohort, hepatitis B vaccination within 24 hours of birth did not increase the risk of seizures or other neurologic disorders. In another cohort of preterm infants identified through Australia's surveillance system, hepatitis B vaccination appeared to have a slight protective effect against bronchopulmonary dysplasia. In an additional cohort where vaccination was administered within 5 days of birth, one serious adverse event was reported: a cough that required hospitalization 37 days after vaccination, which the investigators deemed unrelated.

One study evaluated all-cause mortality after hepatitis B vaccination within 24 hours of birth. In a cohort of preterm infants in Australia, there were no differences in mortality within 3 months of life between vaccinated and unvaccinated infants. Two studies assessed mortality after hepatitis B vaccination within 8 days of birth. In one randomized trial, no deaths occurred during a 7-month follow-up period among infants who received the hepatitis B vaccine within 4 days of birth. In a large US cohort study including more than 350,000 live births between 1993 and 1998, 1,363 neonatal deaths within 29 days were identified. Of these, 72 (5%) occurred in infants who received the hepatitis B vaccine at birth. No significant differences were observed between vaccinated and unvaccinated newborns in rates of expected or unexpected deaths, including deaths due to sudden infant death syndrome.

Limitations of this rapid systematic review include the small number of studies on hepatitis B vaccination within 24 hours, inconsistent reporting of timing, and heterogeneous methods that prevented meta-analysis. Most studies have focused only on short-term outcomes, such as reactogenicity or mortality within 30 days, while long-term outcomes have not been captured.

Dr. Su concluded that the review found no increased risk for allergic reactions, mortality, sudden infant death syndrome, seizures, or other neurologic disease. Compared to infants who did not receive the birth dose, those who did had lower risks of invasive diagnostic procedures, positive cultures, and bronchopulmonary dysplasia. Results on short-term reactogenicity varied across studies.

Non-specific effects following hepatitis B vaccination
Dr. John Su (CDC/NCEZID)

Dr. John Su (CDC/NCEZID) shared data on non-specific effects following hepatitis B vaccination. The ACIP chair requested that the Immunization Safety Office present the 2004 study by Garly and colleagues, "Hepatitis B vaccination associated with higher female than male mortality in Guinea-Bissau: an observational study." In addition, Dr. Su presented the results of a rapid systematic review of non-specific effects (NSEs) of Hepatitis B vaccination, including data on mortality after hepatitis B vaccination. NSEs are effects beyond protection against the target pathogen, potentially mediated by immune system changes; they are distinct from adverse, cross-protective, or indirect effects, and may manifest as changes in all-cause mortality, unrelated infections, or risk of allergic and autoimmune diseases. Live-attenuated and non-live vaccines may differ in their NSEs.

The Garly 2004 study aimed to assess whether hepatitis B vaccination is associated with sex-specific differences in mortality. It was conducted within a two-dose standard measles vaccine trial embedded in the Bandim Health Project surveillance system in Guinea-Bissau. Birth cohorts from March 1994 through February 2000 were enrolled. Children born from March 1996

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to February 1997 were eligible for the hepatitis B vaccine at 7.5, 9, and 10.5 months of age. The hepatitis B product used was a human plasma–derived vaccine not licensed for use in the U.S.

Dr. Su summarized three mortality comparisons. First, across birth cohorts, mortality at 7.5–12 months was compared with mortality at 1.5–7.5 months; overall, the rate ratio was 0.97, but in the year when most children received the hepatitis B vaccine at 7.5 months, it was 1.62 (95% CI, 1.09–2.41). Second, among 5,441 children in the two-dose measles vaccine trial, the mortality rate ratio at 7.5–12 months was 1.81 (95% CI, 1.19–2.75) for hepatitis B-vaccinated children compared to unvaccinated children. Third, among measles-vaccinated children, the female-to-male mortality rate ratio was 1.66 (95% CI 0.80–3.45) through 12 months of age for those who also received hepatitis B vaccine; through 24 months of age, the rate ratio was 2.20 (95% CI 1.07–4.54) with both vaccines versus 0.96 (95% CI 0.70–1.32) with measles vaccine only. The study authors (Garly, et al.) concluded these analyses suggest changes in mortality patterns after hepatitis B vaccine introduction in a high-mortality setting, with a stronger effect among females, raising the possibility of sex-differential non-specific effects.

These analyses were not planned when the trial was designed, and the study was not randomized, so unbiased comparisons over the same time period could not be ensured. Hepatitis B vaccine was administered at 7.5, 9, and 10–10.5 months in this study; therefore, the effects may differ when given at birth or alongside other vaccines, such as BCG. A higher female-to-male mortality ratio could also reflect reduced male mortality.

A rapid systematic review was conducted to [address the question, “What are the non-specific effects of hepatitis B-containing vaccines administered in childhood?”] The review included studies published through August 20, 2025, among infants and children up to six years of age who received either a monovalent hepatitis B vaccine or a combined vaccine, compared with any or no comparator. Outcomes included non-specific effects; studies in any setting and of any duration of follow up were included for review.

Inclusion criteria allowed for clinical trials, observational studies, surveillance reports, and systematic reviews. Eligible populations included infants and children younger than seven years of age who had received a hepatitis B vaccine, either alone or in combination. Included studies evaluated outcomes related to non-specific effects. Exclusion criteria ruled out case reports and case series, narrative reviews, animal studies, children older than seven years, adults, vaccines other than hepatitis B, and studies assessing outcomes outside of non-specific effects.

A total of 2,068 studies were identified. After keyword screening, 237 remained; however, 221 were excluded during the title and abstract review. Sixteen full texts were reviewed, and eight were excluded, resulting in eight studies included in the final review.

Of the eight included studies, four evaluated the hepatitis B vaccine as part of a pentavalent vaccine and four evaluated the monovalent vaccine. Seven were cohort studies and one was a nested case series. Six studies were conducted in low- and middle-income countries and two in high-income countries. Four studies evaluated mortality, five assessed sex-differential mortality, and one examined another non-specific effect.

Among the three studies that evaluated mortality, two cohort studies in high-income countries found no association between hepatitis B vaccination and all-cause mortality. A cohort study conducted in a low- to middle-income country found an increased risk of all-cause mortality following vaccination.

Evidence regarding sex-specific mortality was inconsistent. One study observed both no difference and an increase in the female-to-male mortality ratio. Another study suggested that there is no difference in mortality by sex.

Note: Text enclosed in [brackets] was added following the meeting, per the presenter’s request.

One cohort study in a high-income country evaluated cancer-related and cardiovascular-related mortality and found no effect of hepatitis B vaccination on these outcomes.

Overall, there are few studies available to inform the non-specific effects of hepatitis B vaccination in children. Studies in high-income countries found no association with all-cause mortality, while one study in a low- to middle-income country suggested an increased risk. Evidence regarding sex-specific mortality was inconsistent.

Dr. Su concluded that non-specific effects may vary in settings with different background mortality rates and infectious diseases burden. These effects may not be generalizable across immunization programs and might also vary depending on the specific vaccine product used. For example, Heppacine is not licensed for use in the United States, where the hepatitis B vaccine is administered earlier and often in combination with other routine vaccines. The biological, molecular, and immunologic mechanisms underlying non-specific effects are not fully understood. In particular, the timing between vaccination and the onset of any non-specific effect, as well as the duration of such effects, remains uncertain. The duration of a vaccine's non-specific effect may also be complicated by subsequent vaccinations received.

Discussion

Rick Haupt (Merck), head of the ID Vaccines Medical and Scientific Affairs group, shared a manufacturer statement. He referred to Dr. Langer's presentation, which highlighted the rationale and importance of routine newborn vaccination as a crucial public health strategy to prevent chronic viral hepatitis and its severe long-term consequences. He noted that the risk of developing chronic hepatitis B infection is strongly age-dependent, with up to 90% of infants infected at birth progressing to chronic infection, which can lead to chronic liver disease and liver cancer. Transmission may occur from an infected mother or through close contact with an infected family member. He emphasized that the CDC has reported that one in two people is unaware of their infection status. He stated that Merck's Hep B vaccine, Mercivovax HB, was first approved in the United States in 1986 and has been a foundation of hepatitis B prevention, with more than 330 million doses distributed between 1990 and 2019. Universal infant and childhood vaccination for hepatitis B has resulted in a 99% decline in reported cases of acute hepatitis B among children, adolescents, and young adults under 19 years of age. He concluded that vaccines remain the best defense against many serious diseases, with strong scientific evidence supporting their use. He cautioned that reconsidering newborn hepatitis B vaccination on the established schedule would pose a serious risk to the health of children and the public and could lead to a resurgence of preventable infectious diseases.

Ayman Chit (Sanofi), head of the medical affairs department at Sanofi Vaccines in the United States, shared a manufacturer statement. He emphasized that the company's top priority is ensuring access to safe and effective vaccines. He stated that administration of hepatitis B dose early in life remains the most effective option for preventing hepatitis B infection in infants and children. He noted that scientific evidence strongly supports the safety of both hepatitis B vaccines and combination vaccines that include hepatitis B, and that these vaccines are continuously monitored by manufacturers, public health agencies, and regulators before and after approval. He cautioned that changes to the hepatitis B infant schedule could disrupt implementation and reduce the benefits provided by combination vaccines. Combination vaccines lessen the number of injections infants receive, improve provider workflow, and help limit administration errors. If recommendations change for one component, providers will need to stock both single-antigen and combination products, creating challenges with supply, storage, handling, administration, and documentation. He warned that delaying the hepatitis B birth dose puts infants at risk of infection and reduces families' options to use combination vaccines. He added that such a change would likely cause significant supply disruptions lasting a year or

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longer due to the production lead time, affecting not only combination vaccines but also single-antigen products such as Hib and polio. He concluded that maintaining current recommendations for hepatitis B vaccination is critical to ensure infants remain protected early in life, high-risk infants are not missed, and families continue to have access to widely available combination vaccines that protect against multiple vaccine-preventable diseases.

Dr. Griffin stated that regarding the first presentation, she wanted to know how many of the studies were based on thimerosal-containing vaccination.

Dr. Hause from the Immunization Safety Office stated that she did not have the number on hand but could provide it after a brief review.

Dr. Griffin stated that she asked because there has not been a hepatitis B vaccine containing thimerosal since 2001. She noted that she counted about five or six such studies and questioned the rationale for including them. She asked if any of the studies were designed to have safety as the primary endpoint, since many appeared to focus on immunogenicity.

Dr. Su stated that safety was part of the studies but deferred to colleagues for clarification on whether safety was the primary endpoint.

Dr. Hause stated that several studies evaluated safety as the primary endpoint and that several randomized controlled trials also included safety as a secondary endpoint.

Dr. Griffin asked how many studies were specifically designed with safety as the outcome.

Dr. Hause stated that three studies specifically examined safety as an outcome.

Dr. Griffin clarified that this meant three out of twenty studies and requested to go back to slide 23 from the first presentation.

Dr. Hause clarified that three out of nine studies were presented in the slides.

Dr. Griffin thanked her and requested that slide 23 be pulled up, noting it was a summary slide. She inquired about the commentary on bronchopulmonary dysplasia, pointing out that she had found one article, Morgan et al. (2025), and questioned whether that was the only study used in the summary.

Dr. Hause confirmed that it was.

Dr. Griffin expressed concern, stating that the authors of that study declared seven significant limitations. She highlighted the inability to control for confounding factors, including infections and respiratory support, and noted that clinician perception of newborn stability could also influence vaccination decisions. She emphasized that withholding vaccination in unwell infants could confound results and underestimate risks. She then asked if there were any other studies showing findings related to bronchopulmonary dysplasia.

Dr. Hause stated that the study in question was included because it met the criteria for systematic review. She noted that no other studies identified in the review met the criteria with bronchopulmonary dysplasia as the outcome.

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Dr. Pebsworth referred to slide 15 from the first presentation, which evaluated systemic reactions such as irritability, fussiness, or crying, noting rates of 20–22% among participants. She stated that these rates seemed very high, particularly since they may be early symptoms of neurologic problems requiring long-term follow-up, which is lacking in the available data. She commented on the Institute of Medicine (IOM) reports, clarifying that the IOM did not conclude that the hepatitis B vaccine was safe but instead reviewed multiple conditions and assessed the weight of epidemiologic evidence, mechanistic evidence, and causality conclusions. She noted that the IOM reviewed three reports on hepatitis B between 1994 and 2012 and concluded that the evidence was inadequate to accept or reject a causal relationship between the hepatitis B vaccine and conditions such as encephalitis and encephalopathy. Additionally, the IOM found that of 26 conditions reviewed, this same conclusion applied to at least 24 of them. She listed several of the conditions considered in the IOM report, including encephalitis, encephalopathy, seizures, acute disseminated encephalomyelitis, transverse myelitis, optic neuritis, neuromyelitis Optica, multiple sclerosis onset and relapse, Guillain-Barré syndrome, chronic inflammatory demyelinating polyneuropathy, lupus, vasculitis, polyarteritis nodosa, psoriatic arthritis, and reactive arthritis, emphasizing that the IOM conclusions indicated uncertainty rather than confirmation of safety. She also referenced a 2024 systematic review on the safety of hepatitis B vaccines in preterm infants, noting that it found no publications on the timing of the birth dose and adverse events, and that reporting was limited to short-term outcomes, highlighting that research on the safety of hepatitis B vaccination in preterm infants within seven days of birth, especially regarding long-term morbidity, is lacking. She further referenced a 2016 mouse model study showing that neonatal hepatitis B vaccination impaired behavior and neurogenesis in early adulthood, with the conclusion that vaccination impaired hippocampal LTP and neurogenesis and that the possible mechanism involved alterations in the brain neuroimmune milieu from a systemic TH2 bias. She concluded that there are gaps in knowledge about the effects of hepatitis B vaccination on very young infants and stated that concluding the vaccine is safe may be premature.

Dr. Levi stated that the Garly paper was one of the most well-done examples of a natural randomized experiment. He recalled that children vaccinated between seven and a half months and 12 months showed almost 80% higher mortality compared to other cohorts. He asked why this result was not discussed and whether it was because the focus was on earlier age groups.

Dr. Su asked if Dr. Levi was referring to the Garly paper and clarified that he was reviewing his slides. [This finding was presented on slide nine. In comparison two, among children enrolled in the measles vaccine trial, compared with HBV-unvaccinated children, the mortality rate ratio for children 7.5-12 months of age from the HBV-vaccinated cohort was 1.81 (95% CI 1.19, 2.75).]

Dr. Kulldorff stated that while Dr. Su was reviewing, the discussion could move to Dr. Milhoan.

Dr. Milhoan stated that the neonatal period is a very sacred time for intervention and that medical decisions at this stage must be approached with caution, as any changes in the baby's condition lead to invasive evaluations and treatments. He explained that risks are higher for procedures such as anesthesia and surgery in newborns, particularly premature infants. He emphasized that while public health prioritizes populations, it does not always prioritize individual patients, and decisions for the most vulnerable must be made with utmost caution. He questioned whether seroconversion rates had been evaluated starting at two months rather than at birth, pointing out that while seroconversion occurs at a rate of 26% at birth, higher levels are achieved after subsequent doses, with approximately 95% after the third dose. He suggested that beginning vaccination later might reduce the number of doses required and decrease risk,

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since every injection carries some risk. He asked whether T-cell immunity, which may be more robust early in life, had been considered as part of the vaccine response.

Dr. Levi added that seroconversion rates were 25% after the first dose, 63% after the second dose, and 95% after the third dose.

Dr. Milhoan stated that if vaccination began at two months and continued at six months, the seroconversion rate should be examined to see whether earlier vaccination unnecessarily adds doses. He clarified that he was not advocating against vaccination but instead suggesting that risks could be reduced if the schedule were reevaluated. He also referred to slide 23, which summarized death outcomes, stating that rather than showing a positive effect of hepatitis B vaccination, the data reflected selection bias: healthier children were more likely to be vaccinated early, leading to more favorable outcomes unrelated to the vaccine. He noted that this reflected selection rather than a true protective effect.

Dr. Kulldorff added that this phenomenon is called “healthy vaccination.”

Dr. Milhoan continued by noting that while outcomes reported included allergic reactions and all-cause mortality, other important outcomes were missing. He asked whether data were available on whether infants required advanced care or were coded.

Dr. Su stated that he did not have that information and referred to the investigators of the paper.

Dr. Blackburn asked how the language was decided to recommend vaccination at one month rather than two months, noting that most other countries recommend delaying for hepatitis B-negative mothers. She stated that while she could see justification for this approach, she was concerned when reviewing safety data about the risks of fever and poor feeding. She explained that any fever in a newborn under 28 days is considered a medical emergency and typically prompts a full sepsis workup, spinal tap, hospitalization, and empiric IV antibiotics. She added that, as a parent with firsthand experience, early feeding is essential to successful breastfeeding, and a decreased appetite in the early days of life can have a significant impact. She emphasized that these risks should be taken into consideration when weighing the benefits and harms.

Dr. Kulldorff responded that the decision was related to the fact that the second dose in the U.S. is recommended between one and two months of age, and he noted that he had been personally involved in discussions about the recommendation with CDC staff.

Dr. Malone stated that while concerns about irritability, fever, and poor feeding may or may not be indicators of neurological problems, it is important not to base votes or recommendations on speculation. He emphasized that decisions should be based on data reflecting concrete risks or benefits, rather than hypothetical clinical outcomes for which there is no evidence. He referenced the IOM findings, noting that although neurological outcomes had been considered, there was no evidence to make a causal link either for or against such conditions. He concluded that the committee should not extend beyond the data when making determinations.

Dr. Meissner stated that there is no association or lack of association between the hepatitis B vaccine and bronchopulmonary dysplasia (BPD). He explained that BPD occurs in preterm babies who are typically more than 10 weeks early, weigh less than two pounds, and are often mechanically ventilated. He emphasized that the condition results from barotrauma or trauma associated with mechanical ventilation, making it biologically implausible for the hepatitis B

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vaccine to have any relationship with BPD, and he advised not placing too much concern there. He then referred to the Garly study and asked for clarification, noting that Dr. Su had given excellent presentations, and inquiring whether the vaccine in that study was a human plasma–derived hepatitis B vaccine.

Dr. Su stated that the Garly paper involved a plasma-derived hepatitis B vaccine.

Dr. Meissner explained that the original hepatitis B vaccine was produced from the plasma of people with chronic hepatitis B, which was then inactivated by heat or chemical treatment to prevent infection before being concentrated. He emphasized that this vaccine was very different from the current vaccine, which is made using cloned hepatitis B surface antigen in yeast, resulting in a pure and well-defined product. He stated that the vaccine used in the Garly study was not the same as the modern vaccine and therefore should not be emphasized in current discussions. He further noted that changing the recommendation for neonatal administration of the hepatitis B vaccine would increase the risk of harm without evidence of benefit, as fewer children would complete the full hepatitis B vaccine series if initiation were delayed. He noted that beginning vaccination in the hospital ensures that at least the first dose is administered. He stressed that there is no evidence to suggest that the vaccine becomes less safe over time, that it is extremely safe and pure, and that changing the recommendation could create unjustified public doubts. He concluded that there is no evidence of harm from administering the neonatal vaccine, either from presentations or from his review of the literature and expressed concern about changing the recommendation.

Dr. Malone stated that he agreed with Dr. Meissner that the BPD signal was artifactual. He noted that the reported improvement in risk of BPD in the paper likely reflects healthy vaccine bias or reporting bias. He concurred that the Garly study involved the historic plasma-derived vaccine, which was associated with adverse events not relevant to the modern product. He noted that the question of changing recommendations also raised moral and ethical considerations. He added that what he had not heard was clear data on the risks to premature infants, and he asked for clarification on whether there are differences in safety, effectiveness, immunogenicity, or seroconversion between premature infants and healthy newborns.

Dr. Su responded that he could speak about the safety aspects, noting that the data were limited to the studies that met the inclusion criteria. He stated that a few of those studies addressed adverse events in premature infants, but deferred to other experts in the room for further knowledge on that topic.

Dr. Hause stated that only one study met the criteria for the systematic review that looked at premature infants, which was the Morgan study with the outcome of bronchopulmonary dysplasia. She added that only one study specifically listed the use of a thimerosal-containing hepatitis B vaccine.

Dr. Malone stated that, based on the discussion, there appeared to be insufficient data to assess safety, immunogenicity, and seroconversion in premature infants, and he asked for confirmation.

Dr. Langer responded that under the current recommendation, newborns weighing less than 2,000 grams who are born to hepatitis B-negative mothers should not be vaccinated at birth. He clarified that the recommendation is to wait for one month.

Dr. Milhoan asked whether the one month referred to gestational age or corrected age.

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Dr. Langer stated that he would defer to colleagues on that detail.

Dr. Meissner stated that the recommendation is to wait until one month of age or until discharge from the neonatal unit to home.

Dr. Kulldorff confirmed that this was correct.

Dr. Stein stated that her question concerned the extensive data provided in the summary document, which included many detailed study summaries. She asked for clarification on what is meant by “low confidence.”

Dr. Hause explained that each study was reviewed for risk of bias and graded using standardized tools for systematic review. She stated that results varied by study, particularly in relation to study design, and that details could be provided to the committee after the meeting.

Dr. Stein added that several studies had shown potential long-term risks, but that bias might influence these findings, and she had not reviewed them in detail.

Dr. Hause stated that there are studies examining long-term outcomes in the larger systematic review. However, they were not included in the presentation because they did not assess hepatitis B doses given within the first 24 hours of life, which was the specific request of ACIP. She noted that those studies could be provided to the committee separately.

Dr. Middleman asked two questions. First, she asked what problem exists in the current schedule that prompted the discussion, noting that the hepatitis B immunization schedule has been highly successful, with a favorable benefit-to-risk ratio. She emphasized that while there are always risks and benefits to weigh, risk-based approaches to vaccination have historically not been effective across multiple vaccines. She expressed uncertainty about what specific issue had led to reopening the discussion. Second, she commented on the exclusion of liaison members from working groups, noting that liaison members bring extensive knowledge and represent patients. She emphasized that their perspectives on issues such as adjuvants or neonatal vaccination thresholds add value to vaccine recommendations. She asked how liaison members might be included again to contribute on behalf of their patients and their expertise.

Dr. Kulldorff responded to the second question, explaining that the exclusion of liaison members from working groups was a CDC-wide Federal Advisory Committee Act (FACA) policy, which was outside the control of ACIP. He stated that in the past, ACIP had not been following this requirement, and the change was necessary to align with FACA rules. He agreed that liaison member input is valuable, but clarified that outside experts, including those affiliated with organizations represented by liaison members, are included in working groups. He explained that these experts serve as individuals rather than representatives of their organizations. He concluded that while outside expertise is incorporated, ACIP must comply with FACA policy regarding liaison members. Regarding the first question, he invited Dr. Levi to respond.

Dr. Levi shared two personal experiences. He stated that he had received the hepatitis B vaccine as an adult before traveling to high-risk areas, and that all six of his children received the vaccine on the first day of life without prior discussion or informed consent. He suggested that this illustrates how often informed consent may not occur for this vaccine. He expressed concern about the frequent claim that “there is no evidence of harm,” emphasizing that the relevant question is whether there is evidence of no harm, particularly for a vaccine

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administered on the first day of life to healthy infants. He argued that the risk of not vaccinating on the first day of life is likely negligible during the first several months or even years. He questioned why there have been no large, long-term randomized clinical trials (RCTs) to resolve the debate about safety, stating that the lack of such trials reflects broader problems with the medical system and vaccine research. He reiterated his belief that the hepatitis B vaccine is life-saving and essential for high-risk infants and adults. Still, he stated that arguing from weak evidence undermines trust and is not a scientific approach. He described the absence of long-term RCTs as the “elephant in the room.”

Dr. Fryhofer, a general internal medicine physician in full-time practice and the American Medical Association (AMA) liaison. She disclosed that she had received the hepatitis B vaccine as a medical student after rotating through a hepatitis ward, where she saw severely ill patients. She stated she was thankful the vaccine exists. She explained that the hepatitis B virus primarily affects the liver and can cause chronic infection, cirrhosis, liver cancer, and death. She noted that the virus can be transmitted in utero and through bloodborne routes, and that when transmission occurs in utero, 90% of infants remain chronically infected. She highlighted that administering the hepatitis B vaccine at birth has nearly eliminated perinatal hepatitis B, with only 13 cases reported in 2022. She emphasized that the birth dose is safe and effective and stated that the AMA strongly urges ACIP to maintain the recommendation for newborn vaccination.

Dr. Munoz, a pediatric infectious diseases physician specializing in transplant infectious diseases at an institution that performs the largest number of pediatric liver transplants in the country, and a clinician-investigator with many years of vaccine research experience, asked why the hepatitis B vaccine recommendation is under review and whether there is a specific reason for considering a change. She emphasized that the data presented show significant declines in hepatitis B incidence and long-term consequences due to vaccination, both in children and adults, and that this progress is directly attributable to vaccination. She noted that the vaccine strategy is safe, effective, and widely implemented globally, with U.S. data suggesting that hepatitis B could be eliminated through continued vaccination. She emphasized that risk-based strategies are imperfect due to potential false-negative tests, inadequate prenatal care, limited access, and gaps in understanding vaccine benefits. She warned that changing the recommendation could reintroduce vertical transmission or leave adolescents unprotected, resulting in severe disease. She concluded that the vaccine is very safe, that those at greatest risk would be most affected by changes. She urged the committee to maintain the current recommendation to protect both individuals and the broader public, especially the most vulnerable.

Dr. Paulsen, a liaison with the Pediatric Infectious Disease Society, stated that he agreed with the concerns raised by ACIP members regarding the protection of children in the newborn period, which he described as a sensitive time. He noted that the hepatitis B birth dose ultimately comes down to weighing risks and benefits. He emphasized that CDC presentations consistently showed the risks to be low and that the data specifically focused on the infant birth dose. He highlighted that fever in infants often prompts a sepsis workup, including a lumbar puncture, but that CDC data showed the risk of requiring such a workup was lower in infants who received the hepatitis B vaccine within 24 hours. He concluded that the benefit is avoiding a lifelong, chronic, vaccine-preventable infection. While in an ideal world, all maternal infections would be known and properly managed, public policy must be based on what protects the population broadly. He urged ACIP to continue preventing infection in children rather than treating hepatitis B as an adult problem.

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Dr. Buchanan, representing the National Association of Pediatric Nurse Practitioners, stated that she wanted to echo and reiterate the safety of the vaccine. She shared her personal experience caring for many children and administering the hepatitis B vaccine in clinics, emphasizing that under her care, no child had been harmed by the vaccine. She added that while members were sharing personal accounts, she also wanted to raise the broader question many were asking: why the vaccine's safety is being reconsidered now, given its well-established record of safety over several decades.

Dr. Hayes, representing the American College of Nurse Midwives, stated that in most facilities, when a woman in labor signs the consent form, it includes consent for the hepatitis B vaccine dose. She explained that in her experience, the process functions as a universal consent, with the option for refusal, meaning parents can decline the hepatitis B vaccine if they choose.

Dr. Jshlay, a family physician who provides prenatal care, stated that hepatitis B screening is often done early in pregnancy, but that risk can change over time. She noted that the growing uninsured population, including those losing commercial or Medicaid coverage, increases the likelihood of patients presenting without prenatal care at delivery, making it difficult to obtain timely test results. She added that many patients do not disclose risk information due to embarrassment or stigma. She emphasized that if vaccination approaches differ based on risk, mothers may be stigmatized; universal vaccination avoids this by ensuring all families are treated equally, which supports equity in care.

Dr. Hopkins stated that his greatest concerns related to equity and lack of knowledge. He noted that about 50% of adults in the population, including those presenting for delivery, do not know their hepatitis B status, and congenital hepatitis B infections continue to occur. He stated that removing the birth dose would increase population risk and that equity must remain central in the evidence-to-recommendation framework. He added that while additional long-term data may be needed, as Dr. Levi suggested, it would not make sense to remove a successful intervention while waiting for such data. He concluded that decisions should be made with care and based on the full body of evidence, rather than being rushed.

Dr. Malone stated that the central question repeatedly raised, particularly by liaison representatives, is why the issue of deferring the hepatitis B birth dose to one month is being considered now, given that no clear safety signal has been detected. He suggested that the timing appears to be less tied to scientific evidence and more to public trust, noting that a significant portion of the U.S. population has concerns about vaccine policy, mandates, and the administration of the hepatitis B vaccine at birth without meaningful informed consent. He observed that the birth setting is often stressful and overwhelming, making it difficult for parents to process information and provide truly informed consent, and that some parents feel the vaccine is administered unilaterally by medical professionals. He linked these concerns to broader declines in public trust in vaccines and public health following the COVID-19 pandemic. He referenced Sweden as an example where, despite the absence of vaccine mandates and a hepatitis B birth dose, vaccine uptake is high and infectious disease outcomes are strong, attributing this to greater public trust in Swedish public health. He concluded that the issue before ACIP is not driven by a safety signal but by public discomfort and mistrust, and that while data presented may provide reassurance, many concerns will likely persist. He clarified that he had no direct communication with CDC or HHS leadership on this issue and was offering his perspective based on public opinion trends.

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Proposed recommendations and discussion

Dr. Martin Kulldorff (ACIP Chair)

Proposed Recommendation #1:

All pregnant women should be tested for hepatitis B infection.

Proposed Recommendation #2:

The pediatric vaccine schedule should be updated to reflect the following change:

If a mother tests HBsAG-negative:

-The first dose of the Hepatitis B vaccine is not given until the child is at least one month old.

-Infants may receive a dose of Hepatitis B vaccine before one month, according to individual based decision-making.*

*Also referred to as shared clinical decision-making.

Dr. Kulldorff clarified that if parents choose to have the first dose administered on day one or at any time before one month, even if the mother tests negative, the dose will be covered by CMS, Medicare, Medicaid, and other health insurance providers.

VFC Resolution Update: Hepatitis B Vaccines

Jeanne Santoli (CDC/NCIRD)

Jeanne Santoli (CDC/NCIRD) presented on the resolution with all revisions from the previously approved resolution shown in red. The purpose of the update is to update the Recommended Vaccination Schedule and Intervals section to align with the proposed recommendations regarding the hepatitis B birth dose under discussion today by ACIP. She reviewed the changes to the infant vaccination table, clarifying that for infants weighing at least 2,000 grams and born to mothers who are hepatitis B surface antigen–negative, the timing of the first dose was revised to 1-2 months and the second dose was adjusted to 3-4 months for infants receiving single antigen vaccine. For infants weighing less than 2,000 grams and born to hepatitis B surface antigen–negative mothers, the timing was the same. She explained a revised footnote stating that only the single-antigen hepatitis B vaccine can be given at less than or equal to six weeks of age, replacing prior language that referred to birth. She highlighted two new footnotes reflecting individual-based or shared clinical decision-making for both ≥2,000-gram and <2,000-gram infants with hepatitis B surface antigen–negative mothers, allowing for one dose to be administered before one month of age. She confirmed that there were no changes to children's vaccination schedule table, related table notes, interrupted schedules, minimum dosing intervals, revaccination guidance, recommended dosage, contraindications, or precautions. She closed by noting the standard clause that new guidance published within six months would be incorporated by reference, which was also unchanged.

Votes

Discussion

Dr. Hayes suggested revising the wording slightly to specify the antigen test rather than the antibody test, to provide clearer guidance for clinicians.
Dr. Kulldorff agreed that this was a good suggestion and stated that CDC colleagues could refine the exact language to ensure the proper test was clearly identified.

Vote: Hepatitis B Vaccine Vote #1

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the vaccine into the record:

Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

All pregnant women should be tested for hepatitis B infection.

Motion/Vote: Hepatitis B Vaccine

Dr. Levi motioned to approve the recommended voting language, stating, "All pregnant women should be tested for hepatitis B infection." Dr. Griffin seconded the motion. No COIs were declared. The motion carried with 12 votes in favor, 0 votes opposed, and 0 abstentions. The disposition of the vote was as follows:

12 Favored: Malone, Hibbeln, Pagano, Milhoan, Blackburn, Griffin, Stein, Pollak, Pebsworth, Levi, Meissner, Kulldorff
0 Opposed:
0 Abstained:

Dr. Pebsworth stated that after reviewing the CDC's presentation, specifically slide 18 on the global distribution of vaccination policies, she noted that in 26 countries, the first dose of the hepatitis B vaccine is given to infants born to hepatitis B surface antigen–negative mothers at two or three months of age. She explained that this included most of Europe, listing England, France, Spain, Germany, Ireland, Norway, Denmark, Sweden, and Iceland. She pointed out that the CDC had also reported variable rates of reactogenicity within the first week of life, with data showing systemic reactions among vaccinated infants. According to the data presented, up to 5% developed a fever, 32% were drowsy or sleeping, 3% had reactions categorized as severe, and irritability, fussiness, or crying was reported for 11% within the first 24 hours and 22% within the first five days. She emphasized that these were not trivial reactions and could affect up to one-third of births. She referenced the 2016 Yang study, which reported that hepatitis B vaccination impaired behavior and neurogenesis, and a 2013 study by Celich, published in the European Journal of Pediatrics, which found that 30% of infants developed significant elevations in C-reactive protein without clinical signs of sepsis and with negative blood cultures. She explained that this indicated a robust inflammatory response occurring during a critical window of neurodevelopment, including neurogenesis and synaptic development. She concluded that, given these findings and CDC data on systemic adverse reactions, the committee should exercise caution and consider adopting a more prudent vaccination policy, similar to that of most European countries, where low-risk newborns are not vaccinated on the first day of life and vaccination is typically delayed until two to three months.

Dr. Malone stated that there were differences between what was presented and what was published regarding the findings of the Institute of Medicine. He explained that, in his interpretation, the IOM report indicated that for the 22 most claimed serious harms, all but one could not be assessed because studies had not been conducted to determine whether the vaccine caused harm or not. He argued that interpreting this absence of data as evidence of safety was misleading. He emphasized that case reports and case series suggest potential harm, and that the IOM report did not conclude safety but rather acknowledged a lack of data. He stated that for interventions in pregnancy and newborns, the burden must be to demonstrate safety, not to assume safety until proven otherwise, and he disagreed with the interpretation that the absence of data implies the product is safe.

Dr. Hibbeln stated that he is a strong advocate for clinical decision-making but noted that the wording of the question was logically inconsistent. He explained that the language said the dose should not be given until one month, but also allowed for clinical decision-making, which

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contradicts the prohibition. He suggested modifying the wording to state that the first dose of hepatitis B is not given until the child is one month old, except in cases where clinical decision-making dictates otherwise, which would resolve the inconsistency.

Dr. Kulldorff asked whether changing the wording to “not recommended” would address the concern.

Dr. Hibbeln responded that the phrasing still created conflict, as it both prohibited and allowed administration. He reiterated that the language should specify that the vaccine is not administered until one month, except in cases where a clinical decision is made.

Dr. Pollak raised a point of order, noting that the committee was debating language without a motion on the floor. He reminded members of Robert’s Rules of Order, explaining that a motion must be made before discussion, after which debate can occur. Then a vote should be taken to either accept or reject the proposal.

Dr. Malone moved to indefinitely postpone the question, noting uncertainty around safety, effectiveness, and timing.

Dr. Pollak motioned to table, and Dr. Malone seconded.

Vote: To table the Hepatitis B Vaccine Vote #2

Motion/Vote: Hepatitis B Vaccine

Dr. Pollak motioned to table the second vote on the Hepatitis B Vaccine. Dr. Malone seconded the motion. No COIs were declared. The motion carried with 11 votes in favor, 1 vote opposed, and 0 abstentions. The disposition of the vote was as follows:

11 Favored: Levi, Pebsworth, Hibbeln, Pollak, Griffin, Stein, Blackburn, Milhoan, Pagano, Malone, Meissner
1 Opposed: Kulldorff
0 Abstained:

Discussion

Dr. Meissner, responding to Dr. Malone’s earlier comments, stated that it is challenging to prove the absence of harm and that such a goal is not practical. He emphasized that extensive experience has been accumulated from administering the vaccine within the first 12 to 24 hours of life, and that the concerns raised about irritability or restlessness are not objective measures for assessing safety. He noted that since the motion to table had passed, there would be no votes on the hepatitis B vaccine during this meeting.

Dr. Stein cautioned against making absolute statements such as declaring the vaccine entirely safe or entirely unsafe. She emphasized that the perception of safety often depends on the perspectives of parents and children. She advised that the committee carefully consider the broader literature and patient experiences before reaching a conclusion.

Dr. Meissner responded that no vaccine is 100% safe or 100% effective. He stressed that providers must weigh whether the benefits of protection outweigh possible side effects for each

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patient. He concluded that, overall, the benefits of the newborn hepatitis B vaccine clearly outweigh any potential adverse effects.

Dr. Munoz stated that she was pleased with the decision to table the vote. She emphasized that there have been 30 years of progress in preventing hepatitis B disease and related cancers, and that the concerns raised about safety were based only on case reports and anecdotes rather than substantial evidence. She urged the committee to use proper processes to address potential concerns, including requesting additional studies if needed. She argued that dismissing a successful program would be more harmful than beneficial, given the data presented. She also commented on the previous vote, noting that hepatitis B testing is already a routine standard of care in prenatal and obstetric practice, and she asked what the committee's plan would be regarding that motion.

Dr. Kulldorff responded that hepatitis B testing is currently conducted in about 86–87% of pregnant women, but the goal should be to move closer to 100%.

Dr. Hopkins stated that if the issue of hepatitis B birth dose is revisited, it should undergo a full review by a work group, including the complete evidence-to-recommendations framework, with particular attention to the domains of equity and practical implementation.

Dr. Goldman echoed Dr. Hopkins' comments and asked the chair to explain what process would be used in the future to review evidence. He emphasized the importance of transparency about whether the committee would continue to use the evidence-to-recommendations framework and the GRADE process that work groups have traditionally used to evaluate trial power, quality, bias, and conflicts of interest. He noted that recent discussions had not gone through the work group process and stated that the public should be aware of how future evidence will be vetted. He commended the committee for tabling the vote to allow further discussion but requested clarification on future methodology.

Dr. Kulldorff stated that he hoped the committee could return to the issue at a future meeting and acknowledged that he could not provide a detailed response at that time.

Dr. Middleman stated that the concerns raised were not limited to hepatitis B but reflected broader issues that had been discussed across the committee. She emphasized that no intervention is without risk, noting that even common treatments, such as Tylenol, amoxicillin, or chemotherapy drugs, carry some level of risk, as does everyday activity, such as walking across the street. She explained that the committee's scientific responsibility is to determine whether the benefits outweigh the risks. She urged members to avoid being distracted by isolated studies and to rely on systematic approaches such as the GRADE framework or the evidence-to-recommendations process to evaluate risks and benefits. She emphasized that the consistent use of these methods is crucial for all vaccine decisions and that some concerns arose from their absence in recent deliberations.

Dr. Levi stated that while he appreciated the emphasis on scientific methods, he was puzzled that many of those advocating for rigorous approaches spoke with great confidence despite the absence of gold-standard, long-term randomized clinical trials against a placebo. He noted that such trials do not exist for this intervention and argued that if the committee seeks to uphold scientific rigor, it should do so consistently. He cautioned that confident statements about vaccines being "safe and effective" were being made without the highest standard of evidence and encouraged members to show greater humility and acknowledge the limitations in the available data.

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Dr. Kulldorff reminded the committee that the motion had been tabled. He encouraged those still wishing to comment to bring their remarks forward if the issue is returned at a future meeting.

Dr. Goldman stated that, as Dr. Levi had mentioned, the committee needs gold-standard evidence to guide decisions. He agreed that this is the role of the work groups and emphasized that the public should be adequately informed about the processes used to vet and discuss future vaccines. He emphasized that the evidence-to-recommendations framework was established to establish a consistent standard for evaluating vaccines, but noted that it had not been applied in recent deliberations. He urged the committee to clearly communicate how vaccine decisions will be analyzed in the future so the public can maintain trust, faith, and confidence in the committee's work.

Dr. Kulldorff responded that Dr. Goldman had already raised this comment previously and that he had addressed it at that time.

PUBLIC COMMENT

The floor was opened for public comment on September 18, 2025. The comments made during the meeting are summarized in this document. Members of the public were also invited to submit written public comments to ACIP through the Federal eRulemaking Portal under Docket Number ID CDC-2025-0454. Visit regulations.gov for access to read the comments received.

Ms. Anu Hosangadi
Hepatitis B Foundation

Ms. Hosangadi spoke on behalf of the Hepatitis B Foundation, emphasizing the long-established safety and efficacy of the hepatitis B vaccine. She noted that since 1982, over a billion doses have been administered worldwide with no new or unexpected safety concerns identified through decades of surveillance and studies. She cited multiple CDC and Vaccine Safety Datalink reviews confirming the vaccine's strong safety record, including studies in newborns and infants showing no increase in adverse outcomes. She highlighted the vaccine's effectiveness in providing long-term protection, its safety among pregnant women and individuals with HIV, and the global data supporting continued universal birth-dose administration. Ms. Hosangadi concluded by affirming that maintaining the universal hepatitis B birth dose is a proven, safe, and lifesaving intervention.

Samantha Sears,
National Consumers League

Ms. Sears, representing the National Consumers League, underscored the importance of ACIP grounding its recommendations in medical science, particularly amid rising public distrust and declining vaccination rates. She urged the committee to preserve the integrity of the U.S. immunization system and to combat misinformation through clear, consistent communication. Ms. Sears expressed concern about potential changes to the childhood vaccine schedule, warning that altering established recommendations could create confusion, reduce access, and impose financial burdens on families. She stressed the need for alignment between ACIP, the American Medical Association, and the American Academy of Pediatrics to avoid contradictory messaging and safeguard children's health.

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Dr. Rita Isabel Lechuga, MD, MPH
NASTAD

Dr. Lechuga, director of the hepatitis team at NASTAD, discussed the public health benefits of universal infant hepatitis B vaccination. She traced the policy's origins to ACIP's 1991 recommendation, which led to a sharp decline in childhood hepatitis B cases by replacing failing selective vaccination strategies. She noted that universal vaccination has been both cost-effective and lifesaving, reducing perinatal transmission from tens of thousands of annual cases to fewer than 1,000 today. Dr. Lechuga described hepatitis B as one of the first "anti-cancer" vaccines due to its ability to prevent hepatitis D and liver cancer. She concluded by expressing hope that continued adherence to the universal birth-dose policy will lead the U.S. to eliminate perinatal hepatitis B transmission.

Michele Montandon
Private Citizen

Ms. Montandon, a family physician and former CDC global health leader, expressed deep concern about the growing spread of vaccine misinformation and its effects on public trust and health systems. Drawing from her international experience treating vaccine-preventable diseases, she condemned recent political interference in public health leadership and decision-making, including the removal of ACIP members and changes to vaccine guidance outside standard scientific channels. She cited the tragic consequences of misinformation, including a recent attack on CDC headquarters, and warned that confusion among physicians and families is already escalating. Ms. Montandon urged the restoration of science-based leadership at HHS and CDC, emphasizing that delays or disruptions to vaccination endanger public safety and erode confidence in the healthcare system.

Dr. Judy Stone, MD
Private Citizen

Dr. Stone, an infectious disease physician with over 40 years of experience, provided a powerful account of witnessing children die from vaccine-preventable diseases. She reminded the committee of the tremendous progress vaccines have achieved in reducing child mortality and disease incidence in the U.S. Dr. Stone warned that misinformation and vaccine hesitancy are reversing these gains, citing the resurgence of measles and other infections. She emphasized that measles is highly contagious and can cause severe complications, including hospitalization and death. Dr. Stone urged ACIP to protect access to vaccines, maintain school vaccination requirements, and uphold its duty to safeguard community health, stressing that society must not go back to the pre-vaccine era.

Mr. Scott Bertani
HealthHIV

Mr. Bertani, director of advocacy at HealthHIV, urged the committee to uphold ACIP's legacy as an independent, science-driven body. He highlighted the public health importance of the hepatitis B birth dose and combination vaccines such as MMRV, which protect infants and reduce the long-term disease burden. He noted that declining vaccine uptake threatens individuals with chronic illnesses and immunocompromised populations, including people living with HIV. Mr. Bertani outlined three recommendations: preserve the evidence-based ACIP process, maintain the full immunization schedule as published, and reinstate universal COVID-

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19 vaccination for all individuals aged six months and older. He concluded by stressing that weakening these frameworks risks confusion, stigma, and inequities in access to care.

Evan Sachs
Washington Heights–Inwood Mask Bloc

Mr. Sachs, founder of the Washington Heights–Inwood Mask Bloc, spoke as a mutual aid provider and journalist. He compared vaccination to traffic laws and seatbelt use, describing them as shared rules that protect both individuals and communities. He argued that public health requires collective responsibility, not personal preference, and that vaccines, while not perfect, are overwhelmingly effective and essential for community safety. Mr. Sachs also emphasized the importance of layered protections, including masking, given that no single intervention is 100 percent effective. He encouraged continued public health measures grounded in science and social responsibility.

Ms. Melissa Kadri
Private Citizen

Ms. Kadri, a Master of Public Health student, offered an emotional testimony describing the loss of her uncle to COVID-19 and the subsequent death of her aunt from grief. She spoke about the devastating impact on her family and the broader implications of restricted vaccine access. Ms. Kadri emphasized the importance of maintaining herd immunity and cautioned that delaying or limiting childhood vaccinations contradicts scientific evidence and endangers lives. Using her family's story as an example, she implored the committee not to alter vaccine schedules in ways that could lead to preventable deaths and suffering, urging members to remember the human cost of their decisions.

Due to time constraints, Dr. Kulldorff announced that the discussions and votes on the MMRV and Hepatitis B vaccines would continue on September 19, 2025. Summaries of those discussions and votes are included in the sections above. The meeting was then recessed until September 19, 2025, at 8:30 a.m. EST.

FRIDAY: SEPTEMBER 19, 2025

WELCOME AND ROLL CALL

Call to Order/Roll Call

Dr. Martin Kulldorff, Chair of the ACIP, convened the meeting on September 19, 2025. Dr. Mina Zadeh, ACIP Executive Secretary from the CDC, welcomed the committee, followed by a roll call of members, ex officio members, and liaison representatives, each of whom announced their presence.

AGENCY UPDATES

The Centers for Disease Control and Prevention (CDC)

Dr. Brandi Limbago, representing CDC's National Center for Immunization and Respiratory Diseases (NCIRD), provided updates on response and preparedness activities. As of

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September 16, 2025, CDC confirmed 1,491 measles cases across 42 jurisdictions, the highest since 1992. Of these, 86 cases were linked to 38 outbreaks, compared with 69% of cases and 16 outbreaks in 2024. Most measles introductions originated from U.S. travelers returning from countries with active measles transmission, leading to outbreaks in under-vaccinated communities. Despite these increases, the overall risk to the general population remains low due to high vaccine coverage and population immunity.

She also reported on preparations for the 2025–2026 respiratory virus season, focusing on influenza, COVID-19, and RSV. Current data show low flu and RSV activity but increasing COVID-19 activity nationwide, with elevated emergency department visits and hospitalizations, particularly among children under 5, youth 5–17, and adults 65 and older. CDC is taking a coordinated approach to address these viruses by aligning programs, data systems, outreach, and communications. Additionally, the agency continues to monitor other respiratory pathogens, including Mycoplasma, Group A Streptococcus, and Pertussis.

Dr. Chris Braden provided an update on a significant outbreak response led by the National Center for Emerging and Zoonotic Infectious Diseases. On September 1, CDC received reports from local sources of suspected viral hemorrhagic fever in the Kasai Province of the Democratic Republic of Congo, which was later confirmed as Ebola virus Zaire. The index case was a pregnant woman admitted to Bulap General Hospital on August 20 with high fever, bloody diarrhea, hemorrhaging, vomiting, and weakness; she died on August 25 from multi-organ failure. Two healthcare providers who treated her also became ill and died.

Genomic sequencing at the DRC's National Public Health Laboratory indicated that the virus is genetically distinct from viruses in previous Ebola outbreaks, suggesting a new spillover event from wildlife. The DRC government promptly confirmed the outbreak and collaborated with CDC to initiate an emergency response. CDC has maintained a partnership with DRC for over 20 years, operating a country office since 2002 with about 30 staff members supporting laboratory capacity, workforce training, and public health infrastructure.

As of September 15, there were 37 confirmed cases and 19 deaths, with additional suspected cases under investigation. Approximately 944 contacts have been identified, and vaccination of healthcare workers and contacts began on September 13, with 369 vaccinations completed by September 15. All confirmed cases remain confined to Kasai Province, specifically the Bulabia health zone. The actual extent of the outbreak may be greater than currently known, though no related cases have been reported outside the DRC or in the United States, and the overall risk to the U.S. public remains low.

CDC issued a Health Alert Network advisory for U.S. public health departments and clinicians outlining case identification, testing, and biosafety recommendations. CDC headquarters is coordinating with its DRC country office, which has deployed additional staff to Kasai Province and Kinshasa to assist with response efforts. Technical support focuses on laboratory testing, surveillance, case investigation, contact tracing, and infection prevention and control measures.

Food and Drug Administration (FDA)

Dr. Tracy Beth Hoeg from the Food and Drug Administration (FDA) provided updates on recent regulatory actions and announcements. The four currently approved COVID-19 vaccines, MNEX Spike, Spikevax, Coity, and Newacovid, are indicated for adults aged 65 years and older, as well as for individuals at increased risk for severe COVID-19. Newacovid is authorized for individuals aged 12 years and older, while Spikevax is authorized for those aged six months and

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older. The previous Emergency Use Authorizations (EUAs) for Novavax, Pfizer, and Moderna have been revoked.

For the approved vaccine formulations, there are three ongoing post-marketing commitments, including studies on the persistence of the spike protein and associated symptoms, and randomized, saline placebo-controlled trials to evaluate safety and efficacy. Dr. Hoeg emphasized the importance of these trials, noting that real-world evidence can sometimes be misleading, citing a recent example involving the hepatitis B vaccine and apparent protection against bronchopulmonary dysplasia, which was likely due to healthy vaccine bias.
She also announced that randomized controlled trials will now be required to assess the safety of administering multiple vaccines concurrently. In addition, the live attenuated ICK vaccine for chikungunya virus has been temporarily suspended due to safety concerns.

Centers for Medicare and Medicaid Services (CMS), Health Resources and Services Administration (HRSA), Indian Health Service (IHS), and National Institutes of Health (NIH) did not report updates.

COVID-19 VACCINES

Dr. Retsef Levi (ACIP Work Group Chair) introduced the COVID-19 Work Group's immediate goals, which focused on discussing recently authorized vaccine products and determining which populations and subgroups should receive recommendations. Members discussed three possible options, which were to recommend, not recommend, or make an individual-based decision, and planned to define each later in the day. The work group emphasized the need to clearly communicate all risks and uncertainties to patients, noting that the current Vaccine Information Statement (VIS) does not accurately reflect the full scope of these concerns and should be updated for greater clarity and consistency. Members agreed that ACIP and its work groups should be able to consider any relevant data or information that supports vaccine policy decisions. Three focus clusters were established based on members' expertise to summarize available evidence, identify key issues and knowledge gaps, and develop potential policy options for review by ACIP. The work group reaffirmed its commitment to using all relevant published and unpublished data, including real-world experience, and to focusing on personalized risk-benefit analysis rather than general statements about safety or effectiveness. Members agreed to maintain respectful debate and transparency to ensure all perspectives and opinions are represented.

Dr. Arjun Srinivasan (CDC/NCIRD) shared updates on COVID-19 epidemiology. He explained that the data presented and discussed in this section come from the COVID-19–Associated Hospitalization Surveillance Network (COVID-NET). COVID-NET is one of three RESP-NET platforms, along with RSV-NET and FluSurv-NET, that collect data using similar methods and catchment areas on laboratory-confirmed COVID-19, RSV, and influenza-associated hospitalizations. It is a collaborative effort between CDC and state and local health departments that share data through cooperative agreements.

COVID-NET is a collaborative, population-based surveillance system that collects data from more than 300 acute care hospitals in 185 counties across 13 states, representing about 10% of the U.S. population. It gathers two primary types of information: population-based hospitalization rates and detailed clinical data from a stratified sample of patients. These data include demographics, outcomes, underlying conditions, treatments, and discharge diagnoses.

The system's primary purpose is to monitor laboratory-confirmed COVID-19–associated hospitalizations among children and adults and provide timely information to decision-makers and the public. Hospitalization rates are updated weekly to assess disease burden and trends, while clinical data help identify who is most at risk and evaluate illness severity. A COVID-NET case is counted when a resident of the catchment area tests positive for SARS-CoV-2 within 14 days before or during hospitalization. Similar definitions are used for RSV and influenza surveillance systems.

Dr. Srinivasan noted that there has been ongoing interest in distinguishing between hospitalizations due to COVID-19 and those for COVID-19 illness. During the early stages of the pandemic, when there was no immunity or vaccination and asymptomatic transmission was common, hospitals screened all patients upon admission. This practice often identified patients who tested positive for SARS-CoV-2 but were hospitalized for unrelated reasons, such as surgery or childbirth. To address this, COVID-NET implemented an algorithm to identify hospitalizations primarily due to COVID-19, based on chief complaint and history of present illness. Data using this approach, dating back to March 2020, are posted monthly on the public COVID-NET dashboard. Although routine universal screening of all hospital admissions has largely ended, COVID-NET continues to use this algorithm to maintain consistency in surveillance.

Several factors must be considered when defining hospitalizations due to COVID-19. A positive SARS-CoV-2 test can influence the decision to admit a patient with comorbidities or other underlying conditions. At the same time, the presence of comorbidities or other conditions can also affect the decision to accept a SARS-CoV-2–positive patient. Data obtained from medical records, such as test results, treatments, discharge diagnoses, and coding, may lead to misclassification of hospitalizations as COVID-19-related or unrelated. ICD-10-CM codes in the U.S. are designed for billing and administrative purposes, not surveillance, and may either overcount or undercount true cases. In some instances, a COVID-19 ICD code can be used only to indicate a positive test rather than hospitalization for COVID-19 illness.

COVID-NET uses a standardized process to determine whether hospitalizations are due to COVID-19. This process relies on information from the chief complaint and history of present illness recorded at admission. Hospitalizations are classified as non-COVID-19-related if the admission was for obstetric care, surgery, psychiatric reasons, trauma, or for newborns hospitalized at birth. For remaining cases, if the medical record documents fever, respiratory symptoms, a COVID-19–like illness, or suspicion for COVID-19, the hospitalization is classified as due to COVID-19. Cases that do not clearly fit these criteria are reviewed by two COVID-NET physicians, with a third review if needed. Suppose a patient's medical record indicates that a positive SARS-CoV-2 test was incidental or that the hospitalization occurred for an unrelated reason, such as a localized infection or a surgical procedure. In that case, the case is classified as not related to COVID-19.

Using this algorithm, 87% of hospitalizations among SARS-CoV-2–positive patients in COVID-NET were determined to be due to COVID-19. Rates have increased over time, likely because universal screening of asymptomatic patients is no longer standard. Among children, 89% of hospitalizations were due to COVID-19, and the percentage increased with age in adults. Adults aged 65 years and older accounted for 70% of COVID-19–associated hospitalizations, with 91% of those admissions determined to be primarily due to COVID-19.

COVID-NET balances the need for detailed clinical data with the workload of chart abstraction. Data collection can be limited by timing and access, since ICD-10 codes are assigned after

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discharge and may only be available in billing systems. To address this, surveillance officers also review discharge summaries to capture conditions that developed during hospitalization. Combining discharge summaries with ICD-10 codes provides a more complete picture of each case and reduces bias that can occur when relying solely on billing data for public health surveillance.

COVID-NET examined classifying hospitalizations as being due to COVID-19using two different approaches: ICD-10-CM discharge diagnoses and the network's reason-for-admission algorithm. Data from the 2023–2024 season were used since ICD-10-CM codes are not yet available for the 2024–2025 season. During this period, COVID-NET identified more than 66,000 hospitalizations among patients of all ages, of which 7,279 were sampled for medical record abstraction. Using ICD-10-CM codes and discharge diagnoses, 81% of sampled hospitalizations had a COVID-19 discharge code listed in one of the first nine coding positions, 52% had a sepsis or respiratory-related diagnosis, and 88% had either a COVID-19 ICD-10 code or a respiratory diagnosis. 12% of cases had neither a COVID-19 ICD-10-CM code nor sepsis or respiratory-related discharge diagnosis.

Applying the reason-for-admission algorithm to the same sample, 85% of hospitalizations were classified as due to COVID-19. Of these, 91% also had either a COVID-19 ICD-10 code or a sepsis or respiratory-related diagnosis. Among the remaining 15% classified as hospitalizations with COVID-19, 64% had a COVID-19 ICD-10 diagnosis code.

Dr. Srinivasan summarized that the two classification methods show strong agreement. Overall, 88% of hospitalizations had a COVID-19 ICD-10 code or a respiratory-related diagnosis, and 85% were identified as COVID-19 as the likely primary reason for admission. 92% of hospitalizations identified through the reason-for-admission approach also had a COVID-19 ICD-10 code or a sepsis or respiratory diagnosis. The reason-for-admission approach is more conservative than relying solely on discharge diagnoses and can be completed more quickly. These findings support the notion that COVID-NET's methods provide a balanced approach to timeliness, accuracy, and population representation.

COVID-19–associated hospitalization rates per 100,000 population were determined by age group and reflect the cumulative risk of hospitalization for the 12 months from October 2024 through September 2025. The rates were based on the surveillance standard, which includes hospitalized residents in the COVID-NET catchment area who tested positive for SARS-CoV-2. Hospitalization rates were highest among adults aged 65 to 74 years and 75 years and older, as well as among infants younger than 6 months. Because no vaccine products are approved for infants under 6 months of age, protection against hospitalization must come from maternal vaccination.

A significant proportion of adults hospitalized due to COVID-19 experienced severe in-hospital outcomes, including admission to the intensive care unit and in-hospital death. About 15% of adults hospitalized with COVID-19 were admitted to the ICU, and in-hospital death occurred more frequently among adults aged 50 years and older. Among all adults hospitalized due to COVID-19 who died in the hospital, 84% were aged 50 years and older. These data include only deaths that occurred during hospitalization, although additional COVID-19–associated deaths occur outside the hospital, including some within 30 days after discharge.

Different respiratory viruses affect age groups differently, with the greatest overall impact seen at the extremes of age. Cumulative data show that RSV causes the highest burden of respiratory disease in children under one year. COVID-19 has the greatest impact on older

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adults but also remains a significant cause of hospitalization among infants, with rates comparable to influenza during October 2024-2025, a high-severity influenza season that was the most severe since the 2010–2011 season. COVID-19–associated hospitalization rates among infants younger than 6 months have remained close to those among adults aged 65 to 74 years, but in recent weeks have risen more rapidly, reaching 223 per 100,000 compared to 194 per 100,000 among adults, a 14% higher rate among infants compared to adults aged 65 to 74.

Dr. Srinivasan shared an update to a peer-reviewed study published in 2021, which had informed a previous infographic summarizing the relative risk of hospitalization among individuals with chronic conditions compared to those without. Data sources for the updated analysis included three primary datasets: COVID-NET data on hospitalizations due to COVID-19 from October 2022 through September 2023; the Behavioral Risk Factor Surveillance System (BRFSS), the largest ongoing health survey system in the world that collected data annually from hundreds of thousands of community-dwelling U.S. adults; and population data from the U.S. Census provided by the National Center for Health Statistics.

The analysis methodology was complex. COVID-NET provided weighted counts of individuals hospitalized due to COVID-19 who had underlying conditions, limited to community-dwelling adults aged 18 years and older, for consistency with BRFSS data. Weighted counts of adults with and without chronic diseases of interest were calculated using BRFSS data and state population modeling. Adjusted rate ratios of hospitalization rates for adults with versus without chronic conditions were then calculated. Chronic conditions examined were limited to those included in the BRFSS survey and included coronary artery disease, history of stroke, diabetes mellitus, chronic kidney disease, COPD, asthma, obesity, severe obesity, and current smoker.

Findings showed that the prevalence of most chronic conditions among adults hospitalized due to COVID-19 was higher than in the general population. Among adults, most chronic conditions increased the risk of being hospitalized due to COVID-19. The risk for hospitalization conferred by several conditions, such as coronary artery disease, diabetes, and obesity, appeared to decline with age but this may have reflected challenges in adjusting for coexisting conditions or low prevalence of some diseases within specific age groups; for example, severe obesity was uncommon among adults aged 75 years and older, while COPD was uncommon among adults younger than 50 years.

The analysis also showed that the risk for hospitalization due to COVID-19 increased with both the number of chronic conditions and with age. Having multiple comorbid conditions and older age were the strongest risk factors for hospitalization due to COVID-19 identified among adults. Adults with three or more underlying conditions were nearly six times more likely to be hospitalized due to COVID-19 compared with those with no underlying conditions. Hospitalization rates were 18.5 times higher among adults aged 75 years and older compared with those aged 18 to 49 years, making age 75 and above the greatest identified risk factor for hospitalization.

The analysis had several strengths, including the use of data from a robust COVID-19 hospitalization surveillance system that enabled comparisons across state-level prevalence data and allowed examination of how specific conditions, multiple comorbidities, and age contributed to hospitalization risk. However, there were also limitations. The results remained preliminary and under review. The analysis was limited to community-dwelling adults and did not include children or individuals living in long-term care facilities, where risks may have differed. Some conditions tended to co-occur, such as diabetes and chronic kidney disease, and adjustments

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for these comorbidities could not always be made due to limited data, particularly in younger adults. In addition, differences in rate ratios by outcomes (e.g., ICU admission) or by race and ethnicity could not be assessed due to the sparse data.

Dr. Malone asked whether there was a significant overlap and diagnostic difficulty between COVID-19 and other influenza-like illnesses.

Dr. Srinivasan confirmed that the symptoms of COVID-19 overlapped almost entirely with those of other respiratory illnesses.

Dr. Malone noted that when he had previously asked a CDC representative about the specificity and sensitivity of the diagnostic tests used, he was told those measures were “academic.” He expressed concern that sensitivity and specificity are fundamental to data validity and stated that diagnostic testing for COVID-19 has had limitations in both areas, which were not reflected in the models.

The NCIRD SME explained that the tests used in COVID-NET were FDA-approved diagnostic tests performed in hospitals and medical clinics nationwide. The SME clarified that COVID-NET did not conduct testing directly and that all tests were performed at the treating provider's discretion.

Dr. Malone stated that this confirmed the tests had known limitations in sensitivity and specificity that could affect data interpretation.

The NCIRD SME acknowledged that all clinical tests have defined sensitivity and specificity values but emphasized that the tests used were FDA-approved and used to identify patients who tested positive for SARS-CoV-2.

Dr. Malone added that if the tests were only 80% specific, the underlying classification of COVID-19 cases would be similarly ambiguous.

Dr. Natalie Thornburg, NCIRD laboratory SME, clarified that all tests used in COVID-NET had received FDA authorization through the Center for Devices and Radiological Health and met rigorous FDA test performance requirements, with specificity generally well above 90% both sensitivity and specificity at a similar level.

Dr. Arjun Srinivasan (CDC/NCIRD) shared updates to 2024-2025 COVID-19 implementation considerations. One of the primary sources utilized by the Immunization Services Division to assess vaccination coverage, including COVID-19 and other immunizations, was the National Immunization Survey (NIS). The NIS is a random-digit-dial cellular telephone survey of U.S. adults aged 18 years and older across local jurisdictions and territories. For children, data were reported by a parent or guardian, and all responses were self-reported. The survey included approximately 15,000 adults per week, or about 60,000 adults per month, and the data were weighted to represent the non-institutionalized U.S. population.

COVID-19 vaccination coverage for the 2024–2025 season was reported for adults aged 18 to 49 years, 50 to 64 years, and 65 years and older. From September 2024 through April 2025, coverage for at least one dose reached 44% among adults aged 65 years and older, 25% among those aged 50 to 64 years, and 14% among those aged 18 to 49 years.

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When comparing coverage between the 2023–2024 and 2024–2025 seasons, there was little change among adults aged 18 to 49 years and 50 to 64 years. However, vaccination coverage increased among older adults. For those aged 65 to 74 years, coverage rose by nearly five percentage points, and among adults aged 75 years and older, coverage increased by about eight percentage points. These differences were statistically significant in both age groups ($p < 0.05$).

COVID-19 vaccination coverage estimates for the pediatric population showed that approximately 5.6% of children younger than 4 years were up to date with vaccination according to current recommendations for that age group. Among children aged 5 to 17 years, being up to date was defined as having received at least one vaccination since August; nearly 16% met this criterion. Overall, about 13% of children aged 6 months to 17 years were up to date with their COVID-19 vaccinations by the end of April 2025.

Vaccination coverage among immunocompromised adults aged 18 years and older who received their first COVID-19 vaccine dose in August or September 2024 was 8% fully vaccinated with two doses by the end of March 2025. When analyzed by age, 16.6% of adults aged 50 to 64 years were fully vaccinated compared to 2.4% among those aged 18 to 49 years and 0.8% among those aged 65 years and older.

In summary, COVID-19 vaccination coverage among older adults improved during the 2024–2025 season compared to the previous season, while coverage among adults aged 18 to 64 years remained similar. Approximately 13% of children aged 6 months to 17 years were up to date with their COVID-19 vaccinations by the end of April 2025.

COVID-19 vaccination data for adults aged 18 years and older showed the distribution of vaccination sites among individuals who reported receiving a COVID-19 vaccine in 2024–2025 since August 2024. Data was collected between April 1 and April 27, 2025, from 9,359 respondents. Approximately 67% of adults reported receiving their vaccine at a pharmacy or drugstore, while 29% received theirs in a medical setting, such as a doctor’s office. About 4% received their vaccine in a non-medical location, such as a workplace.

Additional data on vaccination among healthcare personnel were collected through CDC’s National Healthcare Safety Network (NHSN), the nation’s most widely used system for tracking healthcare-associated infections. NHSN provides process measures such as vaccination status for healthcare personnel. CMS-certified skilled nursing facilities and hospitals report both COVID-19 and influenza vaccination data through this system. Data from NHSN showed that influenza vaccination rates among acute care hospital staff and long-term care staff have remained relatively consistent from 2022, when NHSN began collecting vaccination data for healthcare personnel, through the 2024–2025 respiratory virus season. In contrast, COVID-19 vaccination coverage has continued to decline across seasons in both acute care and long-term care settings.

Dr. Arjun Srinivasan (CDC/NCIRD) provided an update on COVID-19 vaccine effectiveness. He first explained the difference between data from randomized controlled trials and real-world evidence to clarify how vaccine performance is evaluated. Randomized controlled trials are used to demonstrate vaccine efficacy under ideal, controlled conditions and to determine whether vaccination prevents disease compared with a placebo or another vaccine. Observational studies provide real-world evidence of vaccine effectiveness (VE) and determine how well vaccines protect populations with existing immunity from prior infection, vaccination, or both. He noted that efficacy and effectiveness are population-level estimates; for example, if a

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vaccine is 80%, it means that 80% fewer vaccinated people will develop the disease compared to an unvaccinated population, not that the vaccine works only 80% of the time.

He described how VE can be measured using several study designs, including case-control, cohort, and test-negative designs. Case-control studies compare vaccinated and unvaccinated individuals within the same population, whereas cohort studies follow at-risk groups over time to determine who develops illness. The test-negative design combines features of both and is widely used by CDC and other countries to measure the VE of COVID-19 vaccines. In this approach, individuals seeking care for respiratory illnesses are included; those who test positive for SARS-CoV-2 are considered cases, and those who test negative serve as controls. This method reduces bias by ensuring that both groups sought care for similar symptoms, minimizing confounding factors such as age and geography.

Dr. Srinivasan emphasized that the test-negative design offers several strengths. It efficiently studies rare outcomes, such as infectious diseases, by reducing bias using controls from the same health facilities. This approach allows for faster, more cost-effective data collection, often yielding results within the same season. When conducted among hospitalized populations, it helps mitigate healthy vaccine bias because both cases and controls are hospitalized for respiratory illness. Additionally, when electronic health record data are used to include the entire eligible at-risk population as controls, the design supports larger sample sizes. It enables stratified analyses by factors such as age and time since vaccination.

Dr. Srinivasan shared VE results from three CDC study platforms that include both children and adults. The first platform, the VISION Network, is a multi-site system utilizing electronic health records from over 300 emergency departments and urgent care clinics, as well as more than 200 hospitals. VISION uses a test-negative design and includes individuals of all ages with COVID-19–like illness and a clinical test result within 10 days before to 72 hours after their healthcare encounter. Cases are defined as those with a positive nucleic acid amplification test (NAT) or antigen test for SARS-CoV-2 and no positive RSV or influenza results, while controls are those with a negative SARS-CoV-2 NAT test and no positive influenza or RSV test, depending on age. Vaccination status is documented through electronic health records and state or city registries.

The second VE platform enrolls only children and includes participation from 26 pediatric hospitals in 20 states. The analysis presented was designed to evaluate the effectiveness of COVID-19 vaccination in pregnant women for preventing COVID-19–related hospitalizations among infants younger than six months.

The third platform, the IVY Network, includes 26 hospitals across 20 U.S. states and, like VISION, uses a test-negative design. However, IVY incorporates active enrollment through patient interviews and nasal swabbing. Participants included in the analysis were adults aged 18 years and older hospitalized with COVID-19–like illness. Cases were defined as those testing positive for SARS-CoV-2 by NAT or antigen testing, while controls were negative for SARS-CoV-2, influenza, and RSV by RT-PCR. Vaccination history was verified through medical records, vaccine registries, and plausible self-reports, and specimens were collected for centralized testing and sequencing.

Dr. Srinivasan also noted that methods for measuring COVID-19 VE have evolved by season. When vaccines were first introduced, absolute VE was measured, comparing health outcomes between vaccinated and unvaccinated individuals. During the bivalent vaccine period, relative VE was assessed, comparing outcomes among people who received a bivalent dose versus

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those who received only the original monovalent vaccine. More recently, analyses have shifted toward seasonal VE, similar to annual influenza evaluations, comparing people who received the current season's COVID-19 vaccine to those who did not, regardless of prior vaccination history.

Dr. Srinivasan presented COVID-19 VE data for 2023 to 2024 across emergency department and urgent care encounters, including results through August 2024, when the 2024 to 2025 vaccines were released. The reference group consisted of individuals who had not received the 2023–2024 COVID-19 vaccine. For those aged five years and older, this group included both unvaccinated individuals and those who had received one or more doses of the original monovalent or bivalent vaccines. For children younger than five years, both vaccinated and reference groups were required to have completed an initial vaccine series, and the 2023–2024 dose could have been part of or in addition to that series.

VE was evaluated by age group (9 months to 4 years, 5 to 17 years, and adults 18 years and older) and by time since vaccination. VE among those who received a 2023–2024 dose 7 to 59 days earlier and 60 to 299 days earlier was compared. Due to limited data, there were not enough children vaccinated 60 to 299 days earlier with positive SARS-CoV-2 tests to further divide the estimates for that group. Overall, VE was observed to be as strong or stronger among children as among adults, consistent with previous seasons' findings, which showed generally comparable VE across age groups.

For the 2024–2025 season, the same analysis framework was used; however, lower numbers of COVID-19 cases and lower vaccination coverage among children reduced statistical power. As a result, VE could not be estimated by time since dose. Instead, overall, VE was calculated for 7 to 179 days after receipt of a 2024–2025 COVID-19 vaccine dose. Findings showed that, similar to the 2023–2024 season, VE remained the same or higher in children than in adults.

Dr. Srinivasan presented VE data on receipt of a 2023–2024 COVID-19 vaccine during pregnancy for protection against emergency department and urgent care visits by pregnancy status. Among women who were pregnant at the time of their COVID-like illness encounter, VE was similar to that observed among non-pregnant women of the same age group. The time since vaccination was comparable across both groups, and the confidence intervals for VE fully overlapped, indicating consistent protection between pregnant and non-pregnant women.

He also shared VE estimates for maternal COVID-19 vaccination in preventing COVID-19–associated hospitalizations among infants, using data from the Overcoming COVID-19 Network during the 2022–2023 season. Maternal VE for infants is essential because infants younger than six months are not eligible for COVID-19 vaccination and have higher rates of severe illness than older children and most adult age groups. Vaccination during pregnancy remains the only means of protecting infants from severe COVID-19. The analysis included mothers who received their last dose of a COVID-19 mRNA vaccine between the first day of pregnancy and 14 days before delivery, compared to mothers who had not received any COVID-19 vaccination before or during pregnancy. VE was highest among the youngest infants, estimated at 54% during the first two months of life and 35% during the first five months of life. This pattern was consistent with findings in older children and adults, showing that VE decreases with increasing time since vaccination.

Dr. Srinivasan presented VE estimates for COVID-19–associated hospitalization among adults aged 65 years and older without documented immunocompromising conditions, using data from the VISION and IVY networks. VE estimates were nearly identical across both networks,

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providing reassurance of the results' consistency. During the seven to 179 days after vaccination, VE was 44% in VISION and 46% in IVY. VE began at 46% in VISION and 42% in IVY, declining to 32% in VISION and 40% in IVY during the 120–179-day period following vaccination. Confidence intervals for this later period were wider due to the smaller number of cases and controls who had been vaccinated four to six months before their encounter.

Dr. Srinivasan presented VE estimates for COVID-19-associated critical illness in adults aged 65 years and older, based on data from the VISION and IVY networks. In VISION, critical illness was defined as admission to intensive care or in-hospital death, and VE estimates were evaluated based on the time since vaccination. The point estimates remained stable across time intervals, including 120 to 179 days after vaccination, indicating relatively durable protection. This was consistent with previous years, showing that VE against the most severe outcomes remained strong over time with little evidence of waning.

In IVY, VE was evaluated for three outcomes of increasing severity, including acute respiratory failure, ICU admission or death, and invasive mechanical ventilation or death, measured during the 7 to 179 days after vaccination. VE was highest at 70% for invasive mechanical ventilation or death, again showing strong protection against the most severe outcomes. Among adults aged 65 years and older with immunocompromising conditions, VISION and IVY both showed similar trends. However, IVY lacked sufficient statistical power to estimate VE by time since vaccination. In VISION, VE appeared to increase over time, a pattern previously observed among immunocompromised adults and likely related to the faster waning of infection-induced immunity in this group. This would make the reference group, consisting of unvaccinated individuals, less protected over time, thereby increasing the apparent VE. For the overall period, VE was 38% in VISION and 36% in IVY, similar to VE observed in non-immunocompromised adults, providing reassurance that the vaccine continued to offer protection in immunocompromised populations.

Dr. Srinivasan summarized that for each respective year, receipt of an in-season COVID-19 vaccine dose provided additional protection against COVID-19–associated emergency department and urgent care visits among children, with similar protection observed across age groups. Among adults, vaccination also provided additional protection against COVID-19–associated emergency department and urgent care visits, hospitalizations in adults aged 65 years and older with and without immunocompromising conditions, and critical illness in adults aged 65 years and older. Protection appeared to be higher and more durable against critical illness compared to less severe outcomes.

He noted that VE should be interpreted as the added benefit of the 2023–2024 or 2024–2025 COVID-19 vaccination in a population with high levels of infection-induced immunity, vaccine-induced immunity, or both. Prior SARS-CoV-2 infection contributes to protection against future disease, but that protection decreases over time. An increase in SARS-CoV-2 circulation in the United States during late summer 2024, just before the 2024–2025 vaccines were approved and authorized, may have resulted in higher population-level immunity against JN.1 lineage strains. This, in turn, could have led to lower measured VE than would be observed in a population with less recent infection.

Dr. John Su (CDC/NCEZID) presented on the detection and evaluation of vaccine safety signals. He defined an adverse event following immunization as any unexpected or harmful medical occurrence occurring after vaccination that is not necessarily caused by the vaccine. He also described a signal as information arising from one or more sources, suggesting a new,

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potentially causal association between an intervention and an event that is considered likely enough to warrant further verification.

Signal detection and evaluation begin with identifying potential signals, which may emerge from clinical observations, such as case reports, or from vaccine safety surveillance systems. Suppose further assessment of the initial information continues to suggest a possible association between a vaccine and an adverse event. In that case, the next step is to conduct a hypothesis-testing study to either verify or rule out the signal. If the evidence confirms a causal association between vaccination and the event, public health actions or additional studies may follow, including evaluations of biological mechanisms or strategies to prevent similar occurrences.

CDC uses four complementary systems that work together to detect and evaluate potential vaccine safety concerns. One of these systems is the Vaccine Safety Datalink (VSD), which he used as an example to illustrate how signal detection and evaluation occur. The VSD is a collaboration between CDC and several integrated healthcare organizations with a combined population of more than 15 million people. It conducts active surveillance using electronic medical record data to detect safety signals and can also evaluate them using more robust study designs. The VSD links vaccination records, healthcare encounters, and patient characteristics into a standard data model for epidemiologic analyses.

The VSD uses rapid cycle analysis (RCA) to monitor a limited number of prespecified adverse events of special interest. Potential cases are identified using ICD-10 codes from healthcare encounters. RCA is designed to detect statistical signals, which are test statistics that exceed a specific threshold. However, a statistical signal does not necessarily indicate a genuine vaccine safety issue and requires further evaluation. Since 2020, the VSD has performed RCA using a vaccinated concurrent comparator method, which compares the incidence of an adverse event during a risk interval (e.g., 1 to 21 days after vaccination) with that during a control interval (e.g., 43 to 63 days after vaccination). This approach inherently adjusts for factors such as calendar time, age, sex, race, and VSD site. Detection using the RCA method is rapid but may include residual bias. When a statistical signal is detected, the VSD conducts additional evaluation using the self-controlled case series method, which requires full follow-up time but is less prone to bias.

Dr. Su noted that the VSD monitors a list of prespecified adverse events of special interest for COVID-19 vaccines, which are also tracked by multiple U.S. federal vaccine safety systems. One of these monitored outcomes is non-hemorrhagic, or ischemic, stroke. The VSD has monitored the risk of ischemic stroke following each dose of the COVID-19 vaccine since 2020 as new vaccine formulations were authorized and recommended. A statistical signal for ischemic stroke was first detected during the 2022–2023 season and again for the 2023–2024 formulation. Over the course of the 2022–2023 season, as more people were vaccinated and post-vaccination follow-up time increased, the rate ratio estimate decreased from a statistically significant level early in the season to a final value of 1.26, which was no longer statistically significant by the end of the monitoring period.

In 2023, CDC and FDA collaborated to further evaluate and communicate the ischemic stroke signal to the ACIP and the public. VSD was the only vaccine safety system to detect a signal for ischemic stroke. Other analyses conducted in the U.S. and in other countries did not observe similar findings. At the time, the interpretation was that the evidence did not support the existence of a vaccine safety concern.

The VSD RCA statistical signal for ischemic stroke during 2022–2023 was explicitly detected among people aged 65 years and older who received the Pfizer vaccine. Further assessment also examined whether the same-day administration of the influenza vaccine influenced the

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findings. During the 2023–2024 season, VSD RCA surveillance again detected statistical signals for ischemic stroke, this time following both the Moderna and Pfizer vaccines, as well as among different age groups from the prior season. These signals were presented to ACIP in 2024.

To further evaluate these findings, VSD conducted self-controlled case-series analyses for both seasons. For the 2022–2023 Pfizer vaccine analysis, subgroup evaluations included individuals who received the COVID-19 vaccine with or without same-day influenza vaccination. Across age groups and both 21-day and 42-day risk intervals, no statistically significant increased risk for ischemic stroke was identified for either separate or same-day administration.

Similarly, the self-controlled case series analysis for the 2023–2024 season, which examined both Pfizer and Moderna vaccines, found no statistically significant increased risk for ischemic stroke following vaccination, regardless of whether the influenza vaccine was administered on the same day.

The FDA also performed a self-controlled case series analysis for the 2023–2024 season among Medicare beneficiaries aged 65 years and older who received a COVID-19 vaccine. The FDA analysis likewise found no evidence of increased risk for ischemic stroke following vaccination with any manufacturer's product.

Dr. Su summarized that the VSD rapid cycle analysis surveillance monitored a list of prespecified adverse events of special interest, including ischemic stroke. The VSD detected statistical signals for ischemic stroke following COVID-19 vaccination during the 2022–2023 and 2023–2024 seasons. However, subsequent signal evaluations using self-controlled case series analyses in the VSD and other data sources did not confirm an increased risk of ischemic stroke.

Dr. Charlotte Kuperwasser from Tufts University School of Medicine and Dr. Wafik El-Deiry from the Legorreta Cancer Center at Brown University presented on safety uncertainties related to mRNA COVID-19 vaccines within the work group. Dr. Kuperwasser explained that the work group reviewed several key areas of scientific uncertainty related to mRNA COVID-19 vaccines. The review focused on four main topics: immune changes, biodistribution, frame shifting, and impurities. For immune changes, literature on both specific and nonspecific immune effects was examined, with an emphasis on the cumulative short- and long-term effects of repeated boosting, an area of emerging research. For biodistribution, clinical and scientific information was reviewed from both published literature and FDA data. Frame shifting was monitored due to its potential to alter protein products and downstream immune responses. Finally, published and unpublished data regarding residual DNA in existing mRNA vaccine products were reviewed.

The work group noted evidence that COVID-19 vaccination, particularly after multiple doses, is associated with a range of immune changes. One of the most well-documented findings is IgG4 class switching, first reported by Irrgang and colleagues, who found that individuals receiving Pfizer's BNT162b2 mRNA vaccine developed anti-spike IgG4 antibodies and IgG4-switched memory B cells within six months of their second dose, with levels increasing further after a third dose. These changes were associated with reduced antibody function consistent with IgG4's role in promoting immune tolerance. Additional studies have reported the production of anti-idiotype antibodies and persistent alterations in IgG glycosylation patterns, which may affect antibody-immune cell interactions and influence inflammatory versus tolerant responses.

The work group also discussed findings of long-lasting shifts in cytokine profiles, with elevated inflammatory cytokines persisting for months, which could increase the risk of recurrent or prolonged infections in some individuals. In addition, research from Akiko Iwasaki's laboratory at

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Yale demonstrated cellular immune changes, including reductions in circulating memory and effector CD4 T cells and increases in TNF-alpha–positive CD8 T cells following vaccination.

Dr. Kuperwasser noted that these and other studies raise questions about the persistence of the immunological changes associated with mRNA vaccination, as well as their long-term clinical significance and consequences. Given the long-term changes in cytokine profiles and T-cell ratios observed in vaccinated individuals, further research is needed to determine how vaccination may influence innate and adaptive immunity over time.

For biodistribution studies, Pfizer did not use the actual spike mRNA in its preclinical studies. Instead, a luciferase reporter mRNA packaged into the same lipid nanoparticles was used to track its movement through the bodies of rodents. The studies found that while most of the mRNA remained at the injection site, notable levels were also detected in the liver. Although this approach may underestimate the low-level or short-term distribution to other tissues, it demonstrates that vaccine components do not remain confined to the injection site.

For Moderna, no dedicated biodistribution study was conducted using the COVID-19 mRNA itself. Instead, data were provided from a surrogate product, CMV mRNA-1647, which used the same lipid nanoparticle formulation. In rat studies, high levels of mRNA were found at the injection site, as well as in multiple organs, including draining lymph nodes, spleen, eye, and liver. Lower levels were detected in additional tissues, including the heart, lungs, testes, and brain. This study indicated that the mRNA could cross the blood–brain barrier.

Consistent with animal studies, vaccine mRNA and spike protein have been detected in humans across multiple tissues, including blood, lymph nodes, heart, and brain. These findings indicate that the mRNA does not remain localized at the injection site. Persistence has been documented to last well beyond the initial hours or days, persisting for weeks in some tissues and, in certain studies, remaining detectable for several months.

Dr. Kuperwasser summarized that neither Moderna nor Pfizer used their actual commercial mRNA vaccine products in their preclinical biodistribution studies. Instead, both relied on surrogate constructs packaged in the same or similar lipid nanoparticles. The results of those studies showed that the mRNA and lipid nanoparticles were not confined to the injection site. Systemic distribution was observed, with evidence that the mRNA can cross the blood–brain barrier.

Consistent with these findings, studies in humans have confirmed that vaccine mRNA can be detected in multiple tissues, including lymph nodes, the heart, the central nervous system, and blood. Persistence was also not limited to the short term; in some reports, mRNA has been detected for weeks to months, and in some instances for as long as 706 days post-vaccination. Dr. Kuperwasser concluded that the data indicate widespread biodistribution and that persistence is more prolonged than initially expected, raising important questions and concerns for ongoing research and safety monitoring.

Dr. El-Deiry explained that the work group examined several additional areas of concern related to mRNA COVID-19 vaccines. The first topic was ribosomal frame shifting, a mechanism used by viruses to express different open reading frames that can facilitate infection. He noted that nucleotide-modified mRNA containing pseudouridine can significantly increase frameshifting, by as much as twofold. Evidence suggests that these unintended off-target proteins may trigger immune responses in humans, including the production of antibodies. However, the immunogenic or toxic properties of these non-spike proteins remain unknown, and the potential

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health consequences of prolonged or persistent production of non-spike proteins have not been studied.

Dr. El-Deiry also highlighted reports of DNA impurities found in Pfizer and Moderna mRNA vaccine vials. The most recent findings were reported by Speicher et al., who analyzed 32 vials representing 16 unique vaccine lots and found evidence of fragmented plasmid DNA in both Pfizer and Moderna vials. All Pfizer vials contained the SV40 enhancer origin of replication, which was not detected in the Moderna vials.

He noted that differences exist between the Pfizer and Moderna mRNA vaccines, primarily involving the SV40 promoter-enhancer origin sequences and the detectable amounts of DNA fragments. He also pointed out that the FDA's limit of 10 nanograms was established for naked DNA, not for DNA encapsulated in lipid nanoparticles, which can carry DNA into cells and their nuclei.

Dr. El-Deiry summarized that both the Pfizer and Moderna mRNA vaccines have been found to contain DNA levels exceeding FDA limits. He noted that these limits do not account for lipid nanoparticles, which can carry DNA into cells and nuclei. Concerns were raised about the potential for disruption of DNA integration and gene activation associated with SV40 promoter–enhancer sequences.

He added that there have not been reliable population-based studies in the U.S. evaluating cancer outcomes following COVID-19 vaccination. However, cancers have been reported in mRNA-vaccinated individuals in temporal association with immunization. A total of 48 case reports have been documented, including 24 cases of primary cutaneous lymphoma. He also referenced a study involving 96 cases of pancreatic ductal adenocarcinoma that found worse outcomes among individuals with higher IgG4 levels, which, as noted by Dr. Kuperwasser, may increase with repeated vaccination. Additionally, a case-control study of 76 colorectal cancer cases reported a higher frequency of mismatch repair–deficient cancers among vaccinated individuals.

Dr. El-Deiry stated that there are significant gaps in knowledge regarding the extent of DNA contamination in current vaccine lots. The biodistribution of any contaminating plasmid DNA capable of persistently producing spike protein, genomic DNA, or integrating into tissues or tumors in vaccinated individuals remains poorly understood. The mechanisms involved, as well as the relationship between the prevalence of adverse outcomes and the extent of contamination, require further investigation.

He added that there is limited understanding of how multiple vaccinations may relate to spike protein persistence, and that more research is needed to clarify potential cancer-related mechanisms. While questions about causality remain, several plausible mechanisms have been proposed. He also noted that variations in host susceptibility to adverse outcomes are emerging for certain other vaccine-related events, which may be relevant to the areas of uncertainty currently under discussion.

Dr. El-Deiry summarized that COVID-19 vaccine safety concerns arise from the unexpected biological activities associated with mRNA gene therapy platforms, raising questions about potential pathogenic mechanisms and protections for human research subjects. He recommended developing proactive, modernized safety surveillance programs that incorporate blood- and tissue-based monitoring, large-scale epidemiologic studies, and AI-driven analyses using reliable, standardized datasets. He emphasized the need for expanded autopsy programs

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to help clarify causality in serious outcomes and for systematic evaluation of COVID-19 vaccine safety. He also called for FDA approval policies calibrated to reflect gene therapy–level risks, with DNA impurity limits that account for lipid nanoparticles, and stressed the importance of stronger pharmaceutical accountability and CDC guidelines that ensure transparent risk disclosure, effective mitigation strategies, and robust informed consent practices.

Dr. Bruce Carleton (University of British Columbia) began by providing his disclosures, noting that the presented work was funded through a grant to the Global Vaccine Data Network (GVDN) supported by CDC. He also acknowledged additional government funding sources in Canada, listed his prior consultancies, and mentioned his current work related to COVID-19 vaccination data genomics, funded by React19. He explained that the GVDN is a collaborative network of 32 countries that continues to expand. In addition to the genomics research being presented, he noted that the network is preparing to publish the largest study to date on myocarditis and pericarditis following COVID-19 vaccination, which will also include analyses of booster doses.

Dr. Carleton explained that although the grant supporting this research was canceled with 48 hours' notice in March, he was able to complete some preliminary work. The study included 50 patients aged 11 to 83 years, representing diverse self-reported ancestries. Genetic ancestry testing is planned to help assess the generalizability of findings. Participants had received either the Pfizer or Moderna COVID-19 vaccines. Most myocarditis cases occurred after the second dose, with some following the first or third doses. Among the 30 patients with available data on symptom onset, the median time to myocarditis symptoms after vaccination was 4 days, with an interquartile range of 3 to 26 days.

The study methods included whole-exome sequencing of 50 myocarditis cases using an exome-capture library preparation on the NovaSeq 6000 system, achieving an average depth of 100x. Sequencing reads were aligned to the GRCh38 human reference genome, and 49 of the 50 samples passed quality control, with one excluded due to insufficient DNA quality. The analysis focused on identifying genetic variants found in at least 50% of the 49 cases, with global allele frequencies of 15% or lower according to ClinVar, a database that provides gene and allele frequency information. This approach helped identify genes that appeared more frequently in the study population than would be expected based on global reference data.

Dr. Carleton shared results from a genetic analysis that examined 18 genes, specifically focusing on the protein-coding region, or exome, of DNA. This approach allowed the identification of rare and known variants of significance. Seven variants across four genes were identified, all of which have been previously linked to the development of myocarditis or cardiac inflammation. Four of these variants were in the *TTN* (titin) gene, as expected given its large size, and three were identified in other genes.

Of the 30 patients with available data on time to onset of myocarditis after COVID-19 vaccination, results showed that as the number of homozygous variants increased, the time between vaccination and symptom onset decreased. While the number of cases was small, Dr. Carleton noted this as an interesting trend.

Among the identified genes, one of particular interest was *LDL receptor-related protein 8 (LRP8)*, a variant associated with cardiovascular inflammation and immune response, particularly in coronary artery disease and myocardial infarction. Ten patients were homozygous for the risk allele, and 19 were heterozygous.

Dr. Carleton discussed findings on the angiotensin II type 1 receptor (AGTR1) gene, which has previously been associated with COVID-19 and cardiovascular disease. In this small patient population, specific *AGTR1* genotypes were linked in earlier studies to more than 90% left

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anterior descending artery stenosis, as well as increased susceptibility to myocardial infarction and essential hypertension. Among the 49 cases analyzed, four patients were homozygous and 24 were heterozygous for the identified variant.

He presented a graphic illustrating how these variants function within the renin–angiotensin system. For *AGTR1*, the variant enhances angiotensin II signaling, leading to hypertension, vasoconstriction, and cardiac hypertrophy. In the case of *LRP8*, the variant reduces *APOE* activity, leading to increased p38 MAPK pathway activation and contributing to cardiac inflammation.

Regarding the *VKORC1* gene, Dr. Carleton explained that it is highly expressed in the heart and is known to be associated with warfarin dosage and vitamin K signaling. The gene has also been linked to arterial vascular disease and vessel calcification. Among the analyzed cases, three patients were homozygous and 24 were heterozygous for the identified variant. He briefly explained that disruption of the vitamin K cycle caused by these risk haplotype variants can result in vessel damage that promotes vascular calcification and atherosclerosis.

Regarding the TTN (titin) gene, Dr. Carleton explained that it is one of the most common causes of dilated cardiomyopathy. Approximately 25% of familial and 18% of idiopathic cardiomyopathy cases are attributed to *TTN* variants. These variants have also been associated with acute myocarditis, showing a higher prevalence in affected cases than in controls, as reported in previous research. In this analysis, three patients were homozygous for all four identified variants, two were homozygous for three variants, and 21 were heterozygous. He noted that *TTN* variants contribute to sarcomere insufficiency, which can lead to dilated cardiomyopathy.

Before the grant was canceled in March, Dr. Carleton explained that the goal had been to collect 275 cases for each of the adverse events listed in the table on the left, along with vaccinated control participants who did not experience adverse events. The study aimed to conduct case-control genetic analyses, beginning with genome-wide studies and then expanding to exome sequencing. The next planned phase would have involved whole-genome sequencing to include broader gene coverage and achieve a more comprehensive analysis of the genome.

As a final point, Dr. Carleton noted that genomic studies have revolutionized drug therapy, stating that more than 500 FDA-approved drugs now include genetic information in their labeling. Applying similar genomic research to vaccine adverse events would serve two key purposes. First, it would help clarify the biological mechanisms underlying the pathophysiology of adverse events. Second, it could enable more personalized vaccine strategies for patients with identified genetic risk variants. For example, individuals at higher risk of myocarditis following mRNA vaccination could be considered for alternative vaccines, such as protein-based or non-adenoviral vector vaccines.

Dr. Arjun Srinivasan (CDC/NCIRD) presented an economic analysis of the COVID-19 vaccine. The objectives of this study were to estimate the annual population-level disease burden and healthcare utilization associated with COVID-19 illness and vaccination, including resource use (e.g., outpatient visits and hospitalizations), total cases, total costs, deaths, and quality-adjusted life years (QALYs) lost. The study also aimed to estimate events averted by COVID-19 vaccination and incremental cost-effectiveness across subgroups defined by age and risk status.

The intervention strategies in the analysis compared vaccination with an updated generic mRNA booster to vaccination with no updated booster, meaning vaccination with either the primary series alone or the primary series plus the current booster. The target population included all U.S. adults, stratified by age groups (18–49 years, 50–64 years, and 65 years and older) and by risk status (high risk for COVID-19 complications or not). Pediatric and adolescent groups were

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excluded due to insufficient data for this phase of the analysis. The time horizon was one year, with long-term costs and QALYs lost due to sequelae and deaths beyond one year included. The study was conducted from a societal perspective using 2024 as the costing year and a 3% discount rate.

Simulation modeling was used to project costs and health outcomes for each age group. The model simulated the probability that an individual would remain disease-free or experience COVID-19 illness. Those who became ill could experience a non-hospitalized episode or require hospitalization, with symptomatic individuals potentially incurring outpatient or emergency department visits. Hospitalized patients could progress to severe illness requiring ICU care or ventilation. All individuals who experienced COVID-19 illness were considered at risk for long COVID, while hospitalized patients had additional probabilities of long-term complications or death.

As simulated individuals moved through the model, they accumulated costs and losses in QALYs associated with each health state. The model also included vaccine-related adverse events such as systemic reactions, anaphylaxis, and severe conditions like myocarditis, each associated with specific costs and QALY losses depending on severity. Every probability, cost, and quality adjustment included a most likely estimate and a plausible range of parameter values. Identical cohorts were analyzed using two submodels: one in which all individuals received a dose of the COVID-19 vaccine and another in which they did not, to compare outcomes between vaccinated and unvaccinated groups.

Key inputs were used to inform the model, many of which were based on unpublished epidemiological data that best reflected the current evidence on COVID-19 illness and vaccination effectiveness. These inputs included categories such as infection rates, hospitalization trends, and long COVID outcomes.

Actual monthly hospitalization rates from COVID-NET data were incorporated to capture changes in hospitalization patterns across seasons, using data from the 2023–2024 season. The analysis used seasonally adjusted vaccine impact (SAVI) to integrate vaccine effectiveness with hospitalization data, accounting for vaccination timing and seasonal variations in illness rates.

Costs included direct medical expenses related to COVID-19 illness and vaccination, as well as productivity losses from both paid and unpaid work resulting from the illness. Time costs for vaccination were also factored in. Quality-of-life adjustments were applied to illness events and vaccine-related adverse events, represented as decrements in QALYs in the model.

The analysis was designed to project disaggregated health and economic outcomes stratified by intervention strategy, age group, and risk subgroup. Outcomes included cases, hospitalizations, deaths, costs, QALYs, adverse events, and the number needed to vaccinate. Incremental cost-effectiveness ratios (ICERs), expressed in dollars per QALY gained, were calculated by comparing an updated COVID-19 dose to no updated dose. This metric measured the additional investment in vaccination or cost savings associated with changes in health outcomes, accounting for offsets from averted illnesses. Uncertainty analyses, including probabilistic sensitivity analysis, univariate and multi-way sensitivity analyses, and scenario analyses, were performed to assess the robustness of the results to variations in input parameters.

Preliminary results from this phase of modeling were still under analysis. The results projected cases, long COVID cases, hospitalizations, ICU stays, and deaths, stratified by age and risk group, based on cohorts of 100,000 individuals. The data showed that the number of COVID-19 cases was relatively similar across age and risk groups. However, hospitalizations, ICU stays, and deaths varied substantially, with a much higher burden of severe illness observed among

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adults aged 65 years and older. Vaccination in this group averted a significant proportion of these severe outcomes, highlighting the greater benefit of vaccination among older adults and those at higher risk for complications.

The results showed ICERs for each age group from a societal perspective. Across all age groups, vaccination required an additional investment, reflected in the incremental costs, but yielded additional health benefits measured in QALYs. ICERs ranged from $498,000 per QALY gained for non–high-risk adults aged 18 to 49 years to $149,000 per QALY gained for non–high-risk adults aged 65 years and older. For high-risk adults, ICERs ranged from $ 44,000 to $ 375,000 per QALY gained, indicating greater cost-effectiveness among older and higher-risk populations.

Results from the probabilistic sensitivity analysis revealed that key input parameters were modeled as distributions, enabling the generation of quasi-confidence intervals for each outcome. The findings demonstrated substantial uncertainty in ICERs for most groups, except for high-risk adults aged 65 years and older. This uncertainty reflects the current state of evidence available for COVID-19, as it is a relatively new pathogen.

Additional results showed the number needed to vaccinate (NNV) to prevent one case, one hospitalization, or one death for each age and risk group. NNV values were lowest among high-risk and older adults, indicating a greater benefit from vaccination in these populations. When ICERs were expressed using alternative health benefit measures such as cost per hospitalization or cost per death averted, the results again showed lower costs for higher-risk and older age groups, reinforcing the cost-effectiveness of vaccination in these populations.

Uncertainty analyses showed that ICERs for the non–high-risk 65 and older age group were highly sensitive to changes in SAVI, probability of hospitalization, and vaccine dose cost. Similar patterns were observed across other age and risk groups; however, the results for high-risk adults aged 65 and older were the most stable when input parameters were varied.

When the probability of hospitalization was increased to its upper bound, ICERs became more favorable across all groups and were cost-saving for the high-risk group aged 65 and older. ICERs were less favorable when using the lower bound for hospitalization probability. Results were also highly sensitive to vaccination costs, particularly the vaccine dose itself. Lowering the cost per dose to $60 reduced ICERs to less than $198,000 per QALY for both high-risk and non–high–risk adults aged 50 and older, making vaccination cost-saving for the high-risk group aged 65 and older.

Few cost-effectiveness analyses include vaccine wastage as a separate cost component. When it is included, this typically occurs for new vaccines, where the price per dose has not yet been established. The conventional assumption is that any costs associated with wastage are already reflected in the price per dose if manufacturers allow returns, or in the administration fee if providers bear the cost of unused doses. Conducting scenario analyses on the price per dose can provide valuable insights when vaccine wastage is not fully accounted for under base assumptions.

This analysis included several limitations. Unpublished data were used to derive key model parameters, including VE, symptomatic illness, and the probabilities of hospitalization and critical illness. Data sources varied in representativeness and generalizability, potentially affecting the precision of estimates. VE values were based on data from a single prior season, and only a few COVID-19 seasons were available to inform estimates of seasonality. Evidence on long COVID remains limited, and the model did not account for reductions in transmission, which represents a conservative approach.

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In summary, vaccination was shown to avert substantial morbidity and mortality across all age and risk groups based on disaggregated outcome estimates. The impact varied considerably by age and risk status. Overall economic favorability declined compared to earlier seasons, reflecting a reduced burden of illness. ICERs for adults aged 65 years and older remained robust across plausible parameter ranges. In comparison, ICERs for adults aged 18 to 49 years and 50 to 64 years were more sensitive to input changes and were favorable only under certain conditions for high-risk adults aged 50 to 64 years.

Sanofi Manufacturer Update

Dr. Katie Sharf, Medical Director for Sanofi and a practicing infectious disease physician, shared that during the pandemic, she served on the front lines treating COVID-19 patients and provided clinical oversight for Oregon's state-run mass vaccination site, which administered more than half a million doses. She introduced Nuvaxovid COVID-19 Vaccine Adjuvanted, a recombinant protein-based COVID-19 vaccine built on a well-established technology platform and the only non–mRNA protein-based COVID-19 vaccine available in the U.S., offering an additional protection option. In May, the FDA fully licensed Nuvaxovid based on phase 3 clinical trial data demonstrating its safety and effectiveness in preventing COVID-19. The vaccine is indicated for adults aged 65 and older and individuals aged 12 through 64 who are at higher risk for severe illness. Other global regulatory agencies, including the European Medicines Agency, also approve it. Dr. Sharf stated that safety and effectiveness remain top priorities, with post-marketing data from over 5 million doses administered globally showing no new safety signals for the 2023–2024 or 2024–2025 formulations. Sanofi continues to monitor and report any safety findings and has begun commercializing the vaccine in the U.S., with shipments already underway to healthcare providers and retailers. She concluded by affirming Sanofi's commitment to expanding awareness and access to Nuvaxovid, ensuring that eligible individuals can obtain the nation's only protein-based, non–mRNA COVID-19 vaccine.

Moderna Manufacturer Update

Dr. Bishoy Rizkalla, representing Moderna Medical Affairs, stated that the COVID-19 pandemic posed an unprecedented global challenge. Moderna partnered with the U.S. government through Operation Warp Speed to deliver one of the first authorized vaccines and has since worked with health authorities worldwide to ensure timely access to updated vaccines as variants emerged. Real-world evaluations involving millions of U.S. recipients demonstrated that updated vaccination provided additional protection, particularly for adults aged 65 and older and individuals with risk factors for severe outcomes. These findings were confirmed during the past winter by CDC and governments in Canada, the UK, and across Europe. Dr. Rizkalla explained that Moderna monitors safety through clinical trials, post-authorization studies, and global pharmacovigilance, reviewing every safety signal that arises. Product labels in more than 90 countries reflect all verified signals. The FDA and other health authorities, including those in Canada, the UK, and Europe, have recently approved the updated 2025–2026 booster, concluding that the benefits outweigh the risks for individuals aged 65 and older, as well as for younger individuals with certain underlying health conditions or risk factors. He noted that one of the day's presentations included claims that were not aligned with the broader body of scientific evidence, some of which extended beyond the support of reference studies or contradicted published data. He clarified that claims of long-term persistence of vaccine-derived spike protein or mRNA are refuted by well-controlled biodistribution studies that meet global regulatory standards and have been reviewed by the FDA, showing no evidence of long-term persistence. He added that such studies cannot distinguish between spike proteins from viral infection and those from vaccination, and that one even reported higher spike levels in unvaccinated controls.

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Residual DNA was also mischaracterized, as it is a tightly regulated quality attribute that is tested by validated, FDA-approved assays. Each vaccine lot is tested by Moderna and independently reviewed by the FDA before release. Both animal studies and real-world monitoring of over one billion doses have shown no evidence of genotoxicity. Dr. Rizkalla emphasized Moderna's commitment to transparency and rigorous assessment of the totality of the evidence, pledging to continue publishing validated data and to collaborate with regulators to assess any potential safety signals. He concluded by underscoring the importance of preserving access to FDA-approved vaccines, affirming that Americans should retain the right to choose protection supported by the full weight of scientific evidence.

Pfizer Manufacturer Update

Dr. Paul Balmer, U.S. Vaccines Medical Affairs Lead at Pfizer, thanked the committee and acknowledged the statements from other manufacturers. He noted that COVID-19 has transitioned from a pandemic to an endemic disease but continues to hospitalize hundreds of thousands of Americans and cause thousands of deaths each year. Dr. Balmer emphasized that Pfizer and BioNTech remain deeply committed to producing safe and effective vaccines that protect lives in the U.S. and globally. The Pfizer-BioNTech COVID-19 vaccine has been reviewed by multiple regulatory authorities, including the FDA, and meets all safety and quality control standards. Pfizer's safety systems work in coordination with U.S. government monitoring programs, with all safety data reported through appropriate channels and supplemented by ongoing scientific studies approved by the FDA. He explained that Pfizer conducts real-world data studies involving millions of people and carefully reviews every reported adverse event, ensuring each is submitted to VAERS, which serves as an early warning system but cannot determine causation. FDA and CDC use additional enhanced safety systems, including COVID-19 pregnancy registries and V-safe real-time reporting, to evaluate causation and monitor for rare safety signals. Since the COVID-19 vaccine's approval in 2020, global regulatory assessments have consistently shown that the benefits of mRNA vaccination outweigh the risks. In the past year alone, vaccination prevented an estimated 68,000 to 100,000 hospitalizations, 13,000 to 18,000 ICU admissions, and 5,000 to 7,000 deaths in the U.S. Dr. Balmer concluded by reaffirming Pfizer and BioNTech's dedication to vaccine safety, quality, and effectiveness through continuous monitoring and research, noting that with more than 5 billion doses distributed worldwide and authorization in 83 countries, the vaccines remain among the most closely monitored medical products ever licensed.

Discussion

Dr. Meissner stated that, as Dr. Malone mentioned, there is nothing unique about COVID-19 as a respiratory viral infection and that it cannot be clinically distinguished from RSV or influenza. He noted the ongoing challenge of distinguishing between patients hospitalized with COVID-19 and those hospitalized because of it, and asked whether CDC physicians or hospital clinicians make those determinations. He noted that Massachusetts addressed this issue early in the pandemic, finding that only about one-third of patients hospitalized with COVID-19 were admitted primarily for the disease, while the rest were incidentally positive. He explained that Massachusetts used dexamethasone treatment as a surrogate marker to help differentiate between true COVID-19 illness and incidental infection. Dr. Meissner emphasized that this is a critical issue and asked for more information on how CDC classifies hospitalizations as COVID-19 illnesses. He then raised a second question regarding vaccination of pregnant women and

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hospitalizations among their infants, expressing skepticism about whether those infants were hospitalized because of COVID-19. He asked what symptoms or criteria distinguished those cases from infants who tested positive but were not admitted.

Dr. Srinivasan noted that CDC data indicated approximately 30% of patients had COVID-19 listed as their principal discharge diagnosis, which coincides with the Massachusetts data referenced by Dr. Meissner. He added that other studies have shown similar findings, with COVID-19 as the primary reason for hospitalization in about 30–50% of cases.

Dr. Meissner responded that SARS-CoV-2 can colonize the pharynx and yield a positive PCR result even in the absence of symptoms, underscoring the importance of distinguishing infection from disease. He said he appreciated CDC's willingness to continue discussing the issue.

Dr. Taylor addressed the topic of infant hospitalizations, explaining that infants hospitalized at the time of birth are excluded from the analysis, as are admissions for labor and delivery, injuries, or scheduled procedures. He explained that determining the primary reason for hospitalization is challenging and relies on the medical record since CDC staff are not the treating clinicians. The agency works with state and local health departments to make the best determinations possible with the available data. He acknowledged that ICD-10 codes and treatment indicators, such as steroid use, each offer incomplete perspectives and that different methods can produce different interpretations. He stated that CDC's approach focuses on identifying hospitalizations where COVID-19 had a meaningful impact on care or admission. Although the process is not perfect, he said the algorithm represents an evidence-based method refined over several years to balance accuracy with timeliness.

Dr. Meissner acknowledged the complexity of the task and commended the team for their efforts. He expressed concern that recommendations for vaccinating pregnant women are being made based on data he considers uncertain and suggested that this uncertainty should be more clearly communicated.

Dr. Patton explained that the COVID-NET system collects all hospitalizations among residents within specific surveillance catchment areas, capturing them at the population level for those counties. She described the detailed process used to determine which hospitalizations are due to COVID-19, noting that the data show significant impacts among children and infants. She stated that one in five infants under six months hospitalized with COVID-19 are admitted to the ICU, one in four children aged 0–17 is admitted to the ICU, and up to 40% of children hospitalized due to COVID-19 experience a severe outcome such as death, ICU admission, or mechanical ventilation. She reiterated that infants hospitalized at birth are excluded from COVID-NET data and clarified that testing decisions are made by hospitals, not by CDC. She emphasized that infants under six months have hospitalization rates comparable to adults aged 65–74, as confirmed by national surveillance and other systems.

Dr. Meissner responded that, according to CDC's own data, weekly hospitalization rates since February have been below 0.8 per 100,000, suggesting the burden is currently low. He argued that decisions about future vaccines should rely on recent data rather than cumulative data, given changes in the virus and population immunity. He pointed out that since October of the

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previous year, hospitalization rates for children under 18 have been less than one per thousand and currently less than 0.4 per 100,000.

Dr. Patton clarified that the figures referenced by Dr. Meissner represent weekly rates, whereas cumulative rates offer a broader annual perspective by dividing total hospitalizations by the population within the surveillance area. She explained that including older children, who are hospitalized at lower rates, can make overall rates appear smaller. She emphasized the importance of examining population-specific data to understand how COVID-19 affects different age groups. Infants under six months have the highest hospitalization rate among all children at 223 per 100,000, followed by infants aged 6–11 months. She concluded that this stratified approach allows the surveillance system to identify which groups are most affected by COVID-19 hospitalizations.

Dr. Meissner acknowledged Dr. Patton's earlier points and agreed they were valid but noted that current hospitalization rates for infants under six months of age appear relatively low and may be overstated. He stated that the virus has become less severe over time and that most individuals now have immunity from prior infection or vaccination, which should be taken into consideration when forming recommendations. He then asked at what point low vaccine uptake influences CDC guidance, questioning whether recommendations should be changed if fewer than 20% of people choose vaccination. He compared this to prohibition, suggesting that issuing recommendations the public is unlikely to follow could undermine CDC's credibility.

Dr. Patton clarified that the cumulative hospitalization rate refers to a single season rather than multiple years and represents data for the most recent year only.

Dr. Griffin noted that Dr. Meissner's comments are relevant to obstetrics and gynecology, particularly regarding vaccination during pregnancy. She said that unaddressed confounding factors, such as maternal comorbidities and vaccination timing, could influence outcomes. She proposed further investigation into conditions like preeclampsia, hypertension, diabetes, and obesity, which are increasingly common in women of childbearing age and may affect infant susceptibility. She then asked several questions related to vaccine safety and regulation, including which regulatory bodies approved Pfizer and Moderna's decision not to use the final product in biodistribution studies, whether the companies were aware of plasmid DNA or SV40 contamination, and if they attempted to replicate those findings or conduct population-level testing. She also asked Dr. Carleton why his study was canceled within 48 hours and requested comments from the CDC presenter regarding vaccine effectiveness data reported by CDC.

Dr. Carleton stated that he was unsure why the grant was canceled. He said that HHS indicated the period of performance ended on March 25 and explained that the grant had been a multi-year project involving international surveillance. He added that this information was provided to him by the principal investigators.

The Moderna representative stated that biodistribution studies were conducted to assess the persistence of the mRNA drug product, lipid nanoparticles, and spike protein. The studies were submitted to the FDA and demonstrated that the components primarily localized to the injection site and draining lymph node, with some detection in other tissues and organs that cleared rapidly, showing no detectable spike protein more than 14 days after injection.

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Dr. Griffin asked whether the final product used in vaccination was also used in these studies.

The Moderna representative responded that the studies used commercially representative material manufactured using the same process as the vaccine product, confirming that the mRNA used was identical to that contained in the administered vaccine.

A Pfizer representative stated that the company's biodistribution studies were conducted in consultation with the FDA and used a luciferase-based product manufactured in the same way as Pfizer's drug substance and lipid nanoparticle formulation.

Dr. Malone asked whether Pfizer had used a less sensitive detection method, noting that whole-body imaging with a VIN camera is less precise than tissue dissection followed by luminescence measurement with a luminometer. He also stated that data submitted to the FDA appeared to have been edited compared to submissions to other regulatory agencies and asked Pfizer to comment.

The Pfizer representative responded that the company had no further comment beyond confirming that all biodistribution studies were conducted in close collaboration with the FDA and were included in the data supporting its licensed product.

A Moderna representative added that the detection method used in the biodistribution study for the COVID-19 vaccine employed methods specific to the spike protein, rather than colorimetric techniques.

Dr. Griffin asked whether the companies measured DNA impurities in their vaccine products.

The Moderna representative explained that each lot is tested for detectable DNA using industry-standard methods designed to detect DNA, not RNA, noting that some alternative methods have limitations in distinguishing between the two.

The Pfizer representative added that Pfizer also measures residual DNA within its product and that its assay is validated to detect DNA, not RNA specifically.

Dr. Malone asked whether the thresholds used to determine lot release for DNA contamination were based on standards developed for naked DNA or whether they reflected the enhanced delivery efficiency of the lipid nanoparticle formulation.

A Pfizer representative responded that the thresholds for residual DNA testing were in line with the WHO's approved guidelines for DNA impurities in vaccine products.

Dr. Malone clarified his question, asking whether the FDA had explicitly established those thresholds for naked DNA.

The Pfizer representative reiterated that the company followed WHO guidelines for residual DNA within vaccine products.

Dr. Malone stated that this response did not directly answer his question.

A Moderna representative explained that the thresholds were explicitly developed for Moderna's product.

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Dr. Malone asked whether alternative lot-release thresholds had been established through integration studies using DNA fragments in the company's delivery formulation.

The Moderna representative stated that all safety data are based on control of these thresholds, which are specific to Moderna's product and form the basis for assessing the product's safety.

Dr. Griffin explained that this issue is especially relevant for obstetricians and gynecologists, as many patients ask whether the vaccine is present in breast milk. She referenced a study by Hanna et al., which found evidence of COVID-19 mRNA vaccines in human breast milk and noted that the authors had NIH grants. She also mentioned another recent study, published in the American Journal of Obstetrics and Gynecology, on the transplacental transmission of COVID-19 mRNA. The study analyzed placental, maternal, and cord blood following vaccination; however, she was unable to access the full article to review potential conflicts of interest. She continued by citing an in vitro study showing intracellular reverse transcription of the Pfizer-BioNTech COVID-19 mRNA vaccine in human liver cell lines. She explained that reverse transcription is the process of converting RNA back into DNA, which was previously thought not to occur with these vaccines. She said this raises potential concerns about genetic and epigenetic effects. She then referenced a rat study by Erdogan et al. that reported prenatal exposure to COVID-19 mRNA vaccines induced autism-like behaviors in male neonatal rats. She said these are the types of studies that prompt questions from parents, and that she was bringing them forward to encourage further discussion and responses from industry and regulatory experts.

A Pfizer representative, serving as the research and scientific lead for the COVID-19 vaccine franchise, stated that, from a biological standpoint, it is not plausible for RNA to reverse-transcribe into DNA or integrate into the human genome. He explained that this process requires specific molecules and enzymes that do not exist in humans and are typically found only in retroviruses.

A Moderna representative agreed with Pfizer's statement and added that the FDA's SEERs letter, issued in 2023, evaluated data from hundreds of millions of individuals and found no evidence or indication of genotoxicity related to mRNA COVID-19 vaccines.

Dr. Milhoan stated that as a pediatric cardiologist, he often hears from parents asking what he would do if it were his own child, particularly when vaccine recommendations are discussed. He noted that vaccine uptake among healthcare providers is currently around 10%, which he believes is significant and reflective of broader hesitancy among the general population. He thanked Dr. Meissner for addressing related concerns and acknowledged Dr. Carleton for raising the importance of individualizing care, even within vaccination strategies. He shared that he is seeing a marked increase in cases of dysautonomia, or dysfunction of the autonomic nervous system, among children. He said this disruption within the community warrants further attention. He added that hospitalization decisions for children are often subjective and situational, explaining that pediatricians sometimes admit children with RSV or COVID-19 primarily for observation rather than due to severe illness. He stated that factors such as parental exhaustion or a need for close monitoring can influence these decisions. He inquired

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whether the length of stay was captured in the hospitalization data or if admissions were categorized as positive or negative.

Dr. Taylor explained that length-of-stay data are collected for patients who meet the case definition and are hospitalized, but exclude cases classified as observation.

Dr. Milhoan clarified that, even when admissions are labeled as observation, children may remain for more than 24 hours, complicating classification. He said this nuance can affect how hospitalization data are interpreted and expressed appreciation for the work being done while noting that such subtleties may obscure the whole picture. He then inquired about vaccine hesitancy and data interpretation, stating that the discussion of vaccine effectiveness appeared to have overlooked whether vaccines prevent infection. He referenced the Cleveland Clinic study of more than 50,000 healthcare workers and asked whether those findings were considered. He also wondered whether vaccine effectiveness data were developed prospectively or retrospectively.

Dr. Srinivasan responded that case data are challenging to interpret because widespread at-home testing makes it impossible to capture the whole universe of cases, unlike earlier in the pandemic when testing occurred primarily in healthcare settings.

An SME representative, Ruth Link-Gelles, explained that previous data had shown vaccine effectiveness against SARS-CoV-2 infection through pharmacy-based testing. However, she noted that, with increased home testing and fewer people seeking testing in pharmacies or outpatient settings, those data are no longer sufficient to assess vaccine effectiveness against infection. She stated that people are now less likely to get formally tested for COVID-like symptoms, making it difficult to capture accurate infection data. Because of this, current analyses focus on emergency department and urgent care visits, as well as hospitalizations, to measure vaccine effectiveness against severe disease, the primary goal of respiratory virus vaccines. She added that when vaccine effectiveness against infection could still be measured, it was consistent with levels typically observed with other respiratory vaccines, such as influenza. Similarly, vaccine effectiveness against hospitalization and severe disease has remained comparable to that of the flu over time.

Dr. Milhoan responded that he raised this issue because early CDC communications stated that receiving the vaccine would prevent COVID-19 infection. At the time, studies often excluded vaccinated individuals from testing for COVID-like illnesses based on that assumption. He said it is now clear that injectable vaccines are limited in their ability to prevent respiratory infections because of a lack of mucosal IgA immunity. He also shared concerns from his background in pharmacology, stating he was surprised by what he perceives as a lack of pharmacologic rigor in evaluating dosing, timing, accumulation, and pharmacokinetics for the vaccine. He questioned how long a biologic that produces another biologic, such as the spike protein, remains active, citing a Yale study that showed the spike protein persisted in blood samples. He concluded by expressing confusion about why, given evidence of contamination, the vaccine has not been withdrawn in the same manner as other biologics or medications when contamination is identified.

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Dr. Hoeg stated that some information on vaccine composition is proprietary but confirmed that the data provided by Pfizer and Moderna to the FDA were within established regulatory limits. She emphasized that the FDA takes product safety and public health very seriously and expressed appreciation for independent researchers who brought these issues to light. She said the FDA is aware of the concerns and is not ignoring them, and that she could only share the information the agency has received from the sponsors regarding DNA levels in their products.

Dr. Milhoan asked whether there were any plans for an independent post-production evaluation by the FDA.

Dr. Hoeg responded that such discussions are ongoing and reiterated that the FDA takes the matter seriously and appreciates those who have raised the concern.

Dr. Pollak asked both CDC and vaccine manufacturers to address antibody production and immunity following COVID-19 vaccination and booster shots. He said many people assume vaccination automatically provides immunity, but experience with influenza vaccines shows that is not always the case. He noted that people often question vaccine effectiveness when they contract COVID-19 or the flu after being vaccinated, and that this uncertainty contributes to vaccine hesitancy. He asked about the percentage of individuals who fail to produce antibodies after vaccination, as this affects the risk-benefit ratio, and questioned the need for boosters if sufficient antibodies have already been generated. He inquired about the antibody titer level at which an individual is considered protected. He suggested that if adequate neutralizing antibodies are produced, boosters may not be necessary, even with emerging viral strains. Dr. Pollak also inquired whether immune response studies considered cytokine gene polymorphisms, which can influence individual inflammatory responses, and whether independent laboratories had confirmed results regarding IgG4 and anti-idiotype antibodies. He concluded by asking whether CDC has data defining antibody levels that indicate protection and whether those levels are used when determining booster recommendations.

An SME representative, Dr. Thornburg from CDC's Laboratory and NCIRD, explained that numerous studies, including those conducted by CDC and vaccine manufacturers, have examined antibody responses following vaccination and infection. She said that most people develop strong neutralizing antibodies that correlate with protection. Still, immunity against upper respiratory viruses is generally not sterilizing due to how the immune system interacts with mucosal surfaces and the continuous evolution of viruses. She noted that it is challenging to define a specific antibody level that guarantees protection, as antibody responses fluctuate over time and can vary with the emergence of new viral lineages. Therefore, while neutralizing antibodies are protective, their effectiveness fluctuates, meaning a test result today cannot reliably predict susceptibility even a week later.

Dr. Malone responded that there are no well-defined or standardized correlates of protection for COVID-19, either cellular or humoral, and that no formal analyses have been completed to establish them. He said that, without this validation, it is inaccurate to claim a correlation between antibody levels and protection.

Dr. Meissner agreed that identifying a correlate of protection is complex but stated that neutralizing or binding antibody levels have been shown to correlate with protection against

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symptomatic infection during the first few months after vaccination. He cited a study published in the *New England Journal of Medicine* as evidence.

Dr. Malone challenged him to identify the study, asserting that protection is more likely driven by cellular immune responses rather than antibodies.

Dr. Meissner agreed, adding that while antibody protection wanes over time, cellular immunity continues to protect against severe disease, such as hospitalization and death. He concluded that correlates of protection are multifaceted, involving multiple components of the immune system, and that any antibody-based correlation is temporary.

Dr. Malone stated that in clinical testing and pathology, defined correlates of protection require rigorous and validated methods. He said that the “soft endpoints” being discussed do not meet that standard and criticized the tendency of some regulatory agencies, including the FDA, to treat antibody titers in animal models as indicators of vaccine effectiveness. He said this practice is unscientific and misleading, emphasizing that an indicator of immune response is not the same as a proven correlate of protection. He explained that defining a true correlate of protection is extremely difficult, even for influenza, where existing correlates only apply to specific vaccine types. He expressed concern that public statements from health officials and media have misrepresented antibody levels as established measures of protection, which he said is inaccurate and contributes to confusion.

Dr. Meissner responded that the issue is indeed complex and agreed with Dr. Malone’s distinction between mechanistic and non-mechanistic correlates of protection. He explained that mechanistic correlates are directly linked to the immune processes that inactivate the virus, while statistical associations with unrelated immune responses are not true correlates. He noted that the definition of correlates of protection depends on the endpoint being measured, whether it is severe disease, mild illness, asymptomatic infection, or complete prevention of infection. Each endpoint involves different immune components, including mucosal IgA, systemic IgG, and multiple T-cell subclasses. He said these factors make it challenging to define a single correlate of protection but added that some studies, such as one published in the *New England Journal of Medicine*, have identified antibody levels that correlate with protection shortly after vaccination.

Dr. Malone asked whether they agreed that antibody titers cannot serve as a surrogate for individual protection and that antibody presence does not necessarily indicate protection.

Dr. Meissner acknowledged that protection.

Dr. Pollak expressed his appreciation for the discussion between Dr. Malone and Dr. Meissner and suggested that any statement issued by the committee should acknowledge that the COVID-19 vaccine does not guarantee 100% protection. He said this clarification is necessary because many members of the public believe that vaccination automatically provides full immunity. He explained that when people realize vaccination may not provide complete immunity, they begin to weigh the benefits and risks differently, which can influence their willingness to get vaccinated. He emphasized that clear communication from the committee is essential to address this misunderstanding.

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Dr. Blackburn thanked the speakers and highlighted the key role of pharmacists in vaccine access. She noted that pharmacies have administered approximately 67% of COVID-19 vaccines to adults aged 18 and above. She stated that maintaining access to vaccines in pharmacy settings is essential for providing timely patient care. She also referred to the earlier discussion about low vaccine uptake among healthcare professionals, reported at around 10%. She asked whether any surveys had been conducted to understand the reasons behind the low uptake. Additionally, she inquired whether higher influenza vaccination rates might have been influenced by flu vaccine mandates in healthcare systems and how this compares to COVID-19 vaccination uptake.

Dr. Black, an SME representative from the Immunization Services Division, responded that the data shown from NHSN are based on facility-reported vaccination coverage submitted to CMS. She explained that these reports may miss undocumented vaccinations and that influenza coverage tends to appear higher because many facilities require flu vaccination and provide it on-site, which improves documentation. She added that survey data show higher coverage rates than facility reports, with about 40% of healthcare personnel overall reporting vaccination and closer to 50% among physicians. When asked about reasons for non-vaccination, most respondents stated that they did not feel at risk of contracting COVID-19 or were not concerned about it. She noted that vaccine demand tends to rise when new variants emerge or disease levels increase. She added that access and convenience, such as whether vaccines are available on site, significantly affect coverage.

Dr. Blackburn then raised concerns about the package insert information for the COVID-19 vaccines Comirnaty and Spikevax, noting that section 13.1 states that the vaccines have not been evaluated for potential carcinogenicity, genotoxicity, or impairment of male fertility. She explained that while this language is standard for many drugs, some medications explicitly state that studies have shown no evidence of tumorigenic or mutagenic effects. Given reports of rising cancer rates and the individual case reports presented earlier, she suggested that additional studies be conducted to assess these concerns more fully. She shared that her mother experienced a dermatologic immune reaction after a COVID booster in early 2022 and was later diagnosed with EGFR-positive lung cancer, as were four others in her small hometown of fewer than 13,000 residents. She questioned whether this could represent a potential cancer cluster and asked whether CDC epidemiologists are tracking such patterns or investigating possible links to vaccines, viruses, or environmental factors. She also expressed concern that the Mississippi Cancer Registry still relies on faxed reporting and does not track biomarkers, which limits surveillance capabilities, and emphasized the need for more robust studies to confirm or rule out potential risks.

Dr. Hoeg responded that while she initially thought the question was directed to CDC, she appreciated the concern and agreed that thorough epidemiological studies are essential to determine whether there is an increase in cancer rates potentially associated with COVID-19 vaccines or specific cancer types. She said these questions would be valuable for CDC to explore further. She noted that novel research methods could be applied to investigate potential carcinogenic risks but acknowledged that such studies are complex and challenging to conduct.

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She reiterated that the FDA's primary responsibility is to protect public health and that the agency takes these questions seriously, appreciating the information being shared.

Dr. Kulldorff commended Pfizer for conducting a randomized, placebo-controlled clinical trial of the COVID-19 vaccine in pregnant women, stating that such studies are essential for understanding vaccine safety in this population. He noted that the trial included approximately 350 participants, split evenly between the vaccine and placebo groups. He stated that the data Pfizer shared appeared to show a fourfold higher rate of birth defects among vaccinated participants. He said his own calculation indicated a p-value of 0.05 and described this as concerning, even with the small sample size. He asked Pfizer to comment on the finding and to confirm whether vaccinations were administered between 22 and 32 weeks of pregnancy.

A Pfizer representative, who serves as the head of Vaccine Clinical Research and Development, clarified that the study was initially designed before vaccination during pregnancy was recommended and was stopped early once those recommendations changed. She said about 350 women were randomized 1:1 between vaccine and placebo and received the vaccine between 24 and 36 weeks of pregnancy. She stated that congenital abnormalities occurred in about 5% of the vaccine group and 3% of the placebo group, not a fourfold increase as suggested. She noted that the observed rates were consistent with the background rates of congenital anomalies in the general population and noted that most such anomalies occur in the first trimester, before vaccination, making causality unlikely.

Dr. Kulldorff said that according to the materials Pfizer provided, there were eight birth defects in the vaccinated group and two in the unvaccinated group, suggesting a four-fold difference. He asked whether those numbers were incorrect.

The Pfizer representative replied that the data could be viewed in different ways, as congenital anomalies may be reported either as serious adverse events or as adverse events of special interest. She stated that upon review of serious adverse events, the rates were approximately 5% versus 3%, and she referred Dr. Kulldorff to the tables published on Pfizer's website for full details.

Dr. Kulldorff asked again whether Pfizer disputed the numbers eight and two.

The representative stated that the data were presented transparently and publicly, reiterating that differences in reporting categories explain the variation.

Dr. Hayes, from the American College of Nurse-Midwives, interjected to note that major birth defects generally occur during the first trimester, before vaccination in this study.

Dr. Kulldorff replied that birth defects are typically identified after birth, which is why he sought clarification on the data.

Dr. Griffin asked for additional details, requesting that Pfizer specify which congenital anomalies were reported, noting that while significant structural development occurs before 24 weeks, certain anomalies can appear later in pregnancy. Dr. Griffin added that certain congenital anomalies can still develop after 24 weeks of pregnancy, such as microcephaly,

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ventriculomegaly, or kidney anomalies. She explained that this was why she had asked Pfizer to specify which anomalies were reported in the study.

Dr. Stein asked whether there was an explanation for the relatively high rate of hospitalization among infants younger than six months and if there were any data on underlying medical conditions or comorbidities in that group.

Dr. Taylor responded that CDC collects data on comorbidities across all age groups. He explained that for some groups, such as children aged 6 to 23 months, prematurity is present in about 20% of cases. Although those data were not included in the slides for this meeting, they have been presented to the committee previously. He said that overall, the patterns of underlying medical conditions are not substantially different in the under-six-month age group. Because many chronic conditions take time to develop, such comorbidities are generally less common among very young infants.

Dr. Patton stated that CDC reviews medical conditions across all patients and that among infants younger than six months hospitalized due to COVID, 71% had no underlying conditions.

Dr. Stein inquired about the effectiveness of vaccines in immunocompromised adults aged 65 and older and whether analyses are stratified by comorbidities, emphasizing the importance of identifying high-risk groups.

SME representative Ruth Link-Gelles explained that CDC collects data on both immunocompromising and non-immunocompromising conditions. Sensitivity analyses that stratify or control for non-immunocompromising underlying conditions consistently show no impact on vaccine effectiveness. In contrast, vaccine effectiveness often differs for people with immunocompromising conditions, so primary analyses stratify by immunocompromised status and may control for other conditions.

Dr. Malone asked whether older adults, who experience immunosenescence, respond to vaccination in the same way as younger cohorts.

The SME representative clarified that “underlying medical conditions” refers to diagnoses such as cancer or diabetes, not age. CDC also stratifies by age. Earlier in the pandemic, when coverage was higher, analyses using 10-year brackets above age 65 showed a decline in effectiveness beginning around age 75. This evidence contributed to the recent recommendation for an additional annual dose for adults aged 65 and above, who may have lower or more quickly waning protection.

Dr. Stein asked about the vaccine safety signal presentation, noting that it included a table of adverse events of special interest and questioning whether the list was complete. She also asked why the analysis focused on stroke and whether other conditions had been considered but not shown.

Dr. Su explained that multiple CDC vaccine safety monitoring systems serve different purposes. He said the VSD conducts detailed statistical analyses, and the example presented focused on stroke. Other systems, such as the Vaccine Adverse Event Reporting System (VAERS), serve as passive surveillance tools designed to detect unusual patterns or new potential safety signals

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rather than determine causality. He said the systems complement each other, each with strengths and limitations, and together they provide comprehensive safety monitoring.

Dr. Stein concluded by commending Dr. Srinivasan's vaccine effectiveness presentation, saying it clearly described the limits of the test-negative design. She said the analysis appropriately focused on individuals presenting with respiratory symptoms and emphasized that these findings represent vaccine effectiveness against severe outcomes, not infection. She agreed with earlier comments that results should be interpreted within that context.

Dr. Hayes, representing the American College of Nurse Midwives, thanked the presenters for their work and commended the quality of the data that have been monitored over the past five years. She also recognized Dr. Tom Shimabukuro for his contributions to the V-safe program, which has been instrumental in collecting data on COVID-19 vaccination during pregnancy. She expressed appreciation for his efforts and the broader team's continued commitment to monitoring vaccine safety in this population.

Dr. Fryhofer, a general internal medicine physician in Atlanta and adjunct associate professor of medicine at Emory University, introduced herself as an ACIP liaison who has served on multiple vaccine workgroups, including the COVID-19 Vaccine Work Group since its inception. She said the presentations on biodistribution and T-cell studies were highly technical, complex, and somewhat confusing. She expressed surprise that such preliminary research was presented to the full committee rather than in a workgroup setting. She emphasized that the findings underscored the need for continued research. She noted that on August 5, HHS canceled $500 million in contracts and 22 grants related to mRNA vaccine development, describing the decision as a major setback that leaves the country more vulnerable to future pandemics and threatens progress in mRNA-based cancer treatments. She said mRNA vaccines developed through Operation Warp Speed were essential to ending the COVID-19 pandemic and remain a critical tool for public health preparedness. She also shared a personal perspective, explaining that she has two grandchildren due in November and expressed concern about whether they will be protected through maternal vaccination and later eligible for their own COVID-19 vaccinations at six months of age. She urged the committee to make vaccines available to protect infants, noting that hospitalization rates are highest among children under two years old and that maternal vaccination can significantly reduce that risk. She expressed concern about what she described as an erosion of committee integrity and transparency in the development of vaccine recommendations. She said data are sometimes selectively used to support specific conclusions rather than reflecting the full body of evidence, undermining trust and introducing bias. She emphasized that in June, the AMA and 79 other medical societies reaffirmed their support for vaccines as the best protection during respiratory virus season, including COVID-19 vaccines. She concluded by saying that while the administration has stated it will continue to make vaccines available to everyone who wants them, recent federal policy decisions appear to contradict that goal.

Dr. Hopkins stated that severe COVID-19 illness continues to cause hospitalizations and deaths, with the greatest impact among adults aged 75 years and older but also causing significant illness in younger adults and children. He noted that while most adults hospitalized with severe disease have comorbidities, many hospitalized children do not. He said vaccines

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remain effective in preventing severe disease across all tested age groups and that vaccination provides additional protection beyond any immunity gained from prior infection. He emphasized that infants under six months of age have no protection unless their mothers were vaccinated during pregnancy and concluded by stressing that access to COVID-19 vaccines must be maintained for everyone who wishes to be vaccinated, adding that low uptake should not be used as a reason to limit access or protection against severe outcomes.

Dr. Paulsen acknowledged that vaccine trust remains low in some populations and emphasized that ACIP should continue to evaluate the science objectively, raising valid concerns when warranted but affirming vaccine safety when supported by evidence. He noted that no medical intervention is entirely risk-free, but vaccines provide significant benefits that outweigh potential risks. He cautioned against basing policy decisions on anecdotal or limited basic science findings and urged the committee to rely on robust data. Regarding Dr. Carleton's findings on myocarditis, he said the research was valuable and deserving of further study but did not outweigh the evidence that vaccines are safe and effective. He highlighted that young children, particularly those aged 6 to 23 months, face hospitalization risks similar to adults aged 50 to 64 and that over half of hospitalized children have no underlying conditions. Dr. Paulsen said that all members share the goal of protecting children and minimizing harm and urged the committee to base its recommendations on data rather than theoretical concerns. He concluded by requesting that the proposed voting language be made publicly available before the presentation to ensure transparency.

Dr. Munoz, representing the Infectious Diseases Society of America, thanked the committee and said she agreed with many of the points made by her liaison colleagues. She emphasized that the discussions raised important scientific questions and highlighted the need for continued funding to advance research. She described mRNA technology as a breakthrough that enabled control of the COVID-19 pandemic both in the United States and globally. She noted that mRNA vaccines have been administered to more people in a short time than almost any other vaccine, providing extensive safety data from clinical trials and effectiveness data from post-authorization studies. Dr. Munoz added that mRNA vaccines have been the primary vaccines used in pregnancy and that strong evidence supports their value in protecting infants who are too young to be vaccinated. She concluded by advocating for continued access and protection for the most vulnerable populations, including older adults, immunocompromised individuals, people with high-risk conditions, and especially children under two years old and infants under six months who rely on maternal antibodies. She urged continued funding, research, and long-term follow-up to support the safe development and application of this technology for future vaccines.

Dr. Buchanan thanked the committee for the discussion on COVID-19 vaccines and said she would like additional clarity on the specific question being addressed regarding vaccine recommendations. She expressed concern about access issues in Georgia, explaining that although earlier statements suggested there should be no barriers, many providers in the state are limiting vaccine availability for their patients. She shared an example of a colleague whose grandchild has not yet been born, but whose mother was denied the COVID-19 vaccine for her two older children by their pediatrician. Dr. Buchanan said this reflects a real and ongoing

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access problem and urged the committee to clarify guidance and ensure that COVID-19 vaccines remain available to all who wish to receive them.

Dr. Retsef Levi (ACIP WG Chair) presented the 2025–2026 COVID-19 vaccine discussion framing. He reported that while the working group did not reach complete consensus, most members shared concerns about how COVID-19 vaccine data are being assessed and communicated. Members felt that current evaluations of protection against severe outcomes such as hospitalization, ICU admission, death, and long COVID are based on low-quality data and uncertain analyses.

Dr. Levi stated that vaccine-related injuries are not adequately recognized by existing monitoring systems, leading affected individuals to receive inadequate care. He emphasized that this lack of recognition is both an ethical and public health issue that undermines trust in vaccination programs.

Dr. Levi noted that published research indicates ongoing safety uncertainties and potential biological adaptations related to mRNA vaccines that are not being thoroughly examined. He recommended more transparent communication of risks and uncertainties to both healthcare providers and patients to support informed consent. The group plans to develop recommendations to enhance diagnosis and support for individuals affected by vaccine injuries, as well as to strengthen safety surveillance systems.

He discussed concerns about the reliability of vaccine effectiveness assessments, stating that the “number needed to vaccinate” (NNV) has not been shared for recently authorized products despite FDA requests. Data from the United Kingdom show higher NNV estimates than those used in U.S. models, raising questions about the accuracy of benefit calculations. Dr. Levi said that with multiple booster cycles completed and less virulent variants circulating, vaccine efficacy should be reassessed using current data and communicated transparently to support informed decision-making.

Dr. Levi addressed methodological issues with current analyses, stating that the test-negative design is not appropriate for evaluating hospitalization or mortality. He said this approach can produce misleading results and may overestimate vaccine effectiveness. While not establishing specific efficacy levels, he called for more rigorous study designs and supported the FDA's plans to conduct new randomized controlled trials. He noted that existing mRNA trials did not show benefits for all-cause mortality or hospitalization and that protection appears short-lived, lasting only a few months. [Adenovirus COVID vaccines did reduce all-cause mortality in the clinical trials.] He added that repeated vaccination may increase vulnerability to other respiratory viruses, referencing evidence of increased RSV susceptibility in children.

He observed that recent data show lower COVID-19 incidence compared to prior years, with reduced severity despite stable vaccination rates. He suggested this may reflect viral evolution toward lower virulence but emphasized the need for continued monitoring.

Dr. Levi reviewed safety issues the group felt CDC has not fully acknowledged, including myocarditis, cardiovascular events, prolonged post-vaccine syndromes, and possible regulatory gaps. He referenced case reports of adolescent deaths following Pfizer vaccination, attributed by pathologists to fulminant myocarditis, noting disagreement with CDC conclusions. He questioned inconsistencies in how vaccine- and infection-related deaths are classified and called for a stronger safety culture and transparent communication.

He cited studies showing subclinical myocarditis in 2 to 3 percent of vaccinated individuals, with elevated troponin levels suggesting heart injury, including among females. He stated that long-term monitoring systems for myocarditis are lacking, which undermines public trust.

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Dr. Levi described post-vaccine syndrome (PVS) as a prolonged, complex condition with overlapping symptoms similar to long COVID. The true frequency is unknown, and current systems do not capture such cases because diagnostic codes are absent. He referenced new research by Professor Christine Stabell Benn indicating that existing safety monitoring is not designed to detect chronic vaccine-related conditions.

He also discussed discrepancies between public messaging and recent findings on mRNA persistence, noting evidence that vaccine components may remain in the body longer than stated on CDC's website. He said products that behave differently from their intended mechanism require closer safety review and transparent reporting.

Vaccination during pregnancy was a key area of debate. While some members supported recommendations for pregnant women, most expressed caution due to limited safety data. The group chose not to bring the issue to a vote and urged the FDA and CDC to reexamine available evidence before issuing further guidance.

Dr. Levi noted that the group felt there were not sufficient data to compare specific vaccine products but highlighted that adenovirus-based vaccines appeared to reduce all-cause mortality in early trials, while mRNA vaccines did not. Some studies, including VA data, suggested Moderna's vaccine provided higher protection with fewer adverse events. He encouraged FDA and CDC to evaluate a broader range of vaccine options to ensure the best balance of risk and benefit.

He emphasized that public trust in COVID-19 vaccines is at a critical low point. He cited surveys showing a decline in confidence in the "safe and effective" message and noted that only about 8% of healthcare workers reportedly agree with current vaccine recommendations. He said restoring trust requires transparency and accountability.

Dr. Levi addressed informed consent, stating that current practices do not ensure patients receive meaningful information. The Vaccine Information Statement does not adequately present risks, benefits, or uncertainties. The working group recommended that CDC create a more comprehensive, plain-language informed consent process for patients and providers that clearly describes known risks and data limitations. Dr. Levi said improving informed consent is essential to rebuilding trust and upholding ethical standards in public health communication.

He explained that this concern led to one of the group's formal recommendations: that CDC establish a more consistent and comprehensive informed consent process. He said this process should use clear, accessible language for both patients and healthcare providers, outlining known risks, data limitations, and areas of uncertainty. He added that strengthening informed consent is vital to rebuilding public trust and ensuring vaccine decisions are made transparently and ethically.

Recommended Updates to the Vaccine Information Statement:

1. Current assessments regarding the protection provided by COVID-19 vaccines and especially seasonal COVID-19 boosters against severe outcomes (e.g., death, hospitalization and long COVID) are of low quality. At best, the additional protection provided by a seasonal booster is moderate and of short duration.
2. There is evidence that repeated seasonal mRNA boosters cause acquired changes in the immune system and may be associated with increased vulnerability to future infections, including SARS-CoV-2 and other respiratory viruses. These risks, as well as potential risks of autoimmunity, chronic inflammation, immune tolerance and impaired immune surveillance including immune fatigue or suppression, are currently not well understood.

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3. There are documented deaths from symptomatic and subclinical myocarditis, pericarditis and potentially other cardiovascular conditions post COVID-19 vaccination, including of healthy children, with probable causal relationship to the mRNA vaccines. This risk is likely relatively small but currently not well understood.
4. Clinical reports demonstrate that in some cases COVID-19 vaccines can cause prolonged and debilitating post vaccine syndrome (PVS). The injuries associated with PVS involve diverse symptoms and conditions, many overlapping with long COVID injuries. Some of the observed symptoms and conditions may include insomnia, chronic pain and fatigue, dysautonomia (e.g., POTS), immune dysregulation and deficiency, autoimmune disorders, severe neuropathy and other neurodegenerative conditions, cardiovascular and neurovascular injuries, and severe clotting. The frequency of PVS and related risk factors are currently not well understood.
5. There is evidence that in some individuals vaccinated with mRNA COVID-19 vaccines, the resulting spike protein, the mRNA and the nano-lipids formulation components persist in different body organs, including lymph nodes and the heart, for a prolonged period of months and possibly years in some patients. Prolonged and persistent exposure to spike, mRNA and nano-lipids particles is associated with post-vaccine syndrome (PVS) injuries as well as potentially other side effects that are currently only partially understood.
6. The safety and the efficacy of COVID-19 vaccination during pregnancy have never been tested in appropriately powered randomized clinical trials. In one randomized trial there was observed numerical imbalance of higher number of babies with congenital malformation among those born to vaccinated women.

Dr. Levi clarified that the group is not asking CDC to adopt specific wording but is urging the agency to update the Vaccine Information Statement and other communication materials to reflect current knowledge and uncertainties better. He said the goal is for CDC to develop clear, balanced language that helps patients and healthcare providers have honest discussions about both the benefits and risks of vaccination. This approach, he explained, would allow for informed consent that accurately reflects what is known and not yet known, ensuring that vaccine guidance remains transparent and aligned with ethical public health communication.

He outlined the guiding principles the working group used when developing vaccination policy recommendations. The group agreed that vaccination should remain within the FDA-authorized population and that benefits, risks, and uncertainties must be clearly communicated as part of informed consent. Members debated whether vaccination guidance should be based on population-level recommendations or individual clinical decisions. The majority supported an individual-based approach, concluding that COVID-19 vaccines should be prescribed by a clinician rather than administered under standing orders. This approach would allow for personalized discussions between patients and healthcare providers about prior infections, immune response, comorbidities, and the balance of risks and benefits. He noted that this level of individual consideration is more appropriate now that the situation is no longer an emergency. While some concerns were raised about access, he said most high-risk individuals are already engaged with healthcare providers, making the prescription-based model reasonable. He added that a minority of members held differing views, which would be shared by Dr. Bernstein.

Dr. Henry Bernstein (Zucker School of Medicine) shared additional considerations from the work group regarding COVID-19 vaccination policy and practices. He emphasized that clear and

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consistent vaccine recommendations are critical for maintaining public confidence, increasing vaccination rates, and reducing disease incidence. When coverage declines due to loss of trust, outbreaks can reemerge, underscoring the importance of transparency and effective communication. He noted that vaccine development is a complex and lengthy process that often takes years and involves collaboration between public and private sectors. Operation Warp Speed was cited as an example of a successful partnership, with COVID-19 vaccines continuing to perform well in preventing severe illness and death.

Dr. Bernstein also highlighted that vaccine safety is rigorously evaluated at every stage, from development to post-implementation monitoring. He commended CDC's unprecedented safety surveillance efforts during the pandemic, describing them as vital for maintaining public trust. He specifically discussed the Vaccine Adverse Event Reporting System (VAERS), explaining that it serves as the nation's early warning system for potential vaccine safety issues. He clarified that while anyone can submit reports to VAERS, the system does not establish causation but serves as a valuable signal-detection tool that identifies patterns warranting further investigation.

Dr. Henry Bernstein explained that COVID-19 vaccine safety monitoring has been extensive, continuous, and remains ongoing. He noted that multiple systems are in place to evaluate safety, including a pregnancy registry that tracks maternal and infant outcomes over time. Rapid-cycle analyses are also conducted to monitor specific outcomes and quickly identify potential concerns warranting further investigation.

He emphasized that the COVID-19 vaccine continues to provide additional protection against COVID-19–related emergency room visits, urgent care visits, hospitalizations, and critical illness. Among children and adults alike, vaccinated individuals experience lower rates of these outcomes than unvaccinated individuals. He added that vaccine effectiveness should be viewed as an added layer of protection in a population where many people already have infection-induced or vaccine-induced immunity, or both.

Dr. Bernstein also highlighted ACIP's three guiding principles: science, safety, and access. Science remains central to ACIP's decisions, and the data continue to show that COVID-19 vaccines are both safe and effective. He emphasized that equitable and easy access to vaccines for everyone who wants them is essential to maintaining public health protection.

Dr. Henry Bernstein discussed ongoing challenges and data related to COVID-19 vaccination, emphasizing how shared clinical decision-making and the requirement for provider prescriptions create unnecessary barriers to vaccination. While healthcare providers routinely discuss the benefits and risks of vaccines with patients, shared clinical decision-making can lead to confusion, as it lacks a clear default in favor of vaccination and is often interpreted as optional. The added requirement for a prescription further complicates access and does not effectively target those at the highest risk of harm.

He noted that the U.S. has approximately 330 million people, including more than 18 million children under the age of five, who are more likely to be infection-naive or unvaccinated, highlighting a key population for ongoing protection efforts. COVID-19 vaccines have demonstrated safety in children ages six months to eleven years, with no confirmed cases of myocarditis in those under five. Rapid-cycle analyses have also shown no increased risk for 22 other prespecified health outcomes following vaccination.

Dr. Bernstein referenced CDC data showing that hospitalization rates for COVID-19 remain highest among infants and young children under two years old, particularly those under six months. Although their overall numbers are small, the population's large size means the impact remains significant. Infants under six months experience hospitalization rates comparable to adults aged 65 to 74, underscoring the importance of maternal vaccination.

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He explained that vaccination during pregnancy provides protective antibodies to newborns and young infants, similar to other vaccines such as RSV, influenza, and Tdap, all of which protect infants too young to be vaccinated. Ongoing monitoring shows no increased risks for maternal, pregnancy, or infant outcomes associated with COVID-19 vaccination during pregnancy, and the benefits continue to outweigh any potential risks. Dr. Bernstein also emphasized that older adults, notably those aged 65 and above, experience reduced immune responses with age and therefore benefit significantly from staying up to date with COVID-19 vaccination.

Key Messages for Consideration:

1. COVID-19 vaccination rates in the younger pediatric population are very low: the primary COVID-19 vaccination series is needed
2. Antepartum vaccination especially helps protect infection-naïve newborns and young infants under 6 months of age
3. Older people do not make as good an immune response as when younger ("Immunosenescence")
4. COVID-19 vaccination matters for pregnant women, pediatric patients especially < 2 years of age, people 65 years and older, those of any age with a weakened immune system or chronic medical conditions, and anyone who feels they want protection for themselves or their family.

Dr. Retsef Levi (ACIP WG Chair) presented the final proposed recommendations from the COVID-19 Vaccine Work Group.

Proposed Recommendations:

1. It is the sense of the committee that the CDC engages in an effort to promote more consistent and comprehensive informed consent processes, and as part of that considers adding language accessible to patients and medical providers to describe at least the six risks and uncertainties included in the WG chair presentation.
2. It is the sense of the committee that state and local jurisdictions should require a prescription for the administration of a COVID-19 vaccination.
3. It is the sense of the committee that in conversations with patients before COVID-19 vaccination, authorized healthcare providers discuss the risks and benefits of the vaccination for the individual patient. The discussion should consider known risk factors for severe outcomes from COVID-19, such as age, prior infections, immunosuppression, and certain comorbidities identified by the CDC, and include a discussion of the potential benefits and risks of vaccination and related uncertainties, especially those outlined in the vaccine information statement, as part of informed consent.
4. The pediatric and adult immunization schedules for administration of FDA-approved COVID-19 vaccines should be updated as follows:
    - Adults 65 and older: Vaccination based on individual-based decision-making*
    - Individuals 6 months to 64 years: Vaccination based on individual-based decision-making—with an emphasis that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.

      **Also known as shared clinical decision making.*

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Discussion for COVID-19 Vaccines Vote #4

Dr. Hibbeln stated that, in his view, the committee's discussions clearly demonstrate that members are not opposed to vaccines. He emphasized that the robust scientific debate, mutual respect among members, and inclusion of external experts reflect a thoughtful, open-minded approach rather than any predetermined stance. He noted that understanding the risks and benefits of vaccines is essential to the committee's work, acknowledging the difficulty of quantifying these factors. Dr. Hibbeln concluded by affirming that the FDA, CDC, and the committee are collectively committed to evaluating and clearly communicating both the risks and benefits of vaccination to the public.

Dr. Meissner requested clarification on whether adults aged 65 and older would be eligible to receive the COVID-19 vaccine at a pharmacy under the proposed recommendation.

Dr. Kulldorff responded that the recommendation ensures coverage with zero cost-sharing under SHIP, ACA plans, and Medicare Part B for all individuals aged six months and older, including children up to age 18. He explained that this means there would be no insurance restrictions on receiving the vaccine.

Dr. Meissner then asked if a prescription would be required.

Dr. Kulldorff clarified that the prescription issue was addressed in a separate vote (Vote #2) and is outside the committee's authority, as state regulations determine prescriptions.

Vote: COVID-19 Vaccines Vote #4

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the vaccine into the record:

> The pediatric and adult immunization schedules for administration of FDA-approved COVID-19 vaccines should be updated as follows:
>
> - Adults 65 and older: Vaccination based on individual-based decision-making*
> - Individuals 6 months to 64 years: Vaccination based on individual-based decision-making—with an emphasis that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.
>
> **Also known as shared clinical decision making.*

Motion/Vote: COVID-19 Vaccines

Dr. Hibbeln motioned to approve the recommended voting language, stating, "The pediatric and adult immunization schedules for administration of FDA-approved COVID-19 vaccines should be updated as follows:

o Adults 65 and older: Vaccination based on individual-based decision-making*

o Individuals 6 months to 64 years: Vaccination based on individual-based decision-making—with an emphasis that the risk-benefit of vaccination is most favorable for individuals

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who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.
*Also known as shared clinical decision making." Dr. Malone seconded the motion. No COIs were declared. The motion carried with 12 votes in favor, 0 votes opposed, and 0 abstentions. The disposition of the vote was as follows:

12 Favored: Meissner, Pollak, Malone, Pagano, Milhoan, Blackburn, Griffin, Stein, Hibbeln, Pebsworth, Levi, Kulldorff
0 Opposed:
0 Abstained:

Discussion for COVID-19 Vaccines Vote #1

Dr. Meissner asked whether the recommendation implied that informed consent must be obtained before COVID-19 vaccination.

Dr. Levi explained that the intent was to send a strong message urging CDC to improve its communication of risks and uncertainties to patients and healthcare providers, including through updates to the Vaccine Information Statement (VIS) and other communication materials. He clarified that the group was not prescribing exact language but strongly recommending that CDC ensure communications support informed consent.

Dr. Hibbeln added that the recommendation encourages CDC to enhance consistency and clarity in its communication but does not impose any formal requirements.

Dr. Malone agreed, noting that the regulation of medical practice and informed consent fall under state, not federal, authority. He stated that the intent was to encourage CDC to provide information that states can use to enhance their own informed consent processes.

Dr. Levi emphasized that the VIS is produced and updated by CDC, making it directly relevant to this recommendation.

Dr. Malone further explained that, historically, informed consent practices and the VIS have involved complex interactions between states and CDC. While the federal government cannot regulate these requirements, CDC can help improve communication and transparency.

Dr. Kulldorff noted that this type of recommendation is usually implemented by CDC without a formal vote, expressing confidence that CDC leadership has the capacity to act on the discussion.

Dr. Meissner then clarified that VIS documents are already legally required for all vaccines and asked if the proposed change would affect the content rather than the requirement itself.

Dr. Levi confirmed that the intent is to update the VIS content to reflect current risks and uncertainties better.

Dr. Middleman commented that vaccine recommendations are typically measurable and policy-focused, whereas this proposal is more clinical in nature. She asked for clarification on the

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phrase “it is the sense of the committee,” emphasizing that ASIP recommendations must remain evidence-based.

Dr. Levi responded that ACIP’s charter allows it to consider broader vaccination policy issues and that the current COVID-19 VIS does not reflect the latest risk information. He said the working group’s recommendations are based on a thorough review of the literature and available evidence, and that transparency about uncertainties is essential. He concluded that communicating known risks, limitations, and uncertainties, even when evidence is incomplete, is fundamental to maintaining public trust and aligns with ACIP’s mission.

Vote: COVID-19 Vaccines Vote #1

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the vaccine into the record:

> It is the sense of the committee that the CDC engages in an effort to promote more consistent and comprehensive informed consent processes, and as part of that considers adding language accessible to patients and medical providers to describe at least the six risks and uncertainties included in the WG chair presentation.

Motion/Vote: COVID-19 Vaccines

Dr. Malone motioned to approve the recommended voting language, stating, “It is the sense of the committee that the CDC engages in an effort to promote more consistent and comprehensive informed consent processes, and as part of that considers adding language accessible to patients and medical providers to describe at least the six risks and uncertainties included in the WG chair presentation.” Dr. Stein seconded the motion. No COIs were declared. The motion carried with 11 votes in favor, 1 vote opposed, and 0 abstentions. The disposition of the vote was as follows:

11 Favored: Meissner, Pollak, Stein, Milhoan, Blackburn, Malone, Pagano, Griffin, Hibbeln, Pebsworth, Levi
1 Opposed: Kulldorff
0 Abstained:

Discussion for COVID-19 Vaccines Vote #2

Dr. Blackburn noted that pharmacists are not currently authorized providers under Medicare Part B and therefore cannot write prescriptions.

Dr. Kulldorff acknowledged that this is the case in some states, where pharmacists do not have the authority to prescribe medications.

Dr. Blackburn added that while pharmacists can often operate under collaborative practice agreements, requiring a prescription would still create a barrier to vaccine access.

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Dr. Kulldorff asked whether she was proposing an amendment to the vote or suggesting that the prescription requirement be removed.

Dr. Blackburn replied that she was suggesting an amendment, as requiring a prescription would not be practical.

Dr. Malone clarified that the prescription requirement is central to the vote and that, unless specific amendment language is proposed, the issue would proceed to a yes-or-no vote.

Dr. Stein said she fully supports informed consent and believes that discussing risks, benefits, and uncertainties is essential. However, she expressed strong concern about requiring a prescription, explaining that underinsured populations and those with limited access to healthcare would face barriers. She noted that these individuals often have the highest risk of comorbid conditions, underscoring the critical need for access.

Dr. Meissner agreed and stated that he is strongly opposed to requiring a prescription. He said that the Vaccine Information Statement already provides much of the information that would be discussed with a physician. Requiring a prescription, he argued, would create a major barrier to vaccine access. He added that individuals should be able to obtain the vaccine for themselves or their children without needing a prescription.

Dr. Hibbeln also expressed concern, noting that about 30 percent of Americans lack ready access to a primary care provider. He said that in Texas and other rural states, access is even more limited. This lack of access would prevent many people from having the required risk-benefit discussions with providers. He agreed with Dr. Blackburn, Dr. Stein, and Dr. Meissner that requiring a prescription would create a significant barrier to implementing the goals of informed consent and equitable vaccine access.

Dr. Levi explained that the vote is intended to give states flexibility to determine their own approaches. He acknowledged concerns about access but questioned whether the argument against prescriptions is consistent, noting that antibiotics and other prescription drugs are not available over the counter for similar reasons. He said the COVID-19 vaccine involves nuanced medical considerations that justify a clinical discussion before administration. He added that most individuals at higher risk already see healthcare providers regularly for other prescriptions, and that in practice, most states would likely find ways to allow pharmacies to participate. He concluded that the goal is to strengthen informed consent and ensure the process is meaningful.

Dr. Griffin said she is sensitive to access concerns but agreed with Dr. Levi that obtaining a prescription encourages informed discussions between patients and providers. She said the process would promote informed consent, similar to that for other medical treatments, such as prescriptions for chronic conditions. She added that access barriers should be addressed separately rather than by eliminating the informed consent step.

Dr. Meissner responded that he disagreed with the comparison between vaccines and antibiotics. He explained that antibiotics are used to treat illness and require timely medical judgment, whereas vaccines are preventive and given to healthy people. He said requiring

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prescriptions for vaccines would raise healthcare costs and create unnecessary barriers. He argued that if a person wants to receive the vaccine, a physician is unlikely to discourage them, so that a prescription would serve little purpose.

Dr. Malone stated that COVID-19 vaccines are already limited to individuals with underlying health conditions, meaning they are not being given to completely healthy populations. He emphasized that informed consent is essential because risk-benefit assessments must be tailored to each individual. He said decisions should be made collaboratively between patients and licensed healthcare providers, ensuring that choices are based on medical evaluation rather than marketing or public messaging.

Dr. Blackburn clarified that pharmacists are licensed healthcare professionals trained in immunology and certified to assess vaccine risks and benefits. She shared data showing that during the 2024–2025 season, 90 percent of COVID-19 vaccines were administered in pharmacies. She said requiring prescriptions would reduce access and create unnecessary barriers, particularly since pharmacists are already trained to provide patient-specific vaccine counseling.

Dr. Meissner reiterated that access is a major concern, noting that it can take him up to a year to see his internist. He said this kind of delay would make it extremely difficult for many people to obtain prescriptions. He emphasized that restricting access is not consistent with ACIP's role and asked for clarification on whether the requirement would apply to all individuals or only to those at high risk.

Dr. Malone clarified that he did not question pharmacists' qualifications and that prescriptive authority is determined by state law. He described the recommendation language as general and said it leaves flexibility for states and local jurisdictions to assess implementation.

Dr. Levi agreed that pharmacists should be part of the solution and said most states already allow pharmacists to provide vaccines under collaborative arrangements. He said the intent is to send a message that informed consent should involve a deliberate and documented discussion. He acknowledged that pharmacy-based vaccinations often lack such debate and said the recommendation aims to improve this process, not to eliminate pharmacy participation.

Dr. Blackburn added that at least 19 states currently require pharmacists' vaccine authority to be tied to ACIP recommendations, and recent confusion about guidance has already affected access. She cited examples of pharmacies like CVS and Walgreens reducing vaccine availability due to unclear policies.

Dr. Goode, representing the American Pharmacists Association, said that many states base pharmacists' vaccination authority directly on ACIP recommendations. If ACIP were to require prescriptions, pharmacists in those states might no longer be permitted to administer the vaccine. She emphasized that pharmacists are among the most accessible healthcare providers and are well-trained to assess the risks and benefits. She reiterated that 90 percent of COVID-19 vaccines have been given in pharmacies and warned that requiring prescriptions would reduce access, worsen health inequities, and limit patient choice.

Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

Dr. Middleman expressed deep concern about treating vaccines like prescriptions, explaining that vaccines are a primary prevention tool, not a treatment. She said requiring prescriptions would overwhelm physicians' offices and create confusion about how vaccine orders work, since vaccines are generally given under standing orders rather than individual prescriptions. She cautioned that adding new barriers to access undermines public health goals and efforts to build trust in vaccination.

Dr. Moehling, representing the Association for Prevention, Teaching, and Research, thanked the committee and echoed the concerns raised by other liaison representatives and Dr. Blackburn. She urged the committee to consider how requiring a prescription carefully would affect access, noting that pharmacists are currently the primary providers administering COVID-19 vaccines to most patients. She pointed out that the committee's previous votes, particularly Vote #4, support individual choice in vaccination decisions, and that Vote #1 emphasized the importance of a more informed consent process, which she fully supports. Dr. Moehling suggested that the committee hear from the CMS representative to clarify how a prescription requirement might limit pharmacists' ability to administer the vaccine and impact overall access to it.

Vote: COVID-19 Vaccines Vote #2

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the vaccine into the record:

> It is the sense of the committee that state and local jurisdictions should require a prescription for the administration of a COVID-19 vaccination.

Motion/Vote: COVID-19 Vaccines

Dr. Hibbeln motioned to approve the recommended voting language, stating, "It is the sense of the committee that state and local jurisdictions should require a prescription for the administration of a COVID-19 vaccination." Dr. Malone seconded the motion. No COIs were declared. The motion carried with 6 votes in favor, 6 votes opposed, and 0 abstentions. The disposition of the vote was as follows:

6 Favored: Milhoan, Malone, Pagano, Griffin, Pebsworth, Levi,
6 Opposed: Meissner, Pollak, Stein, Blackburn, Hibbeln, Kulldorff
0 Abstained:

*Due to a tie (6–6) on the vote, the chair, Dr. Kulldorff, cast the deciding vote. His "no" vote broke the tie, causing the motion to require a prescription for COVID-19 vaccination to fail.

Vote: COVID-19 Vaccines Vote #3

Dr. Martin Kulldorff (ACIP Chair) read the following proposed ACIP voting language for the vaccine into the record:

Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

It is the sense of the committee that in conversations with patients before COVID-19 vaccination, authorized healthcare providers discuss the risks and benefits of the vaccination for the individual patient. The discussion should consider known risk factors for severe outcomes from COVID-19, such as age, prior infections, immunosuppression, and certain comorbidities identified by the CDC, and include a discussion of the potential benefits and risks of vaccination and related uncertainties, especially those outlined in the vaccine information statement, as part of informed consent.

Motion/Vote: COVID-19 Vaccines

Dr. Malone motioned to approve the recommended voting language, stating, "It is the sense of the committee that in conversations with patients before COVID-19 vaccination, authorized healthcare providers discuss the risks and benefits of the vaccination for the individual patient. The discussion should consider known risk factors for severe outcomes from COVID-19, such as age, prior infections, immunosuppression, and certain comorbidities identified by the CDC, and include a discussion of the potential benefits and risks of vaccination and related uncertainties, especially those outlined in the vaccine information statement, as part of informed consent." Dr. Milhoan seconded the motion. No COIs were declared. The motion carried with 12 votes in favor, 0 votes opposed, and 0 abstentions. The disposition of the vote was as follows:

12 Favored: Pollak, Pagano, Stein, Blackburn, Milhoan, Meissner, Griffin, Pebsworth, Levi, Hibbeln, Kulldorff, Malone
0 Opposed:
0 Abstained:

PUBLIC COMMENT

The floor was opened for public comment on September 19, 2025. The comments made during the meeting are summarized in this document. Members of the public were also invited to submit written public comments to ACIP through the Federal eRulemaking Portal under Docket Number ID CDC-2025-0454. Visit regulations.gov for access to read the comments received.

Robert Blancato
National Association of Nutrition and Aging Services Programs

Mr. Blancato spoke on behalf of the National Association of Nutrition and Aging Services Programs, emphasizing the importance of vaccine access for older adults. He highlighted that vaccination is the most effective and cost-efficient way to protect aging populations and reduce hospitalizations. He praised recent CDC guidance expanding RSV vaccine eligibility to adults aged 50 and older and encouraged similar action for COVID-19 vaccines, noting racial and ethnic disparities in hospitalization rates. He urged the ACIP to lower the age-based COVID-19 vaccination recommendation to include younger adults at higher risk. He cited a joint letter from

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the Alliance for Aging Research, signed by more than 75 organizations, calling for equitable, broad access to vaccines. Mr. Blancato concluded by recommending that the ACIP include experts in geriatric care to ensure that older adult perspectives are represented in vaccination policy decisions.

Miss Nissa Shaffi
Allergy and Asthma Network

Miss Shaffi, representing the Allergy and Asthma Network, underscored the importance of maintaining vaccine access and insurance coverage for individuals with asthma, allergies, and chronic respiratory conditions. She expressed concern about recent state-level efforts requiring prescriptions for COVID-19 vaccines, warning that such measures would create barriers, increase disease burden, and threaten herd immunity. Miss Shaffi noted that people with respiratory illnesses face a higher risk of infections such as influenza, COVID-19, and RSV, and that limiting vaccine access could have severe public health consequences. She emphasized that ACIP's recommendations drive insurance coverage under Medicare, Medicaid, and private plans. She urged the committee to preserve strong, evidence-based recommendations to ensure vaccines remain available and affordable for vulnerable populations.

Mr. Noah Louis-Ferdinand
Voices for Vaccines

Mr. Louis-Ferdinand, communications coordinator for Voices for Vaccines, expressed support for ACIP's careful review of the hepatitis B birth dose, affirming the strong evidence of safety and effectiveness. He highlighted that the timely administration of the birth dose prevents chronic infection and liver cancer and is critical because not all mothers are tested for hepatitis B before delivery. He also commented on COVID-19 vaccination, urging the committee to avoid decisions that would limit access for immunocompromised individuals. Mr. Louis-Ferdinand cautioned against spreading misinformation and called for high-quality, evidence-based communication from public health authorities. He noted that claims linking COVID-19 vaccines to cancer or DNA changes are unsupported and emphasized the importance of maintaining scientific rigor in all ACIP deliberations.

Mrs. Candace DeMatteis
Partnership to Fight Infectious Disease

Mrs. DeMatteis, vice president of policy and advocacy for the Partnership to Fight Infectious Disease, voiced concern over changes in ACIP membership and departures from its established evidence-to-recommendations process. She noted that the committee's credibility rests on transparent, science-based decision-making and warned that deviations could erode public trust. Mrs. DeMatteis criticized discussions driven by skepticism rather than new evidence, particularly regarding the hepatitis B birth dose. They cautioned that inconsistent recommendations could disrupt insurance coverage and vaccine access across states. She urged ACIP to recommit to its long-standing deliberative process, emphasizing that rigorous, evidence-based procedures are essential to preserving confidence and ensuring equitable vaccine access.

Dr. Daniel Crawford, DNP
National Association of Pediatric Nurse Practitioners

Dr. Crawford, representing the National Association of Pediatric Nurse Practitioners,

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emphasized that nurses play a vital role in vaccine delivery and public trust. He expressed concern that recent changes to ACIP and the removal of subject matter experts have undermined confidence in the committee's decisions. Dr. Crawford noted that hepatitis B vaccines have an outstanding safety record and prevent thousands of deaths each year. He criticized the committee's decision to remove the combined MMRV vaccine for children under four, stating it created confusion among parents and providers. He urged a return to data-driven deliberations and reaffirmed that vaccines remain among the most effective and safest tools for protecting children's health.

Mrs. Patricia Armstrong
Private Citizen

Mrs. Armstrong spoke as a private citizen, expressing concern about the spread of misinformation and the decline in public confidence in vaccines. She described how false claims about vaccine ingredients and side effects have fueled fear, contributing to the resurgence of diseases such as measles. She called for more substantial public education efforts, including clear, accessible materials, collaborations with media and influencers, and increased outreach to both conservative and liberal audiences. Mrs. Armstrong urged government and health institutions to communicate scientific facts in simple and engaging ways to combat misinformation and prevent further vaccine hesitancy.

Mr. Steven Furr, MD, FAAFP
American Academy of Family Physicians

Dr. Furr, representing the American Academy of Family Physicians, highlighted the essential role of family physicians in vaccine delivery and patient education. Drawing on his decades of experience, he reflected on the dramatic decline in severe infections, such as Haemophilus influenzae type B, following routine vaccination. He expressed concern that recent ACIP changes weaken the evidence-to-recommendation process and reduce transparency by excluding practicing clinicians. Dr. Furr emphasized that universal hepatitis B vaccination at birth remains critical to preventing transmission and that narrowing recommendations for MMRV and COVID-19 vaccines undermines patient autonomy. He urged ACIP to restore scientific integrity, transparency, and consistency to rebuild trust in public health recommendations.

Dr. Richard Dang, PharmD
University of Southern California

Dr. Dang, a pharmacist and associate professor at the University of Southern California, advocated for practical, evidence-based access to vaccines. He opposed requiring prescriptions for COVID-19 vaccines, noting that pharmacists administered most vaccines during the 2024–2025 season and that such requirements would create unnecessary barriers. He stressed that pharmacies are among the most accessible healthcare settings, serving 90 percent of Americans within five miles. Dr. Dang urged ACIP to base recommendations on sound evidence, preserve patient choice, and maintain consistency to avoid confusion. He reaffirmed that COVID-19 vaccines have been extensively monitored, are safe, and should remain available to everyone six months and older who wishes to be vaccinated.

Mr. Richard So, MPH/MPA
Hep B Free

Mr. So, executive director of Hep B Free, spoke about the real-world impact of hepatitis B and

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the importance of maintaining universal infant vaccination. He described stories from affected families and the long-term success of the birth dose in preventing new infections. Mr. So cautioned that framing hepatitis B as a sexual or drug-related disease overlooks other transmission routes and the vulnerability of infants. He noted that when previous birth dose recommendations were suspended, vaccination rates declined, and trust was eroded for years afterward. He urged ACIP to preserve the proven policy of universal birth dose vaccination to protect children and prevent future outbreaks.

Ms. Wendy Lou
Private Citizen (Hepatitis B Patient Advocate)

Ms. Lou shared her personal story as a patient living with chronic hepatitis B, which she likely contracted at birth before the vaccine was available. She described the lifelong medical, financial, and emotional burden of chronic infection and the stigma associated with the disease. Ms. Lou emphasized that the hepatitis B birth dose prevents 90% of infections in newborns and that up to 25 percent of those with chronic infection die from related complications. She credited the vaccine for protecting her children and expressed relief that they are free from the disease. Ms. Lou urged ACIP not to weaken the birth dose recommendation, stating that it saves lives and prevents needless suffering across generations.

With no additional business to be addressed at the September 2025 ACIP meeting, the meeting was officially adjourned.

ACIP MEMBERSHIP ROSTER

CHAIR

KULLDORFF, Martin, PHD
Biostatistician, Epidemiologist
Formerly Harvard University Professor of Medicine
6/13/2025 – 6/30/2029

EXECUTIVE SECRETARY

ZADEH, Mina, PHD, MPH
Designated Federal Officer (DFO)
Supervisory Program Specialist
Office of the Director, Office of the Chief of Staff
Centers for Disease Control and Prevention

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AscensionRx
Term: 9/11/2025-6/30/2029

GRIFFIN, Evelyn, M.D.
Obstetrician and Gynecologist
Baton Rouge General Hospital

Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

Term: 9/11/2025-6/30/2029

HIBBELN, Joseph R., MD, ABNP, CAPT USPHS (Ret.)
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National Institutes of Health
Term: 6/13/2025 – 6/30/2029

LEVI, Retsef, PHD
Professor of Operations Management
MIT Sloan School of Management
Leading expert in Healthcare Analytics
Term: 6/13/2025 – 6/30/2029

MALONE, Robert W., MD, MS
Vaccinologist, Scientist, Biochemist
Contributor to mRNA Vaccine Technology
Term: 6/13/2025 – 6/30/2029

MEISSNER, H. Cody, MD
Professor of Pediatrics
Dartmouth Geisel School of Medicine
Previously Chief of Division of Pediatric Infectious Disease
Tufts-New England Medical Center
Former CDC ACIP member
Former FDA's Vaccine & Related Biological Products Advisory Committee
Term: 6/13/2025 – 6/30/2029

MILHOAN, Kirk, M.D., Ph.D.
Medical Director
For Hearts and Souls Free Medical Clinic
Term: 9/11/2025-6/30/2029

PAGANO, James V., MD, FACEP
Emergency Medicine Physician with More than 40 Years Clinical Experience
Term: 6/13/2025 – 6/30/2029

PEBSWORTH, Vicky, PhD, RN
ACIP Consumer Representative
Focus Bioethics and Vaccine Safety
Research Director
National Vaccine Information Center
Former FDA Vaccines & Related
Biological Products Advisory Committee
Term: 6/13/2025 – 6/30/2029

POLLAK, Raymond, M.D., F.A.C.S., F.R.C.S.
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Term: 9/11/2025-6/30/2029

STEIN, Catherine M., Ph.D.

Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

Professor, Department of Population and Quantitative Health
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Term: 9/11/2025-6/30/2029

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Centers for Medicare and Medicaid Services (CMS)
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Office of Infectious Disease and HIV/AIDS Policy (OIDP)

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Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

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Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

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HOWELL, Molly, MPH
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Association for Prevention Teaching and Research (APTR)
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Association of State and Territorial Health Officials (ASTHO)
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Biotechnology Innovation Organization (BIO)
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Council of State and Territorial Epidemiologists (CSTE)
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Canadian National Advisory Committee on Immunization (NACI)
TUNIS, Matthew, PhD
Executive Secretary, National Advisory Committee on Immunization (NACI)
Centre for Immunization Programs (CIP)
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Infectious Diseases Society of America (IDSA)
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Note: Text enclosed in [brackets] was added following the meeting, per the presenter's request.

International Society for Travel Medicine (ISTM)
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National Association of Pediatric Nurse Practitioners (NAPNAP)
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National Foundation for Infectious Diseases (NFID)
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Pediatric Infectious Diseases Society (PIDS)
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Pharmaceutical Research and Manufacturers of America (PhRMA)
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Society for Adolescent Health and Medicine (SAHM)
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EXHIBIT 12

Case 1:25-cv-11916-BEM Document 185-12 Filed 01/26/26 Page 2 of 3

CDC Newsroom

CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers

RELEASE

For immediate release: October 6, 2025

CDC Media Relations
(404) 639-3286
https://www.cdc.gov/media/

The Centers for Disease Control and Prevention (CDC) today updated its adult and child immunization schedules to apply individual-based decision-making to COVID-19 vaccination and recommend that toddlers receive protection from varicella (chickenpox) as a standalone immunization rather than in combination with measles, mumps, and rubella vaccination.

The immunization schedules adopt recent recommendations by the CDC Advisory Committee on Immunization Practices (ACIP), which were approved last week by Acting Director of the CDC and Deputy Secretary of Health and Human Services Jim O'Neill. The schedules will be updated on CDC.gov by October 7, 2025.

"Informed consent is back," **said Deputy Secretary O'Neill**. "CDC's 2022 blanket recommendation for perpetual COVID-19 boosters deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent. That changes today.

"I commend the doctors and public health experts of ACIP for educating Americans about important vaccine safety signals. I also thank President Trump for his leadership in making sure we protect children from unintended side effects during routine immunization."

Unlike the COVID-19 primary series vaccination pioneered by Operation Warp Speed (OWS) that reached a estimated nearly 85% of the U.S. adult population, just 23% of adults followed the CDC's most recent seasonal booster recommendation according to its National Immunization Survey. The booster shots prompted widespread risk-benefit concerns about their safety and efficacy as the COVID-19 virus became endemic following population-wide immunity acquired during the pandemic and OWS.

ACIP's recommendation emphasized that the risk-benefit of vaccination in individuals under age 65 is most favorable for those who are at an increased risk for severe COVID-19 and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors. The U.S. Food and Drug Administration has approved marketing authorization for COVID-19 vaccines for individuals who have one or more of these risk factors, as well as for individuals age 65 and older.

Individual-based decision-making is referred to on the CDC's immunization schedules as vaccination based on shared clinical decision-making, which references providers including physicians, nurses, and pharmacists. It means that the clinical decision to vaccinate should be based on patient characteristics that unlike age are difficult to incorporate in recommendations, including risk factors for the underlying disease as well as the characteristics of the vaccine itself and the best available evidence of who may benefit from vaccination.

Like routine recommendations, individual-based-decision-making allows for immunization coverage through all payment mechanisms including entitlement programs such as the Medicare, Medicaid, Children's Health Insurance Program, and the Vaccines for Children Program, as well as insurance plans regulated by the Affordable Care Act.

The CDC child and adolescent immunization schedule's new recommendation of standalone chickenpox vaccination for toddlers through age three follows evidence presented PDF to ACIP by the CDC Immunization Safety Office's that healthy 12–23 months old toddlers have increased risk of febrile seizure seven to 10 days after vaccination for the combined measles, mumps, rubella, and varicella vaccine compared to those given immunization for chickenpox separately. The combination vaccine doubles the risk of febrile seizures without conferring additional protection from varicella compared to standalone vaccination.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Whether diseases start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC’s world-leading experts protect lives and livelihoods, national security and the U.S. economy by providing timely, commonsense information, and rapidly identifying and responding to diseases, including outbreaks and illnesses. CDC drives science, public health research, and data innovation in communities across the country by investing in local initiatives to protect everyone’s health.

SOURCES

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CONTENT SOURCE:

Office of Communications (OC)

EXHIBIT 13

Recommended Adult Immunization Schedule for Ages 19 Years or Older

UNITED STATES 2025

Vaccines in the Adult Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
COVID–19 vaccine	1vCOV–mRNA	Comirnaty, mNexspike, Spikevax
	1vCOV–aPS	Nuvaxovid
Haemophilus influenzae type b vaccine	Hib	ActHIB, Hiberix, PedvaxHIB
Hepatitis A vaccine	HepA	Havrix, Vaqta
Hepatitis A and hepatitis B vaccine	HepA–HepB	Twinrix
Hepatitis B vaccine	HepB	Engerix–B, Heplisav–B, PreHevbrio, Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated, egg-based)	IIV3	Multiple
	aIIV3	Fluad
	HD–IIV3	Fluzone High–Dose
Influenza vaccine (inactivated, cell–culture)	ccIIV3	Flucelvax
Influenza vaccine (recombinant)	RIV3	Flublok
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M–M–R II, Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY–CRM	Menveo
	MenACWY–TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB–4C	Bexsero
	MenB–FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY–TT/ MenB–FHbp	Penbraya
Monkeypox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance
	PCV20	Prevnar 20
	PCV21	Capvaxive
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo, Arexvy, mResvia
Tetanus and diphtheria vaccine	Td	Tenivac
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel, Boostrix
Varicella vaccine	VAR	Varivax
Zoster vaccine, recombinant	RZV	Shingrix

*Administer recommended vaccines if vaccination history is incomplete or unknown.
Do not restart or add doses to vaccine series if there are extended intervals between doses.
The use of trade names is for identification purposes only and does not imply endorsement by ACIP or CDC.

Revised October 07, 2025

How to use the adult immunization schedule

1. Determine recommended vaccinations by age **(Table 1)**
2. Assess need for additional recommended vaccinations by medical condition or other indication **(Table 2)**
3. Review vaccine types, dosing frequencies and intervals, and considerations for special situations **(Notes)**
4. Review contraindications and precautions for vaccine types **(Appendix)**
5. Review new or updated ACIP guidance **(Addendum)**

Report

- Suspected cases of reportable vaccine–preventable diseases or outbreaks to the local or state health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc–info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/hcp/imz-schedules/app.html.

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/acip-recs/hcp/vaccine-specific/
- ACIP Shared Clinical Decision–Making Recommendations: www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
- General Best Practice Guidelines for Immunization www.cdc.gov/vaccines/hcp/imz-best-practices/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine–Preventable Diseases (including case identification and outbreak response): www.cdc.gov/surv-manual/php/index.html

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CS310021–E

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2025

Vaccine	19–26 years	27–49 years	50–64 years	≥65 years
COVID–19	1 or more doses of 2025–2026 vaccine (See Notes)			2 or more doses of 2025–2026 vaccine (See Notes)
Influenza inactivated (IIV3, ccIIV3) **Influenza recombinant** (RIV3)	1 dose annually			1 dose annually (HD–IIV3, RIV3, or aIIV3 preferred)
Influenza inactivated (aIIV3; HD–IIV3) **Influenza recombinant** (RIV3)	Solid organ transplant (See Notes)			
Influenza live, attenuated (LAIV3)	1 dose annually			
Respiratory syncytial virus (RSV)	Seasonal administration during pregnancy (See Notes)		60–74 years (See Notes)	≥75 years
Tetanus, diphtheria, pertussis (Tdap or Td)	1 dose Tdap each pregnancy; 1 dose Td/Tdap for wound management (See Notes)			
	1 dose Tdap, then Td or Tdap booster every 10 years			
Measles, mumps, rubella (MMR)	1 or 2 doses depending on indication (if born in 1957 or later)			For health care personnel (See Notes)
Varicella (VAR)	2 doses (if born in 1980 or later)		2 doses	
Zoster recombinant (RZV)	2 doses for immunocompromising conditions (See Notes)		2 doses	
Human papillomavirus (HPV)	2 or 3 doses depending on age at initial vaccination or condition	27–45 years		
Pneumococcal (PCV15, PCV20, PCV21, PPSV23)			See Notes	See Notes
Hepatitis A (HepA)	2, 3, or 4 doses depending on vaccine			
Hepatitis B (HepB)	2, 3, or 4 doses depending on vaccine or condition			
Meningococcal A, C, W, Y (MenACWY)	1 or 2 doses depending on indication (See Notes for booster recommendations)			
Meningococcal B (MenB)	19–23 years	2 or 3 doses depending on vaccine and indication (See Notes for booster recommendations)		
***Haemophilus influenzae* type b** (Hib)	1 or 3 doses depending on indication			
Mpox	2 doses			
Inactivated poliovirus (IPV)	Complete 3-dose series if incompletely vaccinated. Self-report of previous doses acceptable (See Notes)			

Recommended vaccination for adults who meet age requirement, lack documentation of vaccination, or lack evidence of immunity

Recommended vaccination for adults with an additional risk factor or another indication

Vaccination is based on shared clinical decision-making

No Guidance/ Not Applicable

Table 2 Recommended Adult Immunization Schedule by Medical Condition or Other Indication, United States, 2025

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions or indications are often not mutually exclusive. If multiple medical conditions or indications are present, refer to guidance in all relevant columns. See Notes for medical conditions or indications not listed.

VACCINE	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count		Men who have sex with men	Asplenia, complement deficiency	Heart or lung disease	Kidney failure, End–stage renal disease or on dialysis	Chronic liver disease; alcoholism[a]	Diabetes	Health care Personnel[b]
			<15% or <200/mm³	≥15% and ≥200/mm³							
COVID–19	See Notes	Additional doses may be necessary (See Notes)		See Notes							
Influenza inactivated Influenza recombinant		Solid organ transplant (See Notes)	1 dose annually								
LAIV3					1 dose annually if age 19–49 years		1 dose annually if age 19–49 years				
RSV	Seasonal administration (See Notes)	See Notes				See Notes			Liver disease (See Notes)	See Notes	
Tdap or Td	Tdap: 1 dose each pregnancy	1 dose Tdap, then Td or Tdap booster every 10 years									
MMR	*										
VAR	*			See Notes							
RZV		See Notes									
HPV	*	3-dose series if indicated									
Pneumococcal											
HepA											
Hep B	See Notes									Age ≥ 60 years	
MenACWY											
MenB											
Hib		HSCT: 3 doses[c]				Asplenia: 1 dose					
Mpox	See Notes				See Notes						See Notes
IPV		Complete 3-dose series if incompletely vaccinated. Self–report of previous doses acceptable (See Notes)									

- Recommended for all adults who lack documentation of vaccination, **OR** lack evidence of immunity
- Not recommended for all adults, but recommended for some adults based on either age **OR** increased risk for or severe outcomes from disease
- Vaccination is based on shared clinical decision-making
- Additional doses may be necessary based on medical condition or other indications. See Notes.
- Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended *Vaccinate after pregnancy, if indicated
- No Guidance/ Not Applicable

a. Precaution for LAIV3 does not apply to alcoholism.

b. See Notes for influenza; hepatitis B; measles, mumps, and rubella; and varicella vaccinations.

c. Hematopoietic stem cell transplant.

Notes

For vaccination recommendations for persons ages 18 years or younger, see the Recommended Child and Adolescent Immunization Schedule, 2025: www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

Additional Information

- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3–2, Recommended and minimum ages and intervals between vaccine doses, in General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip–recs/general–recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8–1, Vaccination of persons with primary and secondary immunodeficiencies, in General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip–recs/general–recs/immunocompetence.html
- For information about vaccination in the setting of a vaccine–preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no–fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the adult immunization schedule except PPSV23, RSV, RZV, Mpox, and COVID–19 vaccines are covered by the National Vaccine Injury Compensation Program (VICP). Mpox and COVID–19 vaccines are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID–19 vaccination

Shared clinical decision-making

Vaccination based on individual-based decision-making—with an emphasis that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk according to the CDC list of COVID-19 risk factors (see www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html). For additional information on shared clinical decision-making, see www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

Current COVID-19 schedule and dosage formulation available at www.cdc.gov/covidschedule.

Administer an age-appropriate COVID-19 vaccine product for each dose. There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available.

Haemophilus influenzae type b vaccination

Special situations

- **Anatomical or functional asplenia (including sickle cell disease):** 1 dose if previously did not receive Hib vaccine
  - **Elective splenectomy:** 1 dose preferably at least 14 days before splenectomy
- **Hematopoietic stem cell transplant (HSCT):** 3-dose series 4 weeks apart starting 6–12 months after successful transplant, regardless of Hib vaccination history

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Notes

Hepatitis A vaccination

Routine vaccination

- **Any person who is not fully vaccinated and requests vaccination** (identification of risk factor not required): complete 2-dose series HepA (Havrix 6–12 months apart or Vaqta 6–18 months apart [minimum interval: 6 months]) or 3-dose series HepA–HepB (Twinrix at 0, 1, 6 months [minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 5 months])

Special situations

- **Any person who is not fully vaccinated and who is at risk for hepatitis A virus infection or severe disease from hepatitis A virus infection:** complete 2-dose series HepA or 3-dose series HepA–HepB as above. Risk factors include:
  - **Chronic liver disease** including persons with hepatitis B, hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.
  - **HIV infection**
  - **Men who have sex with men**
  - **Injection or noninjection drug use**
  - **Persons experiencing homelessness**
  - **Work with hepatitis A virus** in research laboratory or with nonhuman primates with hepatitis A virus infection
  - **Travel in countries with high or intermediate endemic hepatitis A:** HepA–HepB (Twinrix) may be administered on an accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months.
  - **Close, personal contact with international adoptee** (e.g., household or regular babysitting) in first 60 days after arrival from country with high or intermediate endemic hepatitis A: dose 1 as soon as adoption is planned; preferably at least 2 weeks before adoptee's arrival.
  - **Pregnancy** if at risk for infection or severe outcome from infection during pregnancy
  - **Settings for exposure,** including health care setting serving persons who use injection or noninjection drugs, or group homes and nonresidential day care facilities for developmentally disabled persons (individual risk factor screening not required)

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Hepatitis B vaccination

Routine vaccination

- **Age 19–59 years:** complete a 2- or 3- or 4-dose series
  - 2-dose series only applies when 2 doses of Heplisav–B are used at least 4 weeks apart
  - 3-dose series Engerix–B, PreHevbrio*, or Recombivax HB at 0, 1, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 8 weeks; dose 1 to dose 3 = 16 weeks)
  - 3-dose series HepA–HepB (Twinrix) at 0, 1, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 5 months)
  - 4-dose series HepA–HepB (Twinrix) accelerated schedule of 3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months

***Note:** PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant women.

- **Age 60 years or older without** known risk factors for hepatitis B virus infection **may** receive a HepB vaccine series.
- **Age 60 years or older with** known risk factors for hepatitis B virus infection **should** receive a HepB vaccine series.
- **Any adult age 60 years of age or older** who requests HepB vaccination **should** receive a HepB vaccine series.
  - **Risk factors for hepatitis B virus infection include:**
    - **Chronic liver disease** including persons with hepatitis C, cirrhosis, fatty liver disease, alcoholic liver disease, autoimmune hepatitis, alanine aminotransferase (ALT) or aspartate aminotransferase (AST) level greater than twice the upper limit of normal.
    - **HIV infection**
    - **Sexual exposure risk** e.g., sex partners of hepatitis B surface antigen (HBsAg)–positive persons, sexually active persons not in mutually monogamous relationships, persons seeking evaluation or treatment for a sexually transmitted infection, men who have sex with men

Notes

Hepatitis B vaccination - *continued*

- **Current or recent injection drug use**
- **Percutaneous or mucosal risk for exposure to blood** e.g., household contacts of HBsAg–positive persons, residents and staff of facilities for developmentally disabled persons, health care and public safety personnel with reasonably anticipated risk for exposure to blood or blood–contaminated body fluids, persons on maintenance dialysis (including in–center or home hemodialysis and peritoneal dialysis), persons who are predialysis, and patients with diabetes**
- **Incarceration**
- **Travel in countries with high or intermediate endemic hepatitis B**

****Age 60 years or older with diabetes:** Based on shared clinical decision making, 2-, 3-, or 4-dose series as above.

Special situations

- **Patients on dialysis:** complete a 3- or 4-dose series
  - 3-dose series Recombivax HB at 0, 1, 6 months (Note: Use Dialysis Formulation 1 mL = 40 mcg)
  - 4-dose series Engerix–B at 0, 1, 2, and 6 months (Note: Use 2 mL dose instead of the normal adult dose of 1 mL)
- **Age 20 years or older with an immunocompromising condition:** complete a 2- or 3- or 4-dose series.
  - 3-dose series Recombivax HB at 0,1, 6 months (Note: Use Dialysis Formulation 1ml = 40 mcg)
  - 4-dose series Engerix–B at 0,1,2, and 6 months (Note: Use 2mL dose instead of the normal adult dose of 1mL)
  - 2-doses series Heplisav–B at 0, 1 months
  - 3-dose series PreHevbrio* at 0,1, 6 months

Human papillomavirus vaccination

Routine vaccination

- **All persons through age 26 years:** complete 2– or 3-dose series depending on age at initial vaccination or condition.
  - **Age 9–14 years at initial vaccination and received 1 dose or 2 doses less than 5 months apart:** 1 additional dose
  - **Age 9–14 years at initial vaccination and received 2 doses at least 5 months apart:** HPV vaccination series complete, no additional dose needed
  - **Age 15 years or older at initial vaccination:** 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 12 weeks; dose 1 to dose 3 = 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series of any valency has been completed using the recommended dosing intervals.

Shared clinical decision–making

- **Adults age 27–45 years:** Based on shared clinical decision–making, complete a 2-dose series (if initiated age 9–14 years) or 3-dose series (if initiated ≥15 years).

For additional information on shared clinical decision–making for HPV; see www.cdc.gov/vaccines/hcp/admin/downloads/isd–job–aid–scdm–hpv–shared–clinical–decision–making–hpv.pdf

Special situations

- **Age ranges recommended above for routine and catch–up vaccination or shared clinical decision–making also apply in special situations**
  - **Immunocompromising conditions, including HIV infection**: complete 3-dose series, even for those who initiate vaccination at age 9–14 years.
  - **Pregnancy**: Pregnancy testing is not needed before vaccination. HPV vaccination is not recommended until after pregnancy. No intervention needed if inadvertently vaccinated while pregnant.

Influenza vaccination

Routine vaccination

- **Age 19 years or older:** 1 dose any influenza vaccine appropriate for age and health status annually
  - **Solid organ transplant recipients aged 19–64 years receiving immunosuppressive medications:** HD–IIV3 and aIIV3 are acceptable options. No preference over other age–appropriate IIV3 or RIV3.
  - **Age 65 years or older:** Any one of HD-IIV3, RIV3, or aIIV3 is preferred. If none of these three vaccines is available, then any other age–appropriate influenza vaccine should be used.
- For the 2024–25 season, see www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm
- For the 2025–26 season, see the 2025–26 ACIP influenza vaccine recommendations.

Special situations

- **Close contacts (e.g., caregivers, healthcare workers) of severely immunosuppressed persons who require a protected environment:** should not receive LAIV3. If LAIV3 is given, they should avoid contact with/caring for such immunosuppressed persons for 7 days after vaccination.

Note: Persons with an egg allergy can receive any influenza vaccine (egg-based or non–egg based) appropriate for age and health status.

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Notes

Measles, mumps, and rubella vaccination

Routine vaccination

- **No evidence of immunity to measles, mumps, or rubella:** 1 dose
  - **Evidence of immunity:** Born before 1957 (except for health care personnel, see below), documentation of receipt of MMR vaccine, laboratory evidence of immunity or disease (diagnosis of disease without laboratory confirmation is not evidence of immunity)

Special situations

- **Pregnancy with no evidence of immunity to rubella:** MMR contraindicated during pregnancy; after pregnancy (before discharge from health care facility): 1 dose
- **Nonpregnant women of childbearing age with no evidence of immunity to rubella:** 1 dose
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm^3 for at least 6 months and no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart; MMR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm^3
- **Severe immunocompromising conditions:** MMR contraindicated
- **Students in postsecondary educational institutions, international travelers, and household or close, personal contacts of immunocompromised persons with no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart if previously did not receive any doses of MMR or 1 dose if previously received 1 dose MMR
- **In mumps outbreak settings,** for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm
- **Health care personnel:**
  - **Born before 1957 with no evidence of immunity to measles, mumps, or rubella:** Consider 2-dose series at least 4 weeks apart for protection against measles or mumps or 1 dose for protection against rubella.
  - **Born in 1957 or later with no evidence of immunity to measles, mumps, or rubella:** complete 2-dose series at least 4 weeks apart for protection against measles or mumps or at least 1 dose for protection against rubella.

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Meningococcal vaccination

Special situations for MenACWY

- **Anatomical or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:** 2-dose primary series Menveo or MenQuadfi at least 8 weeks apart; 1 booster dose 5 years after primary series and every 5 years if risk remains
- **Travel in countries with hyperendemic or epidemic meningococcal disease, or for microbiologists routinely exposed to *Neisseria meningitidis*:** 1 dose Menveo or MenQuadfi; 1 booster dose 5 years after primary series and every 5 years if risk remains
- **First–year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:** 1 dose Menveo or MenQuadfi

For MenACWY recommendations **in outbreak setting** (e.g., in community or organizational settings, or among men who have sex with men) and **additional meningococcal vaccination** information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm

Shared clinical decision–making for MenB

- **Adolescents and young adults age 16–23 years (age 16–18 years preferred)* not at increased risk for meningococcal disease:** based on shared clinical decision–making
  - **Bexsero or Trumenba (use same brand for all doses):** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

*To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision–making for MenB, see www.cdc.gov/vaccines/media/pdfs/2025/03/2024-isd-job-aid-scdm-menb-508-remediated.pdf

Notes

Meningococcal vaccination - *continued*

Special situations for MenB

- **Anatomical or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use, or microbiologists routinely exposed to *Neisseria meningitidis*.**
  - **Bexsero or Trumenba (use same brand for all doses including booster doses):** 3-dose primary series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3).
  - **Booster doses:** 1 booster dose one year after primary series and every 2–3 years if risk remains
- **Pregnancy:** Delay MenB until after pregnancy due to lack of safety data in pregnant women. May administer if at increased risk and vaccination benefits outweigh potential risks.

For MenB recommendations **in outbreak setting** (e.g., in community or organizational settings, or among men who have sex with men) and **additional meningococcal vaccination** information, see ww.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Adults may receive a single dose of Penbraya (MenACWY–TT/MenB–FHbp) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. For adults not at increased risk, if Penbraya is used for dose 1 MenB, then MenB–FHbp (Trumenba) should be administered for dose 2 MenB. For adults at increased risk of meningococcal disease, Penbraya may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day **and** at least 6 months have elapsed since most recent Penbraya dose.

Monkeypox virus vaccination

Special situations

- **Any person at risk for monkeypox infection:** complete 2-dose series, 28 days apart.

  Risk factors for monkeypox infection include:
  - Gay, bisexual, or other MSM, or a person who has sex with gay, bisexual, or other MSM who in the past 6 months have had one of the following:
    - A new diagnosis of at least 1 sexually transmitted disease
    - More than 1 sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where monkeypox virus transmission is occurring
  - Persons who are sexual partners of the persons described above
  - Persons who anticipate experiencing any of the situations described above
- **Pregnancy:** There is currently no ACIP recommendation for Jynneos use in pregnancy due to lack of safety data in pregnant women. Pregnant women with any risk factor described above may receive Jynneos.
- **Health care personnel:** Vaccination to protect against occupational risk in healthcare settings is not routinely recommended.

  For detailed information, see www.cdc.gov/mpox/hcp/vaccine-considerations/vaccination-overview.html.

Pneumococcal vaccination

Routine vaccination

- **Age 50 years or older who have:**
  - **Not previously received a dose of PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21
    - If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose
  - **Previously received only PPSV23:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21, at least 1 year after the last PPSV23 dose.
    - If PCV15 is used, no additional PPSV23 doses are recommended.
  - **Previously received both PCV13 and PPSV23 but NO PPSV23 was received at age 65 years or older:** 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.
  - **Previously received both PCV13 and PPSV23, AND PPSV23 was received at age 65 years or older:** Based on shared clinical decision–making, 1 dose of PCV20 or 1 dose of PCV21 at least 5 years after the last pneumococcal vaccine dose.

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Notes

Pneumococcal vaccination - *continued*

Special situations

- **Age 19–49 years with certain underlying medical conditions or other risk factors** who have:**
  - **Not previously received a PCV13, PCV15, PCV20, or PCV21 or whose previous vaccination history is unknown:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21
    - If PCV15 is used, administer 1 dose PPSV23 at least 1 year after the PCV15 dose (may use minimum interval of 8 weeks for adults with an immunocompromising condition,* cochlear implant, or cerebrospinal fluid leak).
  - **Previously received only PCV7:** follow the recommendation above.
  - **Previously received only PCV13:** 1 dose PCV20 or 1 dose PCV21 at least 1 year after the last PCV13 dose
  - **Previously received only PPSV23:** 1 dose PCV15 or 1 dose PCV20 or 1 dose PCV21, at least 1 year after the last PPSV23 dose.
    - If PCV15 is used, no additional PPSV23 doses are recommended.
  - **Previously received PCV13 and 1 dose of PPSV23:**
    - Cochlear implant, cerebrospinal fluid leak, or an immunocompromising condition*: 1 dose PCV20 or 1 dose PCV21 at least 5 years after the last pneumococcal vaccine dose.
    - Alcoholism, chronic heart/liver/lung disease, cigarette smoking, or diabetes mellitus: no additional PCV or PPSV23 doses recommended at this time. Review pneumococcal recommendations when age 50 years or older.

Adults aged 19 years and older who have received PCV20 or PCV21: no additional pneumococcal vaccine dose recommended.

Pregnancy: no recommendation for PCV or PPSV23 due to limited data. Summary of existing data on pneumococcal vaccination during pregnancy can be found at www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm.

PPSV23 not available: adults aged 19 years or older who received PCV15 but have not yet completed PPSV23 series, can complete the series with either 1 dose of PCV20 or 1 dose of PCV21 if they no longer have access to PPSV23.

For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app which can be downloaded here: www.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html.

***Note:** Immunocompromising conditions include chronic renal failure, nephrotic syndrome, immunodeficiencies, iatrogenic immunosuppression, generalized malignancy, HIV infection, Hodgkin disease, leukemia, lymphoma, multiple myeloma, solid organ transplant, congenital or acquired asplenia, or sickle cell disease or other hemoglobinopathies.

****Note:** Underlying medical conditions or other risk factors include alcoholism, chronic heart/liver/lung disease, chronic renal failure, cigarette smoking, cochlear implant, congenital or acquired asplenia, CSF leak, diabetes mellitus, generalized malignancy, HIV infection, Hodgkin disease, immunodeficiencies, iatrogenic immunosuppression, leukemia, lymphoma, multiple myeloma, nephrotic syndrome, solid organ transplant, or sickle cell disease or other hemoglobinopathies.

Poliovirus vaccination

Routine vaccination

- **Adults known or suspected to be unvaccinated or incompletely vaccinated:** administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.* Unless there are specific reasons to believe they were not vaccinated, most adults who were born and raised in the United States can assume they were vaccinated against polio as children.

Special situations

- **Adults at increased risk for exposure to poliovirus who completed primary series*:** may administer one lifetime IPV booster.

***Note:** Complete primary series consists of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

For detailed information, see www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

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Notes

Respiratory syncytial virus vaccination

Routine vaccination

- **Pregnant women of any age:**
  - **Pregnant at 32 weeks 0 days through 36 weeks and 6 days gestation from September through January in most of the continental United States*:** 1 dose **Abrysvo**. Administer RSV vaccine regardless of previous RSV infection.
  - Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab (RSV monoclonal antibody) is recommended to prevent severe respiratory syncytial virus disease in infants.
  - **All other pregnant women:** RSV vaccine not recommended
  - **Subsequent pregnancies:** additional doses not recommended. No data are available to inform whether additional doses are needed in subsequent pregnancies. Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab.

***Note:** Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climate) should follow guidance from public health authorities on timing of administration. Refer to the 2025 Child and Adolescent Immunization Schedule for considerations regarding nirsevimab administration to infants.

Age 75 years or older

- **Unvaccinated:** 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended
- **Previously vaccinated:** additional doses not recommended. No data are available to inform whether additional doses are needed.

Special situations

- **Age 60–74 years:**
  - **Unvaccinated and at increased risk of severe RSV disease**:** 1 dose (Arexvy or Abrysvo or mResvia). Additional doses not recommended.
  - **Previously vaccinated:** additional doses not recommended. No data are available to inform whether additional doses are needed.

Persons 60 years and older can get RSV vaccine at any time but it is best to administer in late summer and early fall before RSV spreads in communities—ideally August through October in most of continental United States. For further guidance, see www.cdc.gov/mmwr/volumes/73/wr/mm7332e1.htm.

****Note:** ***People can self–attest to the presence of a risk factor.*** **The following medical and other conditions increase the risk of severe RSV disease:**

- Chronic cardiovascular disease e.g., heart failure, coronary artery disease, congenital heart disease. Excludes isolated hypertension.
- Chronic lung or respiratory disease e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, cystic fibrosis
- End stage renal disease or dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end–organ damage
- Diabetes mellitus requiring treatment with insulin or sodium–glucose cotransporter 2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness e.g., post–stroke dysphagia, amyotrophic lateral sclerosis, muscular dystrophy. Excludes history of stroke without impaired airway clearance.
- Chronic liver disease e.g., cirrhosis
- Chronic hematologic conditions e.g., sickle cell disease, thalassemia
- Severe obesity (body mass index ≥ 40 kg/m2)
- Moderate or severe immune compromise
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk of severe disease due to viral respiratory infection e.g., frailty, concern for presence of undiagnosed chronic medical conditions, residence in a remote or rural community where escalation of medical care is challenging.

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Notes

Tetanus, diphtheria, and pertussis vaccination

Routine vaccination

- **Completed primary series and received at least 1 dose Tdap at age 10 years or older:** Td or Tdap every 10 years thereafter
- **Completed primary series and did NOT receive Tdap at age 10 years or older:** 1 dose Tdap, then Td or Tdap every 10 years thereafter
- **Unvaccinated or incomplete primary vaccination series for tetanus, diphtheria, or pertussis:** administer remaining doses (1, 2, or 3 doses) to complete 3-dose primary series. 1 dose Tdap followed by 1 dose Td or Tdap at least 4 weeks later, and a third dose of Td or Tdap 6–12 months later (Tdap is preferred as first dose and can be substituted for any Td dose), then Td or Tdap every 10 years thereafter.

Special situations

- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36
- **Wound management:** Persons with 3 or more doses of tetanus–toxoid–containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus–toxoid–containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus–toxoid–containing vaccine. Tdap is preferred for persons who have not previously received Tdap or whose Tdap history is unknown. If a tetanus–toxoid–containing vaccine is indicated for a pregnant woman, use Tdap. For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm

Varicella vaccination

Routine vaccination

- **No evidence of immunity to varicella:** 2-dose series 4–8 weeks apart if previously did not receive varicella–containing vaccine (VAR or MMRV [measles–mumps–rubella–varicella vaccine] for children); if previously received 1 dose varicella–containing vaccine, 1 dose at least 4 weeks after first dose.
  - **Evidence of immunity:** U.S.–born before 1980 (except for pregnant women and health care personnel [see below]), documentation of 2 doses varicella–containing vaccine at least 4 weeks apart, diagnosis or verification of history of varicella or herpes zoster by a health care provider, laboratory evidence of immunity or disease.

Special situations

- **Pregnancy with no evidence of immunity to varicella:** VAR contraindicated during pregnancy; after pregnancy (before discharge from health care facility), 1 dose if previously received 1 dose varicella–containing vaccine or dose 1 of 2-dose series (dose 2: 4–8 weeks later) if previously did not receive any varicella–containing vaccine, regardless of whether U.S.–born before 1980.
- **Health care personnel with no evidence of immunity to varicella:** 1 dose if previously received 1 dose varicella–containing vaccine; 2-dose series 4–8 weeks apart if previously did not receive any varicella–containing vaccine, regardless of whether U.S.–born before 1980.
- **HIV infection with CD4 percentages ≥15% and CD4 count ≥200 cells/mm^3 with no evidence of immunity:** Vaccination may be considered (2 doses 3 months apart); VAR contraindicated for HIV infection with CD4 percentage <15% or CD4 count <200 cells/mm^3.
- **Severe immunocompromising conditions:** VAR contraindicated

Zoster vaccination

Routine vaccination

- **Age 50 years or older*:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon), regardless of previous herpes zoster or history of zoster vaccine live (ZVL, Zostavax) vaccination.

***Note:** Serologic evidence of prior varicella is not necessary for zoster vaccination. However, if serologic evidence of varicella susceptibility becomes available, providers should follow ACIP guidelines for varicella vaccination first. RZV is not indicated for the prevention of varicella, and there are limited data on the use of RZV in persons without a history of varicella or varicella vaccination.

Special situations

- **Pregnancy:** There is currently no ACIP recommendation for RZV use in pregnancy. Consider delaying RZV until after pregnancy.
- **Immunocompromising conditions (including persons with HIV regardless of CD4 count)**:** 2-dose series recombinant zoster vaccine (RZV, Shingrix) 2–6 months apart (minimum interval: 4 weeks; repeat dose if administered too soon). For detailed information, see www.cdc.gov/shingles/hcp/vaccine–considerations/immunocompromised–adults.html

****Note:** If there is no documented history of varicella, varicella vaccination, or herpes zoster, providers should refer to the clinical considerations for use of RZV in immunocompromised adults aged ≥19 years and the ACIP varicella vaccine recommendations for further guidance: www.cdc.gov/mmwr/volumes/71/wr/mm7103a2.htm

Appendix Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4–1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024–25 Influenza Season | MMWR (cdc.gov), *and* Contraindications and Precautions for COVID–19 Vaccination

Vaccines and Other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
COVID–19 mRNA vaccines [Comirnaty, mNexspike, Spikevax]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID–19 vaccine[3]	• Diagnosed non–severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID–19 vaccine[3]; or non–severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID–19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID–19 vaccine • Multisystem inflammatory syndrome in children (MIS–C) or multisystem inflammatory syndrome in adults (MIS–A) • Moderate or severe acute illness, with or without fever
COVID–19 protein subunit vaccine [Nuvaxovid]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a Nuvaxovid[3]	• Diagnosed non–severe allergy (e.g., urticaria beyond the injection site) to a component of Nuvaxovid[3]; or non–severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of Nuvaxovid • Myocarditis or pericarditis within 3 weeks after a dose of any COVID–19 vaccine • Multisystem inflammatory syndrome in children (MIS–C) or multisystem inflammatory syndrome in adults (MIS–A) • Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg)	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture–based inactivated injectable (ccIIV3) [Flucelvax]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[3] of ccIIV3	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV3) [Flublok]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[3] of RIV3	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV3) [Flumist]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg) • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear, or any other cranial CSF leak • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days.	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons aged 5 years or older • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild–type influenza virus infection [e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)] • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
3. Vaccination providers should check FDA–approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. See Package inserts for U.S.–licensed vaccines.

Appendix

Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

Vaccine	Contraindicated or Not Recommended[1]	Precautions[2]
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • Pregnancy: PreHevbrio is not recommended due to lack of safety data in pregnant women. Use other hepatitis B vaccines if HepB is indicated[4]	• Moderate or severe acute illness with or without fever
Hepatitis A–Hepatitis B vaccine (HepA–HepB) [Twinrix]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long–term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody–containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon–gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever
Meningococcal ACWY (MenACWY) (MenACWY–CRM) [Menveo] (MenACWY–TT) [MenQuadfi]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For MenACWY–CRM only: severe allergic reaction to any diphtheria toxoid– or CRM197–containing vaccine • For MenACWY–TT only: severe allergic reaction to a tetanus toxoid–containing vaccine	• Moderate or severe acute illness with or without fever
Meningococcal B (MenB) MenB–4C [Bexsero] MenB–FHbp [Trumenba]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB–4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY–TT/MenB–FHbp) [Penbraya]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction to a tetanus toxoid–containing vaccine	• Moderate or severe acute illness, with or without fever
Mpox [Jynneos]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness, with or without fever
Pneumococcal conjugate (PCV15, PCV20, PCV21)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria–toxoid–containing vaccine or to its vaccine component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (e.g., anaphylaxis) to a vaccine component	• Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures), not attributable to another identifiable cause, within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain–Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus–toxoid–containing vaccine • History of Arthus–type hypersensitivity reactions after a previous dose of diphtheria–toxoid containing or tetanus–toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus–toxoid–containing vaccine • Moderate or severe acute illness with or without fever • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized
Varicella (VAR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long–term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody–containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin–containing products • Moderate or severe acute illness with or without fever
Zoster recombinant vaccine (RZV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever • Current episode of herpes zoster

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip–recs/general–recs/contraindications.html.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip–recs/general–recs/contraindications.html.
3. Vaccination providers should check FDA–approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.–licensed vaccines are available at www.fda.gov/vaccines–blood–biologics/approved–products/vaccines–licensed–use–united–states.
4. For information on the pregnancy exposure registry for persons who were inadvertently vaccinated with PreHevbrio while pregnant, please visit www.prehevbrio.com/#safety.

Addendum

Recommended Adult Immunization Schedule for Ages 19 Years or Older, United States, 2025

In addition to the recommendations presented in the previous sections of this immunization schedule, ACIP has approved the following recommendations by majority vote since October 24, 2024.

Vaccines	Recommendations	Effective Date of Recommendation*
Meningococcal (MenACWY-CRM/MenB-4C, Penmenvy)	MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit in: 1. healthy persons aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccine and 2. persons aged = 10 years who are at increased risk for meningococcal disease (e.g., because of persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia)	June 25, 2025
RSV (Abrysvo, Arexvy, mResvia)	Adults 50–59 years of age who are at increased risk of severe RSV disease[a] may receive a single dose of RSV vaccine[b,c]. a. CDC will publish Clinical Considerations that describe chronic medical conditions and other risk factors for severe RSV disease for use in this risk-based recommendation. b. At this time, RSV vaccination is recommended as a single dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose. c. RSV vaccine can be administered with any product licensed in this age group. As of March 27, 2025, that includes GSK's Arexvy and Pfizer's Abrysvo. There is no preferential recommendation for any licensed product over another.	June 25, 2025
Influenza	ACIP reaffirms the recommendations for routine annual influenza vaccination of all persons aged = 6 months who do not have contraindications for the 2025–2026 season	July 22, 2025
Influenza	ACIP recommends only single-dose formulations of annual influenza vaccines that are free of thimerosal as a preservative for three populations: - Children 18 years or younger - Pregnant women - All adults	July 22, 2025
Note: As of May 29, 2025, the schedule incorporates the HHS directive regarding COVID-19 vaccine recommendations. (Changes were made to tables and notes for COVID-19 vaccines in pregnant women).		

*The effective date is the date when the recommendation was adopted and became official.

EXHIBIT 14

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger

UNITED STATES 2025

Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody (Nirsevimab)	RSV-mAb	Beyfortus
Vaccine	**Abbreviation(s)**	**Trade name(s)**
COVID-19 vaccine	1vCOV-mRNA	Comirnaty, mNexspike, Spikevax
	1vCOV-aPS	Nuvaxovid
Dengue vaccine	DEN4CYD	Dengvaxia
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel Infanrix
Haemophilus influenzae type b vaccine	Hib (PRP-T) Hib (PRP-OMP)	ActHIB Hiberix PedvaxHIB
Hepatitis A vaccine	HepA	Havrix Vaqta
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated: egg-based)	IIV3	Multiple
Influenza vaccine (inactivated: cell-culture)	ccIIV3	Flucelvax
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M-M-R II Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB-4C	Bexsero
	MenB-FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/ MenB-FHbp	Penbraya
Monkeypox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15 PCV20	Vaxneuvance Prevnar 20
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo
Rotavirus vaccine	RV1 RV5	Rotarix RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac Tdvax
Varicella vaccine	VAR	Varivax
Combination vaccines *(use combination vaccines instead of separate injections when appropriate)*		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	DTaP-IPV/Hib	Pentacel
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix Quadracel
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by ACIP or CDC.

Revised October 07, 2025

How to use the child and adolescent immunization schedule

1. Determine recommended vaccine by age **(Table 1)**
2. Determine recommended interval for catch-up vaccination **(Table 2)**
3. Assess need for additional recommended vaccines by medical condition or other indication **(Table 3)**
4. Review vaccine types, frequencies, intervals, and considerations for special situations **(Notes)**
5. Review contraindications and precautions for vaccine types **(Appendix)**
6. Review new or updated ACIP guidance **(Addendum)**

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/hcp/imz-schedules/app.html

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html
- ACIP Shared Clinical Decision-Making Recommendations: www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/surv-manual/php/

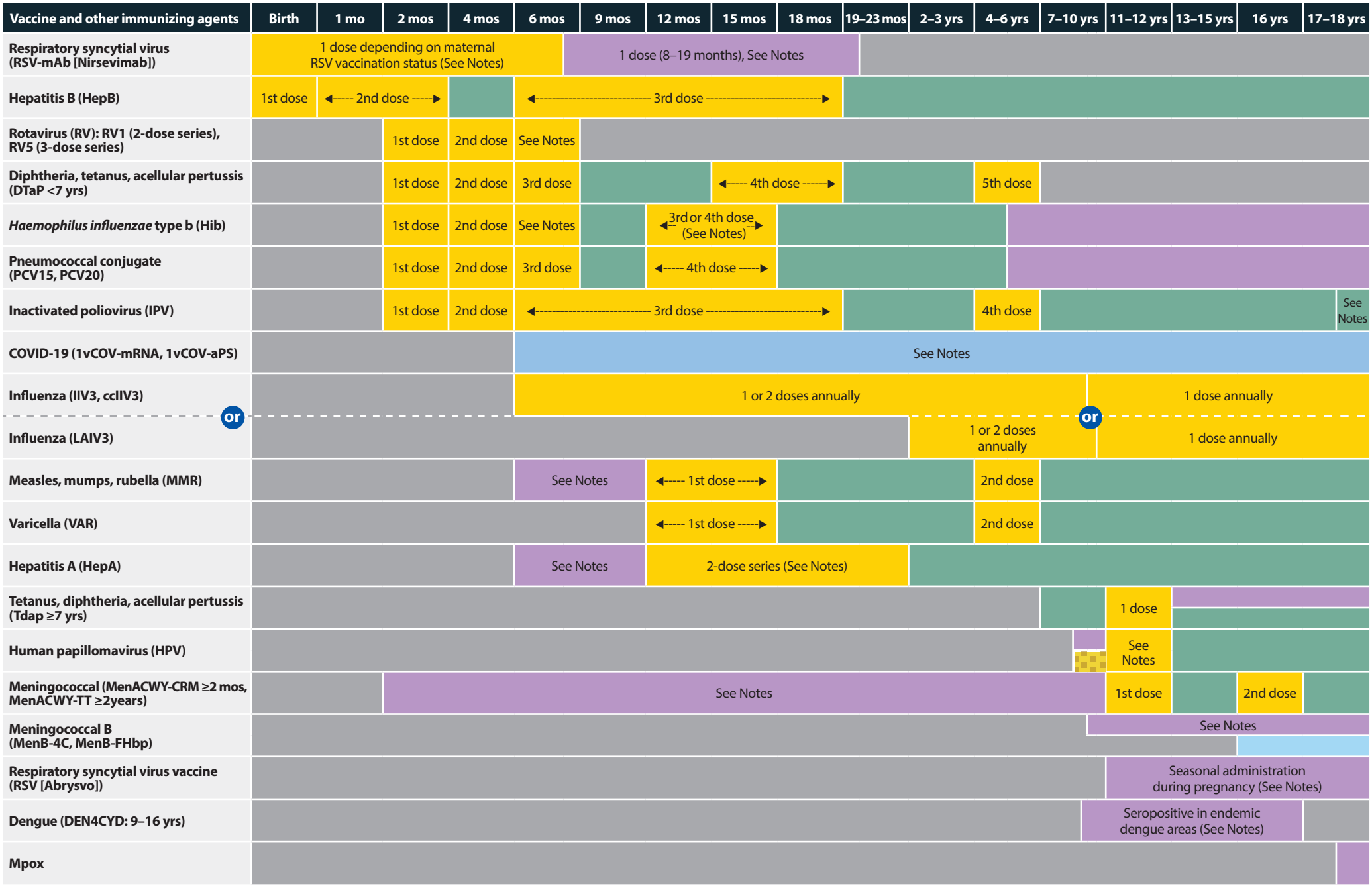
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Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).



Range of recommended ages for all children
Range of recommended ages for catch-up vaccination
Range of recommended ages for certain high-risk groups or populations
Recommended vaccination can begin in this age group
Vaccination is based on shared clinical decision-making
No Guidance/ Not Applicable

Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2025

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the Notes that follow.**

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Children age 4 months through 6 years					
Hepatitis B	Birth	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose** minimum age for the final dose is 24 weeks		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days.	**4 weeks**	**4 weeks** maximum age for final dose is 8 months, 0 days		
Diphtheria, tetanus, and acellular pertussis	6 weeks	**4 weeks**	**4 weeks**	**6 months**	**6 months** A fifth dose is not necessary if the fourth dose was administered at age 4 years or older ***and*** at least 6 months after dose 3
Haemophilus influenzae type b	6 weeks	**No further doses needed** if first dose was administered at age 15 months or older. **4 weeks** if first dose was administered before the 1st birthday. **8 weeks (as final dose)** if first dose was administered at age 12 through 14 months.	**No further doses needed** if previous dose was administered at age 15 months or older **4 weeks** if current age is younger than 12 months ***and*** first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib, Pentacel, Hiberix), Vaxelis or unknown **8 weeks *and* age 12–59 months (as final dose)** if current age is younger than 12 months ***and*** first dose was administered at age 7–11 months; **OR** if current age is 12–59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose was administered at younger than 15 months; **OR** if both doses were PedvaxHIB and were administered before the 1st birthday	**8 weeks (as final dose)** This dose only necessary for children age 12–59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	**No further doses needed** for healthy children if first dose was administered at age 24 months or older **4 weeks** if first dose was administered before the 1st birthday **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after	**No further doses needed** for healthy children if previous dose was administered at age 24 months or older **4 weeks** if current age is younger than 12 months ***and*** previous dose was administered at <7 months old **8 weeks (as final dose for healthy children)** if previous dose was administered between 7–11 months (wait until at least 12 months old); **OR** if current age is 12 months or older ***and*** at least 1 dose was administered before age 12 months	**8 weeks (as final dose)** This dose is only necessary for children age 12–59 months regardless of risk, or age 60–71 months with any risk, who received 3 doses before age 12 months.	
Inactivated poliovirus	6 weeks	**4 weeks**	**4 weeks** if current age is <4 years **6 months (as final dose)** if current age is 4 years or older	**6 months (minimum age 4 years for final dose)**	
Measles, mumps, rubella	12 months	**4 weeks**			
Varicella	12 months	**3 months**			
Hepatitis A	12 months	**6 months**			
Meningococcal ACWY	2 months MenACWY-CRM 2 years MenACWY-TT	**8 weeks**	See Notes	See Notes	
Children and adolescents age 7–18 years					
Meningococcal ACWY	Not applicable (N/A)	**8 weeks**			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	**4 weeks**	**4 weeks** if first dose of DTaP/DT was administered before the 1st birthday **6 months (as final dose)** if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday	**6 months** if first dose of DTaP/DT was administered before the 1st birthday	
Human papillomavirus	9 years	**Routine dosing intervals are recommended.**			
Hepatitis A	N/A	**6 months**			
Hepatitis B	N/A	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose**		
Inactivated poliovirus	N/A	**4 weeks**	**6 months** A fourth dose is not necessary if the third dose was administered at age 4 years or older ***and*** at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years **OR** if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	**4 weeks**			
Varicella	N/A	**3 months** if younger than age 13 years. **4 weeks** if age 13 years or older			
Dengue	9 years	**6 months**	6 months		

Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2025

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions are often not mutually exclusive. If multiple conditions are present, refer to guidance in all relevant columns. See Notes for medical conditions not listed.

Vaccine and other immunizing agents	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count[a]		CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Heart disease or chronic lung disease	Kidney failure, End-stage renal disease or on dialysis	Chronic liver disease	Diabetes
			<15% or <200/mm³	≥15% and ≥200/mm³						
RSV-mAb (nirsevimab)		2nd RSV season		1 dose depending on maternal RSV vaccination status (See Notes)			2nd RSV season for chronic lung disease (See Notes)	1 dose depending on maternal RSV vaccination status (See Notes)		
Hepatitis B										
Rotavirus		SCID[b]								
DTaP/Tdap	DTaP Tdap: 1 dose each pregnancy									
Hib		HSCT: 3 doses	See Notes			See Notes				
Pneumococcal										
IPV										
COVID-19	See Notes	Additional doses may be necessary (See Notes)		See Notes						
Influenza inactivated		Solid organ transplant: 18yrs (See Notes)								
LAIV3							Asthma, wheezing: 2–4 years[c]			
MMR	*									
VAR	*									
Hepatitis A										
HPV	*	3-dose series (See Notes)								
MenACWY										
MenB										
RSV (Abrysvo)	Seasonal administration (See Notes)									
Dengue										
Mpox	See Notes									

Recommended for all age-eligible children who lack documentation of a complete vaccination series

Not recommended for all children, but recommended for some children based on increased risk for or severe outcomes from disease

Vaccination is based on shared clinical decision-making

Additional doses may be necessary based on medical condition or other indications. See Notes.

Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction

Contraindicated or not recommended
*Vaccinate after pregnancy, if indicated

No Guidance/ Not Applicable

a. For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

b. Severe Combined Immunodeficiency

c. LAIV3 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

Notes

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule, 2025.

Additional information

- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3-2, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/imz-best-practices/timing-spacing-immunobiologics.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Barnett ED, Lynfield Ruth, Sawyer MH, eds. *Red Book: 2021–2024 Report of the Committee on Infectious Diseases*. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021:72–86).
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the child and adolescent vaccine schedule are covered by VICP except dengue, PPSV23, RSV, Mpox and COVID-19 vaccines. Mpox and COVID-19 vaccines are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID-19 vaccination (minimum age: 6 months [Spikevax], 5 years [Comirnaty], 12 years [mNexspike, Novaxovid])

Shared clinical decision-making

Vaccination based on individual-based decision-making —with an emphasis that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk according to the CDC list of COVID-19 risk factors (see www.cdc.gov/covid/hcp/clinical-care/underlying-conditions.html). For additional information on shared clinical decision-making, see www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html

Current COVID-19 schedule and dosage formulation available at www.cdc.gov/covidschedule.

Administer an age-appropriate COVID-19 vaccine product for each dose. There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available.

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Dengue vaccination (minimum age: 9 years)

Routine vaccination

- Age 9–16 years living in areas with endemic dengue **AND** have laboratory confirmation of previous dengue infection
  - 3-dose series administered at 0, 6, and 12 months
- Endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau. For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm?s_cid=rr7006a1_w and www.cdc.gov/dengue/index.html
- Dengue vaccine should not be administered to children traveling to or visiting endemic dengue areas.

Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

Routine vaccination

- 5-dose series (3-dose primary series at age 2, 4, and 6 months, followed by booster doses at ages 15–18 months and 4–6 years)
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

Special situations

- **Children younger than age 7 years with a contraindication specific to the pertussis component of DTaP:** May administer Td for all recommended remaining doses in place of DTaP. Encephalopathy within 7 days of vaccination when not attributable to another identifiable cause is the only contraindication specific to the pertussis component of DTaP. For additional information, see www.cdc.gov/pertussis/hcp/vaccine-recommendations/td-offlabel.html.
- **Wound management in children younger than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine:** For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm.

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Haemophilus influenzae type b vaccination
(minimum age: 6 weeks)

Routine vaccination

- **ActHIB, Hiberix, Pentacel, or Vaxelis:** 4-dose series (3-dose primary series at age 2, 4, and 6 months, followed by a booster dose* at age 12–15 months)
  - *Vaxelis is not recommended for use as a booster dose. A different Hib-containing vaccine should be used for the booster dose.
- **PedvaxHIB:** 3-dose series (2-dose primary series at age 2 and 4 months, followed by a booster dose at age 12–15 months)
- **American Indian and Alaska Native infants:** Vaxelis and PedvaxHIB preferred over other Hib vaccines for the primary series.

Catch-up vaccination

- **Dose 1 at age 7–11 months:** Administer dose 2 at least 4 weeks later and dose 3 (final dose) at age12–15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at age 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- **Dose 1 before age 12 months and dose 2 before age 15 months:** Administer dose 3 (final dose) at least 8 weeks after dose 2.
- **2 doses of PedvaxHIB before age 12 months:** Administer dose 3 (final dose) at age12–59 months and at least 8 weeks after dose 2.
- **1 dose administered at age 15 months or older:** No further doses needed
- **Unvaccinated at age 15–59 months:** Administer 1 dose.
- **Previously unvaccinated children age 60 months or older who are not considered high risk:** Catch-up vaccination not required.

For other catch-up guidance, see Table 2. Vaxelis can be used for catch-up vaccination in children younger than age 5 years. Follow the catch-up schedule even if Vaxelis is used for one or more doses. For detailed information on use of Vaxelis see www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm.

Special situations

- **Chemotherapy or radiation treatment:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.
- **Hematopoietic stem cell transplant (HSCT):**
  - 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant, regardless of Hib vaccination history
- **Anatomic or functional asplenia (including sickle cell disease):**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated* persons age 5 years or older
  - 1 dose
- **Elective splenectomy:**
  Unvaccinated* persons age 15 months or older
  - 1 dose (preferably at least 14 days before procedure)
- **HIV infection:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated* persons age 5–18 years
  - 1 dose
- **Immunoglobulin deficiency, early component complement deficiency, or early component complement inhibitor use:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

Unvaccinated* = Less than routine series (through age 14 months) **or no doses (age 15 months or older)*

Hepatitis A vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination

- **2-dose series** (minimum interval: 6 months) at age 12–23 months

Catch-up vaccination

- **Unvaccinated persons through age 18 years should complete a 2-dose series** (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents age 18 years or older may receive HepA-HepB (Twinrix) as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

International travel

- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (www.cdc.gov/travel/):
  - **Infants age 6–11 months**: 1 dose before departure; revaccinate with 2 doses (separated by at least 6 months) between age 12–23 months.
  - **Unvaccinated age 12 months or older**: Administer dose 1 as soon as travel is considered.

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Hepatitis B vaccination
(minimum age: birth)

Routine vaccination

- **Mother is HBsAg-negative**
  - 3-dose series at age 0, 1–2, 6–18 months **(use monovalent HepB vaccine for doses administered before age 6 weeks)**
    - Birth weight ≥2,000 grams: 1 dose within 24 hours of birth if medically stable
    - Birth weight <2,000 grams: 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2,000 grams)
  - Infants who did not receive a birth dose should begin the series as soon as possible (see Table 2 for minimum intervals).
  - Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the birth dose.
  - **Minimum intervals (see Table 2):** when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations.
  - **Final (3rd or 4th) dose:** age 6–18 months **(minimum age 24 weeks)**
- **Mother is HBsAg-positive**
  - **Birth dose (monovalent HepB vaccine only):** administer **HepB vaccine** and **hepatitis B immune globulin (HBIG)** in separate limbs within 12 hours of birth, regardless of birth weight.
  - **Birth weight <2000 grams:** administer 3 additional doses of HepB vaccine beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**.
  - Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.
- **Mother is HBsAg-unknown**

  If other evidence suggestive of maternal hepatitis B infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to have chronic hepatitis B infection), manage infant as if mother is HBsAg-positive.
  - **Birth dose (monovalent HepB vaccine only):**
    - Birth weight ≥2,000 grams: administer **HepB vaccine** within 12 hours of birth. Determine mother's HBsAg status as soon as possible. If mother is determined to be HBsAg-positive, administer **HBIG** as soon as possible (in separate limb), but no later than 7 days of age.
    - Birth weight <2,000 grams: administer **HepB vaccine** and **HBIG** (in separate limbs) within 12 hours of birth. Administer 3 additional doses of **HepB vaccine** beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**.
  - If mother is determined to be HBsAg-positive or if status remains unknown, test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.

Catch-up vaccination

- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months. See Table 2 for minimum intervals.
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation **Recombivax HB** only).
- Adolescents age 18 years may receive:
  - **Heplisav-B:** 2-dose series at least 4 weeks apart
  - **PreHevbrio*:** 3-dose series at 0, 1, and 6 months
  - **HepA-HepB (Twinrix):** 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

Special situations

- Revaccination is generally not recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- **Post-vaccination serology testing and revaccination** (if anti-HBs <10mIU/mL) is recommended for certain populations, including:
  - Infants born to HBsAg-positive mothers
  - Persons who are predialysis or on maintenance dialysis
  - Other immunocompromised persons
  - For detailed revaccination recommendations, see www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm.

***Note:** PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant women.

Human papillomavirus vaccination
(minimum age: 9 years)

Routine and catch-up vaccination

- HPV vaccination routinely recommended at **age 11–12 years (can start at age 9 years)** and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated.
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9–14 years at initial vaccination**: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - **Age 15 years or older at initial vaccination**: 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 12 weeks; dose 1 to dose 3 = 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series **of any valency** has been completed using recommended dosing intervals.

Special situations

- **Immunocompromising conditions, including HIV infection:** 3-dose series, even for those who initiate vaccination at age 9–14 years.
- **History of sexual abuse or assault:** Start at age 9 years
- **Pregnancy:** Pregnancy testing not needed before vaccination; HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant

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Notes

Influenza vaccination
(minimum age: 6 months [IIV3], 2 years [LAIV3],18 years [recombinant influenza vaccine, RIV3])

Routine vaccination

- Use any influenza vaccine appropriate for age and health status annually:
  - **Age 6 months–8 years** who have received fewer than 2 influenza vaccine doses before July 1, 2024, or whose influenza vaccination history is unknown: 2 doses, separated by at least 4 weeks. Administer dose 2 even if the child turns 9 years between receipt of dose 1 and dose 2.
  - **Age 6 months–8 years** who have received at least 2 influenza vaccine doses before July 1, 2024: 1 dose.
  - **Age 9 years or older:** 1 dose
  - **Age 18 years solid organ transplant recipients receiving immunosuppressive medications:** high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines are acceptable options. No preference over other age-appropriate IIV3 or RIV3.
- For the 2024–25 season, see www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm.
- For the 2025–26 season, see the 2025–26 ACIP influenza vaccine recommendations.

Special situations

- **Close contacts (e.g., household contacts) of severely immunosuppressed persons who require a protected environment:** should not receive LAIV3. If LAIV3 is given, they should avoid contact with, or caring for such immunosuppressed persons for 7 days after vaccination.

Note: Persons with an egg allergy can receive any influenza vaccine (egg-based or non-egg based) appropriate for age and health status.

Measles, mumps, and rubella vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination

- 2-dose series at age 12–15 months, age 4–6 years

Catch-up vaccination

- **Unvaccinated children and adolescents:** 2-dose series at least 4 weeks apart*

Special situations

- **International travel**
  - **Infants age 6–11 months:** 1 dose before departure; revaccinate with 2-dose series at age 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.*
  - **Children age 12 months or older:**
    - Unvaccinated: 2-dose series (separated by at least 4 weeks*) before departure
    - Previously received 1 dose: administer dose 2 at least 4 weeks after dose 1*
- In mumps outbreak settings, for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm

***Note:** MMRV not recommended for ages 12–47 months or ages 13–18 years. Minimum interval between MMRV doses is 3 months.

Meningococcal serogroup A,C,W,Y vaccination
(minimum age: 2 months [MenACWY-CRM, Menveo], 2 years [MenACWY-TT, MenQuadfi]), 10 years [MenACWY-TT/MenB-FHbp, Penbraya])

Routine vaccination

- 2-dose series at age 11–12 years; 16 years

Catch-up vaccination

- **Age 13–15 years:** 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- **Age 16–18 years:** 1 dose

Special situations

Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

- **Menveo***
  - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
  - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
  - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- **MenQuadfi**
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

Travel to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj (www.cdc.gov/travel/):

- **Children younger than age 24 months:**
  - **Menveo* (age 2–23 months)**
    - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
    - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
    - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)

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Notes

Meningococcal serogroup A,C,W,Y vaccination
- continued

- **Children age 2 years or older:** 1 dose Menveo* or MenQuadfi

First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits: 1 dose Menveo* or MenQuadfi

Adolescent vaccination of children who received MenACWY prior to age 10 years:

- **Children for whom boosters are recommended because of an ongoing increased risk of meningococcal disease** (e.g., those with complement component deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk.
- **Children for whom boosters are not recommended** (e.g., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

**Menveo has two formulations: lyophilized and liquid. The liquid formulation should not be used before age 10 years. See www.cdc.gov/vaccines/vpd/mening/downloads/menveo-single-vial-presentation.pdf.*

Note: For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Children age 10 years or older may receive a single dose of Penbraya as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day (see "Meningococcal serogroup B vaccination" section below for more information).

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Meningococcal serogroup B vaccination
(minimum age: 10 years [MenB-4C, Bexsero; MenB-FHbp, Trumenba; MenACWY-TT/MenB-FHbp, Penbraya])

Shared clinical decision-making

- **Adolescents not at increased risk age 16–23 years (preferred age 16–18 years)* based on shared clinical decision-making.**
  - **Bexsero or Trumenba (use same brand for all doses):** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

*To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision-making for MenB, see www.cdc.gov/vaccines/hcp/admin/downloads/isd-job-aid-scdm-mening-b-shared-clinical-decision-making.pdf

Special situations

Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use.

- **Bexsero or Trumenba (use same brand for all doses including booster doses)** 3-dose series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3)

For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Children age 10 years or older may receive a dose of Penbraya (MenACWY–TT/MenB–FHbp) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. For age-eligible children not at increased risk, if Penbraya is used for dose 1 MenB, MenB-FHbp (Trumenba) should be administered for dose 2 MenB. For age-eligible children at increased risk of meningococcal disease, Penbraya may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day **and** at least 6 months have elapsed since most recent Penbraya dose.

Monkeypox virus vaccination
(minimum age: 18 years [Jynneos])

Special situations

- **Age 18 years and at risk for monkeypox infection:** complete 2-dose series, 28 days apart.

  Risk factors for monkeypox infection include:
  - Gay, bisexual, or other MSM, or a person who has sex with gay, bisexual, or other MSM who in the past 6 months have had one of the following:
    - A new diagnosis of at least 1 sexually transmitted disease
    - More than 1 sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where monkeypox virus transmission is occurring
  - Persons who are sexual partners of the persons described above
  - Persons who anticipate experiencing any of the situations described above
- **Pregnancy:** There is currently no ACIP recommendation for Jynneos use in pregnancy due to lack of safety data in pregnant women. Pregnant women with any risk factor described above may receive Jynneos.

For detailed information, see www.cdc.gov/mpox/hcp/vaccine-considerations/vaccination-overview.html

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Pneumococcal vaccination
(minimum age: 6 weeks [PCV15], [PCV 20]; 2 years [PPSV23])

Routine vaccination with PCV
- 4-dose series at 2, 4, 6, 12–15 months

Catch-up vaccination with PCV
- Healthy children ages 2–4 years with any incomplete* PCV series: 1 dose PCV
- For other catch-up guidance, see Table 2.

Note: For children **without** risk conditions, PCV20 is not indicated if they have received 4 doses of PCV13 or PCV15 or another age appropriate complete PCV series.

Special situations
Children and adolescents with cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; or diabetes mellitus:

Age 2–5 years
- Any incomplete* PCV series with:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23.
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 administer at least 8 weeks after the most recent PCV dose.

Age 6–18 years
- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.**
- Received PCV before age 6 years but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: 1 dose PCV20 or 1 dose PPSV23 administer at least 8 weeks after the most recent PCV dose.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: no further doses of any PCV or PPSV23 indicated.

Children and adolescents on maintenance dialysis, or with immunocompromising conditions such as nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; or sickle cell disease or other hemoglobinopathies:

Age 2–5 years
- Any incomplete* PCV series:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.

Age 6–18 years
- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or 1 dose of PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.**
- Received PCV before age 6 years but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no additional dose of PCV or PPSV23
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer either PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose and at least 5 years after dose 1 PPSV23.

Pregnancy: no recommendation for PCV or PPSV23 due to limited data. Summary of existing data on pneumococcal vaccination during pregnancy can be found at www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm

For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app, which can be downloaded here: wcms-wp.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html

**Incomplete series* = Not having received all doses in either the recommended series or an age-appropriate catch-up series. See Table 2 in ACIP pneumococcal recommendations at stacks.cdc.gov/view/cdc/133252

***When both PCV15 and PPSV23 are indicated, administer all doses of PCV15 first. PCV15 and PPSV23 should not be administered during the same visit.*

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Poliovirus vaccination
(minimum age: 6 weeks)

Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended on or after age 4 years and at least 6 months after the previous dose.

Catch-up vaccination

- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- **Adolescents age 18 years known or suspected to be unvaccinated or incompletely vaccinated:** administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.* Unless there are specific reasons to believe they were not vaccinated, most persons aged 18 years or older born and raised in the United States can assume they were vaccinated against polio as children.

Series containing oral poliovirus vaccine (OPV), either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s_%20cid=mm6601a6_w.
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements.
  - Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
  - Doses of OPV administered on or after April 1, 2016, should not be counted.
  - For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w.
- For other catch-up guidance, see Table 2.

Special situations

- **Adolescents aged 18 years at increased risk of exposure to poliovirus and completed primary series*:** may administer one lifetime IPV booster

***Note:** Complete primary series consist of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

For detailed information, see: www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

Respiratory syncytial virus immunization
(minimum age: birth [Nirsevimab, RSV-mAb, Beyfortus])

Routine immunization

- **Infants born October – March in most of the continental United States***
  - Mother did not receive RSV vaccine or mother's RSV vaccination status is unknown or mother received RSV vaccine in previous pregnancy: administer 1 dose nirsevimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **less than 14 days** prior to delivery: administer 1 dose nirsevimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **at least 14 days** prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html)
- **Infants born April–September in most of the continental United States***
  - Mother did not receive RSV vaccine or mother's RSV vaccination status is unknown or mother received RSV vaccine in previous pregnancy: administer 1 dose nirsevimab shortly before start of RSV season.*
  - Mother received RSV vaccine **less than 14 days** prior to delivery: administer 1 dose nirsevimab shortly before start of RSV season.*
  - Mother received RSV vaccine **at least 14 days** prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html)

Infants with prolonged birth hospitalization** (e.g., for prematurity) discharged October through March should be immunized shortly before or promptly after discharge.

Special situations

- **Ages 8–19 months with chronic lung disease of prematurity requiring medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season; severe immunocompromise; cystic fibrosis with either weight for length <10th percentile or manifestation of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable)**:**
  - 1 dose nirsevimab shortly before start of second RSV season*
- **Ages 8–19 months who are American Indian or Alaska Native:** 1 dose nirsevimab shortly before start of second RSV season*
- **Age-eligible and undergoing cardiac surgery with cardiopulmonary bypass**:** 1 additional dose of nirsevimab after surgery. See www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

***Note:** While the timing of the onset and duration of RSV season may vary, administration of nirsevimab is recommended October through March in most of the continental United States (optimally October through November or within 1 week of birth). Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdiction with tropical climate) should follow guidance from public health authorities (e.g., CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

****Note:** Nirsevimab can be administered to children who are eligible to receive palivizumab. Children who have received nirsevimab should not receive palivizumab for the same RSV season.

For further guidance, see www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm and www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html

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Notes

Respiratory syncytial virus vaccination (RSV [Abrysvo])

Routine vaccination

- **Pregnant at 32 weeks 0 days through 36 weeks and 6 days gestation from September through January in most of the continental United States*:** 1 dose Abrysvo. Administer RSV vaccine regardless of previous RSV infection.
  - Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab (RSV monoclonal antibody) is recommended to prevent severe respiratory syncytial virus disease in infants.
- **All other pregnant women:** RSV vaccine not recommended
- **Subsequent pregnancies:** additional doses not recommended. No data are available to inform whether additional doses are needed in subsequent pregnancies. Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab.

***Note:** Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climate) should follow guidance from public health authorities (e.g., CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

Rotavirus vaccination (minimum age: 6 weeks)

Routine vaccination

- **Rotarix:** 2-dose series at age 2 and 4 months
- **RotaTeq:** 3-dose series at age 2, 4, and 6 months
- If any dose in the series is either **RotaTeq** or unknown, default to 3-dose series.

Catch-up vaccination

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

Tetanus, diphtheria, and pertussis (Tdap) vaccination (minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

Routine vaccination

- **Age 11–12 years:** 1 dose Tdap (adolescent booster)
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36

Note: Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

Catch-up vaccination

- **Age 13–18 years who have not received Tdap:** 1 dose Tdap (adolescent booster)
- **Age 7–18 years not fully vaccinated* with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- **Tdap administered at age 7–10 years:**
  - **Age 7–9 years** who receive Tdap should receive the adolescent Tdap booster dose at age 11–12 years
  - **Age 10 years** who receive Tdap do not need the adolescent Tdap booster dose at age 11–12 years
- **DTaP inadvertently administered on or after age 7 years**:
  - **Age 7–9 years**: DTaP may count as part of catch-up series. Administer adolescent Tdap booster dose at age 11–12 years.
  - **Age 10–18 years**: Count dose of DTaP as the adolescent Tdap booster dose.
- For other catch-up guidance, see Table 2.

Special situations

- **Wound management** in persons age 7 years or older with history of 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons age 11 years or older who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant adolescent, use Tdap.
- For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm.

**Fully vaccinated* = 5 valid doses of DTaP or 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

Varicella vaccination (minimum age: 12 months)

Routine vaccination

- 2-dose series at age 12–15 months, 4–6 years
  - Dose 2 may be administered as early as 3 months after dose 1 (a dose inadvertently administered after at least 4 weeks may be counted as valid).

Catch-up vaccination

- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have a 2-dose series:
  - **Age 7–12 years**: Routine interval: 3 months (a dose inadvertently administered after at least 4 weeks may be counted as valid)
  - **Age 13 years and older**: Routine interval: 4–8 weeks (minimum interval: 4 weeks)

Note: MMRV not recommended for ages 12–47 months or ages 13–18 years (administer MMR and varicella vaccines separately for these age groups). Minimum interval between MMRV doses is 3 months.

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Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

Guide to Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4-1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024–25 Influenza Season | MMWR (cdc.gov), *and* Contraindications and Precautions for COVID-19 Vaccination

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
COVID-19 mRNA vaccines [Comirnaty, mNexspike, Spikevax]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine[3]	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID-19 vaccine[3]; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
COVID-19 protein subunit vaccine [Nuvaxovid]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a Nuvaxovid[3]	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of Nuvaxovid[3]; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of a Nuvaxovid • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg)	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable (ccIIV3) [Flucelvax]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[3] of ccIIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV3) [Flublok]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[3] of RIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV3) [Flumist]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg) • Children age 2–4 years with a history of asthma or wheezing • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear or any other cranial CSF leak • Children and adolescents receiving aspirin or salicylate-containing medications • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons age 5 years old or older • Persons with underlying medical conditions other than those listed under contraindications that might predispose to complications after wild-type influenza virus infection, e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus) • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should **NOT** be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. See Package inserts for U.S.-licensed vaccines.

Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
Dengue (DEN4CYD)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Lack of laboratory confirmation of a previous dengue infection	• Pregnancy • HIV infection without evidence of severe immunosuppression • Moderate or severe acute illness with or without fever
Diphtheria, tetanus, pertussis (DTaP)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP	• Guillain-Barré syndrome (GBS) within 6 weeks after previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid-containing vaccine • For DTaP only: Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized • Moderate or severe acute illness with or without fever
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Younger than age 6 weeks	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • Pregnancy: PreHevbrio is not recommended due to lack of safety data in pregnant women. Use other hepatitis B vaccines if HepB is indicated[4]	• Moderate or severe acute illness with or without fever
Hepatitis A-Hepatitis B vaccine (HepA-HepB) [Twinrix]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended.*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity and children younger than age 4 years	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever • For MMRV only: Personal or family (i.e., sibling or parent) history of seizures of any etiology • If using MMRV, see Varicella/MMRV for additional precautions
Meningococcal ACWY (MenACWY) MenACWY-CRM [Menveo] MenACWY-TT [MenQuadfi]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Men ACWY-CRM only: severe allergic reaction to any diphtheria toxoid— or CRM197—containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	• For MenACWY-CRM only: Preterm birth if younger than age 9 months • Moderate or severe acute illness with or without fever
Meningococcal B (MenB) MenB-4C [Bexsero] MenB-FHbp [Trumenba]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY-TT/MenB-FHbp) [Penbraya]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction to a tetanus toxoid-containing vaccine	• Moderate or severe acute illness, with or without fever
Mpox [Jynneos]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness, with or without fever
Pneumococcal conjugate (PCV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria-toxoid-containing vaccine or its component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
RSV monoclonal antibody (RSV-mAb)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[5]	• Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Rotavirus (RV) RV1 [Rotarix] RV5 [RotaTeq]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe combined immunodeficiency (SCID) • History of intussusception	• Altered immunocompetence other than SCID • Chronic gastrointestinal disease • RV1 only: Spina bifida or bladder exstrophy • Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid–containing vaccine • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized • Moderate or severe acute illness with or without fever
Varicella (VAR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity and children younger than age 4 years	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever • If using MMRV, see MMR/MMRV for additional precautions

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.
4. For information on the pregnancy exposure registry for persons who were inadvertently vaccinated with PreHevbrio while pregnant, please visit www.prehevbrio.com/#safety.
5. Full prescribing information for BEYFORTUS (nirsevimab-alip) www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf.

Addendum

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

In addition to the recommendations presented in the previous sections of this immunization schedule, ACIP has approved the following recommendations by majority vote since October 24, 2024.

Vaccines	Recommendations	Effective Date of Recommendation*
Meningococcal (MenACWYCRM/ MenB-4C, Penmenvy)	MenABCWY vaccine may be used when both MenACWY and MenB are indicated at the same visit in: 1. healthy persons aged 16–23 years (routine schedule) when shared clinical decision-making favors administration of MenB vaccine and 2. persons aged ≥10 years who are at increased risk for meningococcal disease (e.g., because of persistent complement deficiencies, complement inhibitor use, or functional or anatomic asplenia)	June 25, 2025
Influenza	ACIP reaffirms the recommendations for routine annual influenza vaccination of all persons aged ≥ 6 months who do not have contraindications for the 2025–2026 season	July 22, 2025
Influenza	ACIP recommends only single-dose formulations of annual influenza vaccines that are free of thimerosal as a preservative for three populations: - Children 18 years or younger - Pregnant women - All adults	July 22, 2025
RSV monoclonal antibody (Clesrovimab)	ACIP recommends infants aged < 8 months born during or entering their first RSV season who are not protected by maternal vaccination receive one dose of clesrovimab.	August 4, 2025
Note: As of May 29, 2025, the schedule incorporates the HHS directive regarding COVID-19 vaccine recommendations. (Changes were made to tables and notes for COVID-19 vaccines in pregnant women and children/adolescents ages 6 months through 17 years who are not moderately or severely immunocompromised).		

*The effective date is the date when the recommendation was adopted and became official.

EXHIBIT 15

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
AGENDA

Thursday, December 4, 2025

8:00 AM	**Welcome, Roll Call, and Opening Statement**	Dr. Robert Malone (ACIP Vice Chair) Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
8:30 AM	**Hepatitis B – Recap**	Dr. Robert Malone (ACIP Vice Chair)
	Policy Context and Schedule Comparison	Dr. Vicky Pebsworth (ACIP Childhood and Adolescent Immunization Schedule Workgroup Chair)
	Burden of Disease	Dr. Cynthia Nevison (Presenter)
	HBV Vaccine Safety	Mr. Mark Blaxill (CDC)
	Discussion (ACIP members and ex officios)	
	Discussion (Liaisons)	
10:40 AM	**Hepatitis B Vaccine Manufacturers**	Dr. Candice Robinson (GSK) Dr. Michelle Goveia (Merck) Dr. Ayman Chit (Sanofi)
	Q&A (ACIP members, ex-officios, liaisons)	
11:05 AM	**Lunch**	

11:35 AM	**Hepatitis B Vaccines (continued)**	
	Summary of the Information and Presentation of the Vote Language	Dr. Vicky Pebsworth (ACIP Childhood and Adolescent Immunization Schedule Workgroup Chair)
	VFC Presentation	Dr. Jeanne Santoli (CDC)
	CMS Comments	Mr. Andrew Johnson (CMS, ACIP ex officio)
	Discussion (ACIP members and ex officios)	
	Discussion (Liaisons)	
1:50 PM	**Perspectives from People with Lived Experience**	
2:00 PM	**Public Comments**	
2:30 PM	**Votes**	Dr. Robert Malone (ACIP Vice Chair)
	Hepatitis B Vaccine	
	Hepatitis B Vaccine - VFC	
3:15 PM	**Coverage Implications**	
	VFC Comments	Dr. Georgina Peacock (CDC/NCIRD)
	CMS Comments	Mr. Andrew Johnson (CMS, ACIP ex officio)
3:25 PM	**Break**	
3:30 PM	**Update on Work Groups**	Dr. Robert Malone (ACIP Vice Chair)
3:35 PM	**Agency Updates**	*CDC, CMS, FDA, HRSA, IHS, NIH*
3:45 PM	**Adjourn**	

Friday December 5, 2025

8:00 AM	**Welcome and Roll Call**	Dr. Robert Malone (ACIP Vice Chair) Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
8:20 AM	**Hepatitis B Vaccine Discussion and Votes**	Dr. Vicky Pebsworth (ACIP Childhood and Adolescent Immunization Schedule Workgroup Chair)
	Discussion (ACIP members and ex officios)	
	Discussion (Liaisons)	
	VFC presentation	Dr. Jeanne Santoli (CDC)
	Vote: Hepatitis B Vaccine	Dr. Robert Malone (ACIP Vice Chair)
	Vote: Hepatitis B Vaccine - VFC	
10:20 AM	**Break**	
10:30 AM	**Childhood/Adolescent Immunization Schedule** Evolution of the Childhood/Adolescent Vaccination Schedule in the U.S. and Vaccine Schedule Comparison: U.S. and other Developed Countries Discussion (ACIP members and ex officios) Discussion (Liaisons)	Mr. Aaron Siri (Presenter)
12:40 PM	**Lunch**	
1:10 PM	**U.S. vs. Danish Vaccine Schedule**	Dr. Tracy Beth Hoeg (FDA, ACIP ex officio)
	Discussion (ACIP members and ex officios)	
	Discussion (Liaisons)	
2:30 PM	**Adjourn**	

EXHIBIT 16

An official website of the United States government

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Navigate to:

FOR IMMEDIATE RELEASE
December 5, 2025

Contact: HHS Press Office
202-690-6343
Submit a Request for Comment

ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus

ATLANTA — December 5, 2025 — The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) today voted 8 to 3 to recommend individual-based decision-making for parents deciding whether to give the hepatitis B vaccine, including the birth dose, to infants born to women who test

negative for the virus. For those infants not receiving the birth dose, ACIP suggested in its recommendation that the initial dose be administered no earlier than two months of age.

Individual-based decision-making, known on the CDC immunization schedules as shared clinical decision-making, means that parents and health care providers should consider vaccine benefits, vaccine risks, and infection risks, and that parents consult with their health care provider and decide when or if their child will begin the hepatitis B vaccine series. The committee said parents and health care providers should consider whether there are infection risks such as a household member who has hepatitis B or frequent contact with persons who have emigrated from areas where hepatitis B is common.

ACIP also voted to recommend that when evaluating the need for a subsequent hepatitis B vaccine dose in children, parents should consult with health care providers to decide whether to test antibody levels to hepatitis surface antigen to evaluate adequacy of protection through serology results.

These recommendations on hepatitis B immunization maintain consistency of coverage for all payment mechanisms, including entitlement programs such as the Vaccines for Children Program, Children's Health Insurance Program, Medicaid, and Medicare, as well as insurance plans through the federal Health Insurance Marketplace. ACIP on September 19, 2025, voted to recommend that all pregnant women be tested for the hepatitis B virus, a test that is covered across all insurance programs.

Today's votes <https://www.youtube.com/live/kugxrupkal4> were preceded yesterday <https://www.youtube.com/live/lpthhpbfagi> by presentations to ACIP on the hepatitis B disease burden, vaccine safety, and comparative nation immunization policies as well as briefings from representatives of the vaccine manufacturers.

A presentation [PDF, 1.41 MB] <https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/02-nevison-hepatitis-b-508.pdf> from Cynthia Nevison, Ph.D., on the decline of the hepatitis B disease burden since 1985 concluded that the universal birth dose contribution to acute case decline is likely small. It identified sharp declines in post-transfusion hepatitis B transmission due to advanced blood screening, improved dialysis practices, and needle exchange programs. It also acknowledged a 2019 study that

found 57.9% of estimated births to women who test positive for the hepatitis B surface antigen were attributable to non–US-born women, mainly from high-endemicity countries. The study reported that 0.5% of pregnancies in the U.S. are to women who test positive for the hepatitis B surface antigen, which is the most significant risk to newborns for being infected with the virus.

ACIP Childhood/Adolescent Schedule Workgroup Chair Vicky Pebsworth, Ph.D., RN, presented [PDF, 487 KB] <https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/01-pebsworth-hepatitis-b-508.pdf> the policy context and historical and international comparison of the immunization schedule for hepatitis B. The United States' universal recommendation of the hepatitis B vaccine birth dose is an outlier among developed countries with low hepatitis B prevalence.

"The American people have benefited from the committee's well-informed, rigorous discussion about the appropriateness of a vaccination in the first few hours of life," **said Deputy Secretary of Health and Human Services and CDC Acting Director Jim O'Neill**.

A recommendation from ACIP becomes part of the CDC immunization schedule once it is adopted by the CDC director.

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Last revised: December 5, 2025

Submit a request for comment

For media inquiries, please submit a request for comment.

EXHIBIT 17

CDC Newsroom

CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus

RELEASE

For immediate release: December 16, 2025

CDC Media Relations
(404) 639-3286
https://www.cdc.gov/media/

ATLANTA — December 16, 2025 — The Centers for Disease Control and Prevention (CDC) today adopted individual-based decision-making for hepatitis B immunization for parents deciding whether to give the hepatitis B vaccine, including the birth dose, to infants born to women who test negative for the virus. For those infants not receiving the birth dose, it is suggested that the initial dose be administered no earlier than two months of age.

Individual-based decision-making, referred to on the CDC immunization schedule as shared clinical decision-making, means that parents and health care providers should consider vaccine benefits, vaccine risks, and infection risks, and that parents consult with their health care provider and decide when or if their child will begin the hepatitis B vaccine series. Parents and health care providers should consider whether there are infection risks such as a household member who has hepatitis B or frequent contact with persons who have emigrated from areas where hepatitis B is common.

The child immunization schedule will be updated to reflect the recent recommendations by the CDC Advisory Committee on Immunization Practices, which were approved today by Acting Director of the CDC and Deputy Secretary of Health and Human Services Jim O'Neill. The CDC will also update applicable clinical guidance for hepatitis B vaccines to reflect and implement the new recommendation.

"This recommendation reflects ACIP's rigorous review of the available evidence," **said Acting Director of the CDC and Deputy Secretary of Health and Human Services Jim O'Neill.** "We are restoring the balance of informed consent to parents whose newborns face little risk of contracting hepatitis B."

The CDC is reviewing ACIP's secondary recommendation that parents should consult with a health care provider on serology testing to determine whether a subsequent hepatitis B vaccine dose is needed. For infants born to mothers who test positive for hepatitis B or whose status is unknown, the currently recommended birth dose of hepatitis B vaccine and immunoglobulin continues with no change.

The adoption of individual-based decision-making for hepatitis B immunization maintains consistency of coverage through all payment mechanisms, including entitlement programs such as the Vaccines for Children Program, Children's Health Insurance Program, Medicaid, and Medicare, as well as insurance plans through the federal Health Insurance Marketplace.

Fact Sheet: Hepatitis B Immunization

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Whether diseases start at home or abroad, are curable or preventable, chronic or acute, or from human activity or deliberate attack, CDC’s world-leading experts protect lives and livelihoods, national security and the U.S. economy by providing timely, commonsense information, and rapidly identifying and responding to diseases, including outbreaks and illnesses. CDC drives science, public health research, and data innovation in communities across the country by investing in local initiatives to protect everyone’s health.

SOURCES

CONTENT SOURCE:
Office of Communications (OC)

EXHIBIT 18

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

Decision Memo

DATE: January 5, 2026

TO: Jim O'Neill, Acting Director, Centers for Disease Control and Prevention (CDC)

FROM: Jay Bhattacharya, MD, PhD, Director, National Institutes of Health
Mehmet Oz, MD, MBA, Administrator, Centers for Medicare and Medicaid Services
Marty Makary, MD, MPH, Commissioner of Food and Drugs

SUBJECT: DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule

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PURPOSE

This memorandum proposes a revised childhood and adolescent immunization schedule for your review and approval.

RECOMMENDATION AND ACTION REQUESTED

After considering the data and recommendations contained in TAB 1, "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries," and your discussions with relevant health officials, you should approve the revised immunization schedule.

BACKGROUND AND SUMMARY OF RECOMMENDED ACTION

On December 5, 2025, the President directed the Department of Health and Human Services (HHS) and the Centers for Disease Prevention and Control (CDC) to review best practices from peer, developed nations regarding core childhood vaccination recommendations and the scientific evidence underlying those practices. The President further instructed that, "if [HHS and CDC] determine that those best practices are superior to current domestic recommendations, update the United States core childhood vaccine schedule to align with such scientific evidence and best practices from peer, developed countries while preserving access to vaccines currently available to Americans."

As part of this review, you discussed childhood immunization recommendations and policy with health officials from Japan, Germany, and Denmark. You also discussed immunizations with CDC and Food and Drug Administration (FDA) officials with duties and responsibilities related to vaccine safety and efficacy, respectively.

TAB 1 is the review of peer nations' best practices and the scientific evidence underlying those practices. Dr. Tracy Beth Høeg, Acting Director of the FDA Center for Drug Evaluation and Research (CDER), and Dr. Martin Kulldorff, Chief Science and Data Officer, HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), authored TAB 1 in consultation with subject matter

officials at CDC, FDA, the National Institutes of Health (NIH), and the Centers for Medicare and Medicaid Services (CMS). After a careful review of the current U.S. childhood and adolescent immunization schedule, peer nations' schedules and best practices, and the underlying evidence and data, TAB 1 recommends adopting a revised childhood and adolescent immunization schedule that is based on those vaccines for which there is broad-based international consensus. The consensus vaccines are recommended for all children.

The recommended schedule includes consensus vaccines for measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type B (Hib), pneumococcal disease, human papillomavirus (HPV), and varicella. This vaccine schedule reflects the Danish schedule except that this revised schedule adds the varicella vaccine, which is not currently on the Danish schedule. TAB 1 proposes that the CDC recommend these vaccines for all children.

In addition to the consensus vaccines, the schedule recommended in TAB 1 includes immunizations for high-risk groups and immunizations based on shared clinical decision making. Unlike the consensus vaccines, these are immunizations for which there is not broad-based consensus and TAB 1 discusses the scientific evidence regarding why they should not be recommended for all children.

TAB 1 does not assess and propose any changes to recommendations for high-risk populations. Those immunizations include: Respiratory syncytial virus (RSV) monoclonal antibodies, and hepatitis A, hepatitis B, meningococcal B, meningococcal ACWY, and dengue.

TAB 1 also proposes that CDC's recommended childhood and adolescent immunization schedule list vaccines for hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 be based on shared clinical decision making. The CDC applies shared clinical decision-making recommendations when evidence indicates that individuals may benefit from vaccination based on an analysis of the individual's characteristics, values, and preferences, the provider's medical judgment, and the characteristics of the vaccine being considered.

The recommendation to realign the CDC's immunization schedule under a framework built on 11 consensus vaccines is not a significant departure from the current recommended immunization construct. The current CDC schedule (TAB 2) categorizes routine immunization recommendations into three general categories: (1) population-based (i.e., age-based, including catch-up), (2) risk-based (i.e., immunosuppression, other underlying medical conditions, work-related, or other special circumstances that increase risk of illness), and (3) shared clinical decision-making-based.

Under the new framework, measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib, pneumococcal disease, HPV, and varicella constitute category 1, the population-based category of routine immunizations, and are recommended for all children. Immunizations currently recommended for high-risk groups continue to be recommended for high-risk groups under category 2 in the preceding paragraph. Hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 remain on the schedule based on shared clinical decision-making, category 3 above.

Finally, consistent with the President's direction to "preserv[e] access to vaccines currently available to Americans," all the immunizations listed in the preceding paragraphs are (i) on the current schedule, (ii) will remain on the revised schedule, and, therefore, (iii) continue to be covered without cost sharing by

private insurance and covered by Medicaid, Children's Health Insurance Program (CHIP), and the Vaccines for Children Program.

*** Figure 1 on pages 2-3 of TAB 1 illustrates the proposed schedule with recommended doses and ages.**

DISCUSSION

Before reviewing and assessing the current childhood and adolescent immunization schedule relative to those of peer nations, it is important to first understand what, if any, problems currently exist with childhood immunization in the United States.

Current Problem: Decreased Vaccine Uptake and Trust

Childhood vaccination rates in America have fallen over the past five years. From the 2019/20 to 2023/24 school year, there was a decline in childhood measles, mumps, and rubella (MMR) vaccination from 95.2% to 92.7%. In the 2024-2025 academic year, 16 states had MMR vaccination rates below 90%, which is below the critical threshold for herd immunity for measles. Consequently, in 2025 there were nearly 50 measles outbreaks and over 1,800 measles cases attributed to those outbreaks. Finally, although the CDC still recommended the COVID-19 booster for all children in 2023, the uptake was less than 10%.

Robust immunization programs are an essential public health tool, but those tools are only effective when there is public trust. Unscientific belief that vaccine-acquired immunity was superior to infection-acquired immunity combined with inaccurate CDC claims that the COVID-19 vaccine would prevent infection and transmission eroded public trust in the COVID-19 vaccine.

The loss of trust in the COVID vaccines coincided with less adherence to the full CDC childhood vaccine schedule, which has resulted in lower immunization rates of well-established vaccines, such as those for measles, rubella, pertussis, and polio.

Current Problem: Knowledge Gaps Concerning Safety

The Institute of Medicine (IOM) stated in a report that "vaccines—like all drugs or medical interventions—are neither 100 percent risk-free nor 100 percent effective." The United States administers significantly more doses of childhood immunizations than its peer nations, yet there is a significant knowledge gap due to a dearth of randomized vaccine trials and limited post-licensure infrastructure for monitoring potential adverse reactions and long-term chronic events.

The U.S. has a limited post-licensure infrastructure focused on monitoring potential adverse reactions that occur within a few days or weeks after vaccination. This includes the Vaccine Adverse Event Reporting System (VAERS), but the two key components are CDC's Vaccine Safety Datalink (VSD) and FDA's Biologics Effectiveness and Safety (BEST) System. These systems typically conduct limited safety review using risk windows after vaccination which inject significant bias and severely limits the potential to detect serious harms, but despite this and other serious limitation, these systems within a year of vaccine approval have confirmed serious harm, including intussusception after rotavirus

vaccines, febrile seizures after the MMRV vaccine, and anaphylaxis and myocarditis after the mRNA COVID-19 vaccines. Additionally, current surveillance systems are underutilized to detect long-term harms.

International Comparison of Childhood Vaccine Schedules

As illustrated in Table 2 on page 15 of TAB 1, the United States currently recommends more childhood vaccines than any peer nation, and more than twice as many vaccine doses as some European nations.

While a set of consensus vaccines is consistently recommended in all peer countries, several vaccines included in the current CDC childhood and adolescent immunization schedule (e.g., hepatitis A, varicella, influenza, rotavirus and meningococcal vaccines) are limited in their recommendation or excluded in some other developed countries. Each disease addressed by the U.S. child immunization schedule poses a health risk, but the level of threat varies widely by disease and sometimes by individual underlying risk factors. The mere existence of a vaccine does not automatically make it appropriate for every child, nor does it necessarily justify universal vaccination.

There is global variation in the universal use and timing of numerous childhood vaccines. Although these differences sometimes reflect the unique epidemiology of diseases in each region, they more often arise from uncertain science and knowledge gaps, which lead to inadequately informed assessments of risks and benefits that are subject to differing interpretations. Disagreement among states and professional societies in the U.S. further underscores the need and opportunity for a more adaptable childhood immunization schedule.

Broad-based insurance coverage of both consensus and non-consensus immunizations should remain in effect following the updates to the vaccine schedule. Identifying the consensus vaccines on the schedule would help Americans follow the schedule while making all vaccines available for parents also wanting non-consensus immunizations. Through proper vaccine research, it is important to improve our understanding of populations who are most likely to benefit from individual vaccines as well as situations where vaccination may not be needed.

Recommended Immunization Schedule Based on Assessment of Peer Nations and Scientific Evidence

Immunizations Recommended for All Children: These are immunizations that are important for all children to receive. They include measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib and pneumococcal disease vaccines. These are consensus vaccines that are part of the recommended childhood immunization schedules for all 20 peer nations, with the exception of mumps in Japan. While the safety/risk profile is not fully understood, and in need of further study, there is consensus among peer nations that they provide material benefits against the target disease. Focusing on these vaccines is more likely to reverse the declining uptake of these vaccines.

In addition to the vaccines listed above for which there is nearly unanimous peer nation agreement, HPV and varicella vaccines should also be included.

The scientific evidence for the HPV vaccine—increasingly recognized by peer nations in their own recommendations—supports one dose instead of two when given to children. Australia, parts of Canada, Ireland, Spain, and the United Kingdom have already changed their recommendations to one dose.

The varicella zoster virus causes chickenpox (typically in children) and, for those infected, can reemerge as shingles (typically in adults). The uncertainty of its long-term consequences on adults is one reason why some countries have been cautious about adding the varicella vaccine to the childhood schedule, but similar caution may be warranted regarding a removal once there has been widespread use of this vaccine. The rate of two dose vaccination for varicella among American children is estimated at 92%. Partial population varicella vaccination (60-80% for two doses) could increase the average age at which the population naturally gets chickenpox when this disease could cause more complications, and hence there is a consensus among peer nations that once vaccination for chicken pox has become widespread, stopping use of this vaccine could cause certain complications. For these reasons, the varicella vaccine should remain a consensus vaccine.

Immunizations Recommended for Certain High-Risk Groups or Populations: Like all medical products, vaccines have different risk-benefit profiles for different people. This can either be because of underlying comorbidities, unusual exposure to the disease, or the risk of disease transmission to others. For example, the hepatitis A vaccine when children travel internationally to an endemic area or the birth dose of the hepatitis B vaccine for infants born to mothers that are hepatitis B positive. TAB 1 does not propose any changes in immunization recommendations for high-risk populations.

Immunizations Based on Shared Clinical Decision-Making: Shared clinical decision-making recommendations are individually based and informed by a discussion between the health care provider and the patient or parent/guardian, something that should occur for all vaccines. It is not always possible or pragmatic for public health officials to clearly define who will benefit from a vaccine, who has the relevant risk factors, or who are at risk of exposure. Parents and physicians, who know the child, may be better placed to make that judgement. With shared clinical decision-making, the characteristics of the individual are considered, including their likelihood of being exposed to the diseases, their risks of morbidity and mortality if contracting the diseases, their likelihood of benefitting from the vaccine, their likelihood of vaccine adverse reactions, and their risk of transmitting the disease to others. Sometimes, it is also important to consider personal and family preferences, beliefs, and knowledge, including when a patient presents specific information regarding the pre-and-post licensure safety data of a vaccine or presents specific familial experience with a vaccine. While non-consensus immunizations are not routinely recommended for all children, all these vaccines will continue to be available for anyone who wants them and will be covered by Medicaid, CHIP, the Vaccines for Children Program, and private health insurance.

- Hepatitis A: When hepatitis A vaccines were approved in the 1990s, the primary candidates for vaccination were "travelers to regions of endemic disease, children living in high prevalence areas, homosexual males, users of illicit intravenous drugs, persons working directly with nonhuman primates or hepatitis A virus, patients older than 30 years of age with chronic liver disease, and persons who have received a liver transplant or are awaiting one." Those had disappeared in the U.S. by 2006, at which time a 2-dose regiment at age 12 to 23 months was added to the universally recommended childhood immunization schedule. In 2006, the annual incidence rate of hepatitis A

was very low at around 1 per 100,000 and it remains similarly low. The annual mortality rate is 1 per 10 million, with the highest rate among older men.

Among peer nations, Greece is the only one with a routine childhood vaccine recommendation. Given the low U.S. incidence and mortality, and the lack of randomized placebo-controlled safety data, the benefit-risk ratio is at best very low for most children. There is a clear benefit, but still undefined risk, for children travelling to high endemic countries in the developing world.

- Hepatitis B: Together with hepatitis B immune globulin, it is important that infants are administered the hepatitis B vaccine at birth if the mother is HBsAg-positive or status is unknown. If the mother tests negative, only two of the 20 peer nations recommend routine vaccination at birth: Australia and Portugal, while two countries do not recommend it at all. At their December 2025 meeting, the ACIP followed the majority of peer nations and voted to no longer recommend the birth dose if the mother tested negative. Instead, it recommended shared clinical decision-making, taking the risk profile of each unique child into account.

- Rotavirus: Rotavirus is a common infection, and prior to the rotavirus vaccine, nearly every child would be infected, both in the U.S. and abroad. In the developing world, many children die from dehydration after catching the virus, and there is a greater opportunity for benefit from vaccination. In the U.S., it can cause hospitalization for gastroenteritis, but the virus poses almost no risk of either mortality or chronic morbidity.

  Data from CDC indicate that among all U.S. children <15 years of age, there were an average of 3.3 deaths per year with the rotavirus diagnostic code listed on the death certificate between 1999 and 2005. This was after the RotaShield vaccine was withdrawn from the market in 1999 and before the RotaTeq vaccine was approved in 2006. Another vaccine, Rotarix, was approved in 2008. After these vaccines were recommended for all children, there were 1.6 deaths per year from 2009 to 2020. There may be many reasons for this very small decrease in mortality that are unrelated to the vaccine, including improved medical care, changes in diagnostic practices, or random fluctuations.

  RotaShield was removed from the market due to an excess risk of intussusception. The newer current vaccines have a lower intussusception risk, at around 1 or 2 per 100,000 vaccinated children. Reasonable people can reach different conclusions about recommending the rotavirus vaccine for all children. Among peer nations, Belgium, Denmark and Portugal do not recommend it. Denmark has cited the very low risk of mortality and chronic morbidity to nearly all children in their rationale for not adding the vaccine to their childhood immunization schedule.

- Meningococcal disease: Among peer nations, 15 recommend meningococcal vaccination for all children while five limit it to high-risk groups. The incidence of meningococcal disease has declined during the past decades, both in countries with and without the routine vaccine recommendations for children, and the magnitude of the decline appears to be independent of vaccination policy. The current incidence in the U.S. is 0.12/100,000 or about one case per million per year.

  In a 2011 position paper, the World Health Organization (WHO) recommended that countries with more than 2 cases per 100,000 population/year maintain a "large scale meningococcal vaccination program," while only vaccinating the high-risk population in countries with lower rates. In the

United States, the current incidence rate is around 0.1 per 100,000 is much lower than the WHO suggested cut-off.

The current meningococcal vaccines recommended for all children (Menveo, Menquadfi, and Penbraya) were not evaluated in large-scale double-blind placebo-controlled randomized trials before FDA approval.

Considering the low incidence rates of meningococcal disease in the U.S., the meningococcal vaccine should not be part of the consensus recommended vaccine schedule. High-risk children and adolescents, such as children with certain types of immune deficiencies, may have a greater chance of benefiting from the vaccine.

- Influenza: The primary purpose of the childhood influenza vaccine in children is to reduce hospitalizations and mortality in children, as well as transmission to the elderly, who are of higher risk for death but there are no randomized controlled trials demonstrating these benefits. There are a few post-licensure randomized placebo-controlled trials for the influenza vaccine. The most comprehensive review was done in 2018 by the Cochrane Collaboration. They found that "in children aged between 3 and 16 years, live influenza vaccines probably reduce influenza (moderate-certainty evidence)" infections while "inactivated vaccines also reduce influenza (high certainty evidence)." Only a few of the trials evaluated school and parental work absenteeism, not finding a statistically significant reduction. There was no evidence about reduced transmission. The trials could not evaluate differences in hospitalizations or mortality, as there were none or few in either group, so they provide no evidence that the vaccines reduce hospitalization or deaths. There was not much information about children under 2 years old.

  The conclusion of the Cochrane systematic review of randomized trials in children was that "Decision-makers' attention to the vaccination of very young children is not supported by the evidence summarised in our review. Although there is a growing body of evidence showing the impact of influenza on hospitalisations and deaths of children, at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza."

  There have been some observational studies with mixed results. A test-negative case-control study claimed to show that childhood influenza vaccine reduces hospitalization, but that is a notoriously biased study design with highly implausible results.

  While there is a scarcity of reliable safety data, the influenza vaccines are not without risk. The seasonal vaccine has been linked to Guillain Barré syndrome. During the 2009/2010 H1N1 influenza pandemic, the Pandemrix pandemic vaccine was found to cause narcolepsy among vaccinated children and adolescents. The Cochrane systematic review, noted that "the lack of safety data for inactive vaccines in younger children is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA and Canada" and that "the manufacturers' refusal to release all safety outcome data from trials carried out in young children, together with obvious reporting bias and inconsistencies in the primary studies, does not bode well for a fair assessment of the safety of live attenuated vaccines."

Considering the evidence, and lack of evidence, it is understandable that public health agencies in different countries have come to different conclusions about the influenza vaccine for children. Among the 20 peer countries, only Austria and Canada recommend an annual influenza vaccine for all children >6 months and all adolescents. Another six recommend the shot for all children in selected age ranges. The remaining twelve peer nations do not recommend the influenza vaccine for all children in any age group.

Based on both the evidence and uncertainties, the influenza vaccine should not be recommended for all children, but it should be available through insurance for all children >6 months old, through shared-clinical decision making.

- COVID-19**:** In 2022, Denmark became the first peer nation to remove its universal recommendation of the COVID-19 vaccine for children, with the director of its public health authority recognizing that there was little benefit in giving this vaccine to children. Since then, all other peer nations have followed. At their September 2025 meeting, the ACIP voted that shared clinical decision-making should be applied to the COVID-19 vaccine for U.S. children and adolescents.

Finally, if you approve the revised schedule, you should also later recommend to the Secretary that HHS agencies fund and conduct gold standard medical research to assess overall health outcomes related to all immunizations on the revised schedule (i.e., immunizations recommended for all children, immunizations recommended for high-risk groups, and immunizations based on shared clinical decision making), the interaction effects between different immunizations as well as other aspects of the immunization schedule—something that is needed to close the knowledge gap.

EXECUTION

If approved, the revised childhood and adolescent immunization schedule will be published in an upcoming *Morbidity and Mortality Weekly Report*. CDC will also publish the CDC-adopted recommendation on the applicable CDC website and also update the childhood and adolescent schedule in alignment with this decision.

DECISION

After thoroughly reviewing the assessment in TAB 1 and further considering the childhood immunization recommendations based on my discussions with CDC, FDA, and peer, developed nation health officials, I have determined that the CDC will adopt the revised childhood and adolescent immunization schedule, as stated in Figure 1 of TAB 1. Specifically, the CDC immediately recommends: (1) immunization for the measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib, pneumococcal disease, HPV, and varicella for all children; (2) specified immunizations for high-risk groups (Respiratory syncytial virus (RSV) monoclonal antibodies, and hepatitis A, hepatitis B, meningococcal B, meningococcal ACWY, and dengue); and (3) immunization for hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 based on shared clinical decision making, as stated in Figure 1 of TAB 1.

Approved: ✓ **Disapproved:** _____ **Would like briefing:** _____

J O'Neill

Jim O'Neill
Acting Director, CDC

January 5, 2025
Date

TABS

1. "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries"
2. Current CDC Recommended Childhood and Adolescent Immunization Schedule

EXHIBIT 19

Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries

January 2, 2026

Tracy Beth Høeg, MD, Ph.D., Acting Director for the Center for Drug Evaluation and Research and FDA Ex Officio member to ACIP, and **Martin Kulldorff, Ph.D.**, Chief Science and Data Officer for the Assistant Secretary for Planning and Evaluation, in consultation with experts at CDC, FDA, NIH, and CMS.

Executive Summary

On December 5, 2025, President Trump issued a Presidential Memorandum[1] directing the Secretary of the U.S. Department of Health and Human Services (HHS) and the Acting Director of the Centers for Disease Control and Prevention (CDC) to review best practices from peer, developed nations regarding childhood vaccination recommendations and the scientific evidence underlying those practices. The President instructed them to update the U.S. core childhood vaccine schedule if they determine that superior practices exist abroad.

This assessment is a scientific, evidence-based, data-driven response to the President's directive. It argues that a change in the U.S. childhood vaccine schedule is necessary. It compares the U.S. with peer nations, examines vaccine uptake and trust, addresses clinical and epidemiological considerations and knowledge gaps, analyzes vaccine mandates, and outlines recommendations and next steps for immediate and long-term action.

The U.S. is a global outlier among peer nations in the number of target diseases included in its childhood vaccination schedule and in the total number of recommended vaccine doses.[2]

The Acting CDC Director should immediately consider updating the Childhood Immunization Schedule to keep vaccines for 10 diseases—measles, mumps, rubella, polio, pertussis, tetanus, diphtheria, Haemophilus influenzae type B (Hib), pneumococcal disease, and human papillomavirus (HPV)—for which peer, developed nations share international consensus, as well as varicella (chickenpox) (the "consensus vaccines") in the category of vaccines recommended for all children. These consensus vaccines will represent the core childhood vaccine schedule. This report does not substantively address the consensus vaccines. All other vaccines currently on the U.S. schedule (the "non-consensus vaccines") should be recommended for high-risk groups and populations and/or through shared clinical decision-making, by taking individual patient characteristics into account (Figure 1). No vaccine should be moved to the "not recommended" category.

Therefore, the Acting CDC Director should update the childhood immunization schedule to reflect these three distinct components:

IMMUNIZATIONS RECOMMENDED FOR ALL CHILDREN

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20–23 mos	2–3 yrs	4–6 yrs	7 yrs	8 yrs
Diphtheria, tetanus, acellular pertussis (DTaP < 7 yrs)			1st dose	2nd dose	3rd dose				4th dose					5th dose		
Tetanus, diphtheria, acellular pertussis (Tdap ≥ 7 yrs)																
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	3rd dose			3rd / 4th dose								
Pneumococcal conjugate (PCV15, PCV20)			1st dose	2nd dose	3rd dose			4th dose								
Inactivated poliovirus (IPV < 18 yrs)			1st dose	2nd dose	3rd dose									4th dose		
Measles, mumps, rubella (MMR)								1st dose						2nd dose		
Varicella (VAR)								1st dose						2nd dose		
Human papillomavirus (HPV)																

Vaccine and other immunizing agents	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Diphtheria, tetanus, acellular pertussis (DTaP < 7 yrs)									
Tetanus, diphtheria, acellular pertussis (Tdap ≥ 7 yrs)			1st dose						
Haemophilus influenzae type b (Hib)									
Pneumococcal conjugate (PCV15, PCV20)									
Inactivated poliovirus (IPV < 18 yrs)									
Measles, mumps, rubella (MMR)									
Varicella (VAR)									
Human papillomavirus (HPV)			1 dose						

Some children should get a dose at this age depending on the vaccine brand.

IMMUNIZATIONS RECOMMENDED FOR CERTAIN HIGH-RISK GROUPS OR POPULATIONS

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20–23 mos	2–3 yrs	4–6 yrs	7 yrs	8 yrs
Respiratory syncytial virus (RSV-mAb) [1]	1 dose															
Respiratory syncytial virus (RSV-mAb) [2]	1 dose						2nd dose									
Hepatitis B (HepB) [3]	1st dose	2nd dose			3rd dose											
Dengue [4]																
Meningococcal ACWY [5]			2, 3 or 4 dose series													
Meningococcal B [6]																
Hepatitis A (HepA) [7]					1 dose											

Vaccine and other immunizing agents	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Respiratory syncytial virus (RSV-mAb) [1]									
Respiratory syncytial virus (RSV-mAb) [2]									
Hepatitis B (HepB) [3]									
Dengue [4]	3 dose series								
Meningococcal ACWY [5]									
Meningococcal B [6]		1 dose							
Hepatitis A (HepA) [7]									

[1] All children whose mother did not have the vaccine should get one dose.

[2] High-risk children, such as those with chronic lung disease, should receive a second dose at ages 8 to 19 months.

[3] Vaccination recommended for infants born to women who tested positive for the hepatitis B virus or whose status is unknown.

[4] Recommended ONLY if living in areas with endemic dengue AND with a laboratory confirmation of previous dengue infection.

[5] For high-risk groups (e.g., those with anatomic or functional asplenia or HIV infection), those traveling to countries with hyperendemic or epidemic meningococcal disease, and first-year college students living in residential housing, vaccination is recommended.

[6] Recommended for high-risk groups, e.g., with anatomic or functional asplenia, and during outbreaks.

[7] Vaccination recommended for international travel to areas with high or intermediate hepatitis A endemicity.

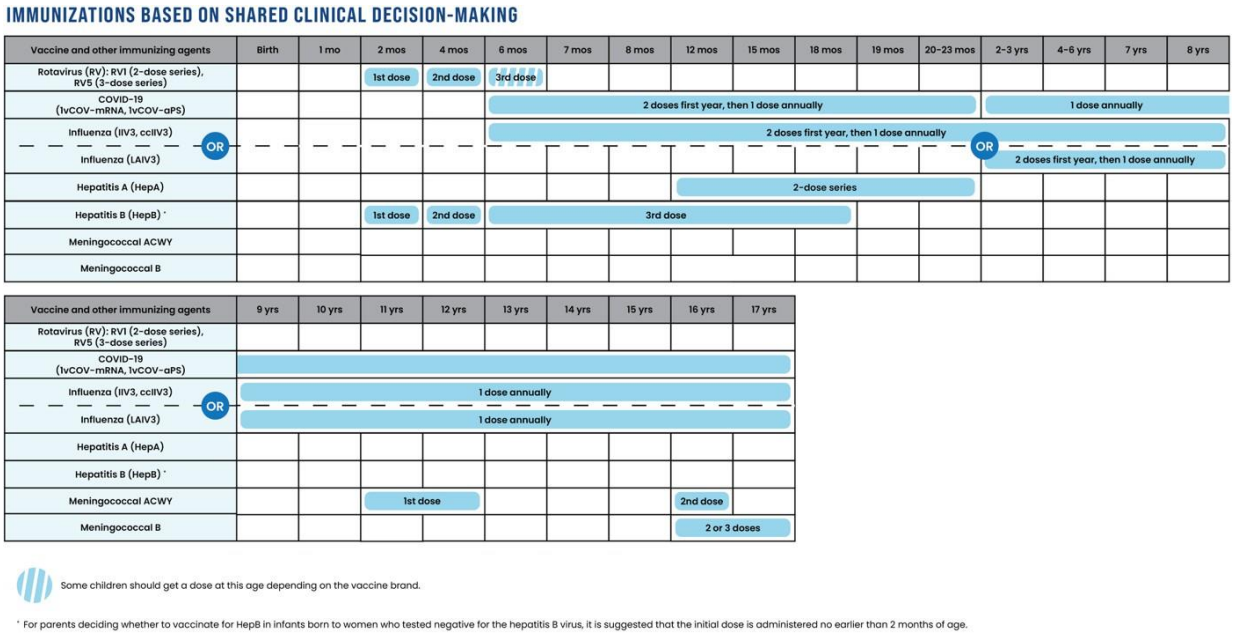


Figure 1: Proposed immunization schedule from birth up to age 18, with recommendations for all children (yellow), recommendations for high-risk groups or populations (purple), and immunizations with shared clinical decision-making (blue), all available and covered by insurance for all children and adolescents without cost sharing.

Importantly, all immunizations recommended by the CDC at the end of 2025—and covered by insurance at that time—should remain covered by insurance without cost sharing, as they should all remain on the schedule. This would include all diseases covered by the 2025 childhood and adolescent immunization schedule. By comparison, in many European countries, vaccines not recommended for routine use are typically not covered. By distinguishing non-consensus vaccines as options based on individual risk factors, we can better define those risk factors and identify the children who are most likely to have a net-benefit from these vaccines.

Between 2020 and 2024, trust in health care declined steeply from 71.5% to 40.1%, coinciding with school closures, other lockdowns, mandatory face masks, COVID-19 vaccination mandates with their de facto denial of infection acquired immunity, and other public health recommendations that lacked scientific rationale and went against basic principles of public health.[3] The distrust of public health agencies during the pandemic has spilled over to other recommendations made by these agencies, including those with respect to vaccines. Over the same period, there was a decline in childhood vaccination rates across the country, with, for example, a reduction in measles, mumps, and rubella (MMR) vaccination from 95.2% to 92.7%.[4,5] This has increased the potential risk for measles cases.[6]

Instead of implementing vaccination mandates, most peer nations maintain high childhood vaccination rates through public trust and education (Table 1). This is in contrast to the U.S.,

where individual states can set mandatory vaccination requirements for children as a requirement to attend school.[7] Among the fundamental principles of public health are respect for personal autonomy and self-determination, and informed consent is a cornerstone of medical care.[8,9,10] While vaccine mandates may increase short-term vaccination rates,[11] coercive measures can also have negative consequences on trust that may decrease long-term vaccination rates for consensus vaccines.[12,13,14] Increased emphasis on personalized medicine would improve informed consent and the doctor patient relationship, leading to a better educated and empowered public. The increased emphasis on shared clinical decision-making would help restore trust in public health recommendations made by CDC.

Vaccines are intended to benefit children by preventing them from being infected by certain infectious diseases. But, like all medicines, vaccines come with risk that must be balanced against their benefits.[15] Before and after licensure, manufacturers have inadequate incentives to study vaccine adverse effects. Regulatory bodies, including the FDA and the CDC have sometimes been slow to identify adverse effects in post-market studies.[16] Vaccine safety and risks are therefore often poorly characterized, quantified, or understood. Scientifically valid rates of adverse events are rarely available to determine the relationship, if any, between our country's immunization schedule and the increasing prevalence of chronic diseases in American children.[17] Medical interventions given to healthy children to prevent diseases, rather than treat or cure them, should have the highest standard of safety pre-and-post marketing.[18]

To address the safety concerns regarding the child and adolescent immunization schedule, HHS should fund gold standard scientific research, including large placebo-controlled randomized trials as needed, both on individual vaccines, combination of vaccines, and vaccination schedules. Putting aside the ethics of administering a medical product that was not properly trialed to affirm its safety, this can be ethically accomplished by, among other methods, randomizing the timing of vaccination.[19] HHS should also fund and conduct observational studies concerning long-term chronic adverse effects of both individual vaccines and the immunization schedule. This will better inform patients/parents and physicians moving forward, increase trust in public health, and improve the state of vaccine science globally.

This assessment only considers immunizations that CDC recommended for all children at the end of 2024. It does not consider the timing or order of vaccines, nor the number of doses, with the exception of the HPV vaccine.

Bringing the U.S. pediatric immunization schedule in line with the consensus of peer nations while keeping non-consensus vaccines available for high-risk groups and populations and/or through shared clinical decision-making is a balanced approach to reform and restore trust in public health. Coupled with an evaluation of potential vaccine harms, this reform seeks to restore

public confidence, provide much-needed clarity for parents of young children, and preserve the benefits of immunization programs.

1. Vaccine Uptake and Trust

In 1980, American children following the CDC immunization schedule received 23 vaccine doses in 7 shots against 7 different diseases (1 MMR, 5 DTP, 1 Td) plus 4 OPV drops. In 2024, the recommended number of routine vaccines had risen to at least 84 vaccine doses in at least 57 shots for 17 diseases, plus the RSV monoclonal antibody immunization for a total of 18 diseases.[20,21,22,23,24,25,26,27] This is more than other developed nations (Table 2).[28]

1.1 Vaccine Uptake

In the decade before the COVID-19 pandemic, the U.S. had high and stable childhood vaccination rates.[29] This changed with the pandemic lockdowns, which generated a drop in childhood vaccine uptake across all age groups (Figure 2). While the vaccination rates have rebounded, the created gaps have never been compensated for through catch-up vaccinations.[30]

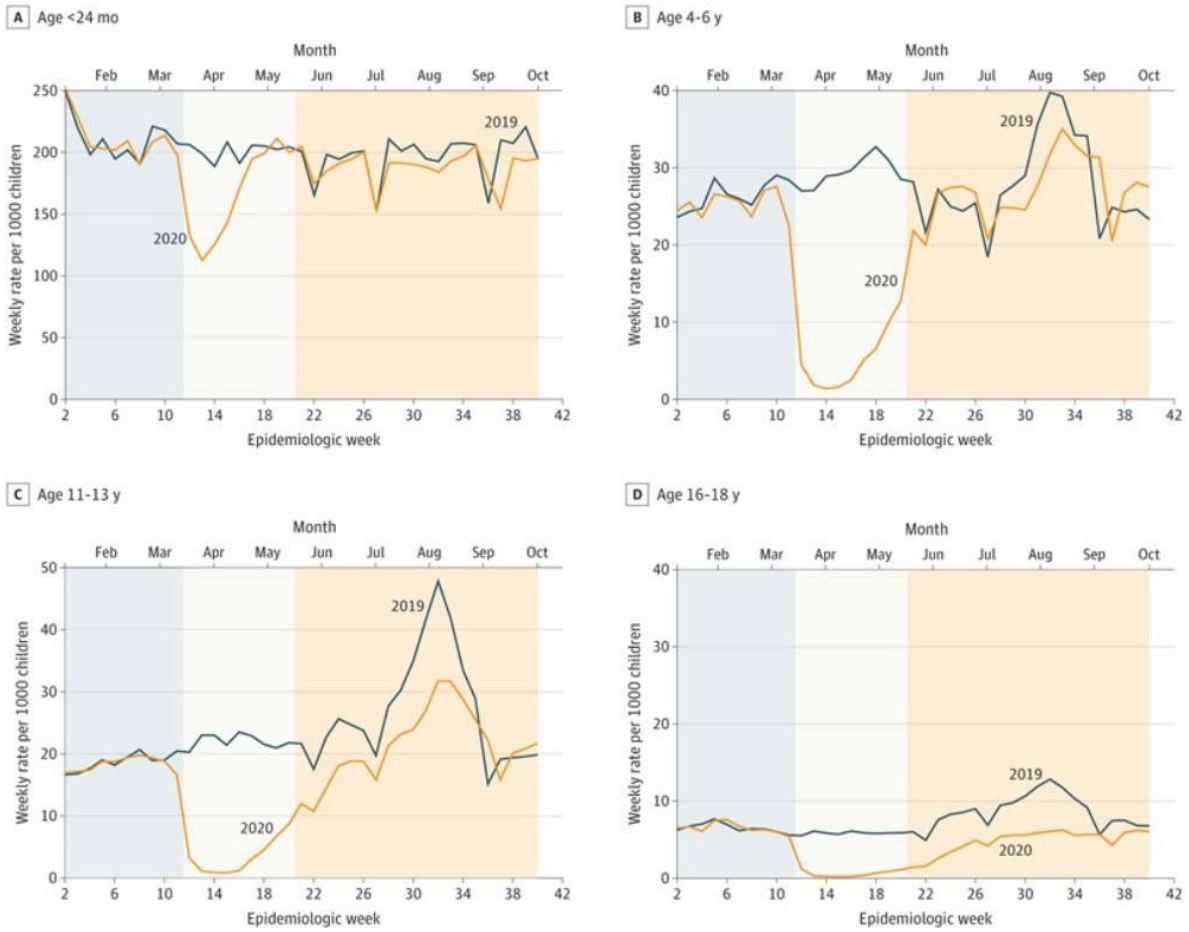


Figure 2: Childhood vaccine uptake by age during the 2020 lockdowns compared to 2019, in health plans providing data to CDC's Vaccine Safety Datalink.[31]

A fundamental principle of public health is trust.[32] For the public to trust public health agencies, those agencies must trust the public, which includes providing accurate information and being honest when the scientific knowledge is incomplete. This particularly fell apart during the COVID-19 pandemic. With COVID-19 vaccine mandates and false CDC claims that vaccine-acquired immunity was superior to infection-acquired immunity[33,34,35,36] and that the COVID-19 vaccine would prevent infection and transmission,[37,38,39] the public lost trust in the COVID-19 vaccine. For example, while CDC still recommended the COVID-19 booster for all children in 2023, the uptake was less than 10%.[40]

The loss of trust during the pandemic not only affected the COVID-19 vaccine uptake. It also contributed to less adherence to the full CDC childhood immunization schedule, with lower rates of consensus vaccines such as measles, rubella, pertussis, and polio.[41] From the 2019-2020 to 2023-2024 school years, childhood vaccination rates against measles, mumps, and rubella (MMR) declined from 95.2% to 92.7%.[42]

Even when the national vaccination rate is very high, lower regional rates can lead to cases of these diseases. Some states have vaccination rates below the estimated community immunity threshold for both measles and rubella.[43] In the 2024-2025 school year, 16 states had MMR vaccination rates below 90% (Figure 3). Rubella has a community immunity threshold of 83-85%,[44] leaving some states, such as Idaho and Wisconsin, at risk of rubella cases.

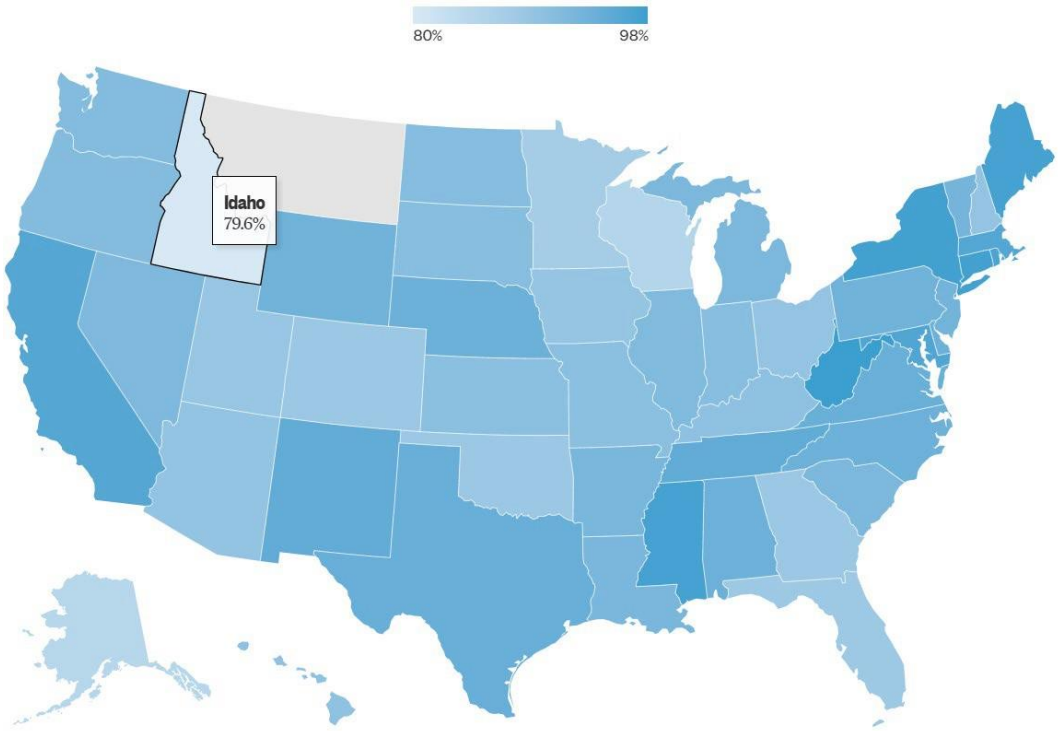


Figure 3: Vaccination rates by state for the second dose of the measles, mumps and rubella vaccination among kindergarteners during the 2023-2024 school year.[45]

1.2 Measles Outbreaks

When vaccine uptake for certain diseases decreases below a certain percentage of the community, it may lead to disease transmission or cases of those diseases.[46] For measles, minimum vaccination coverage threshold is estimated to be above 90%, below which the risk of cases increases.[47,48] Up until December 31, there had been 49 measles outbreaks reported in 2025 across the U.S., noting that an "outbreak" is defined as three or more related cases, and 88% of confirmed cases (1,820 of 2,065) were outbreak-associated[49] (Figure 4).

The U.S., Canada, and much of Europe have recently seen increasing measles cases and Canada recently lost its measles elimination status.[50]

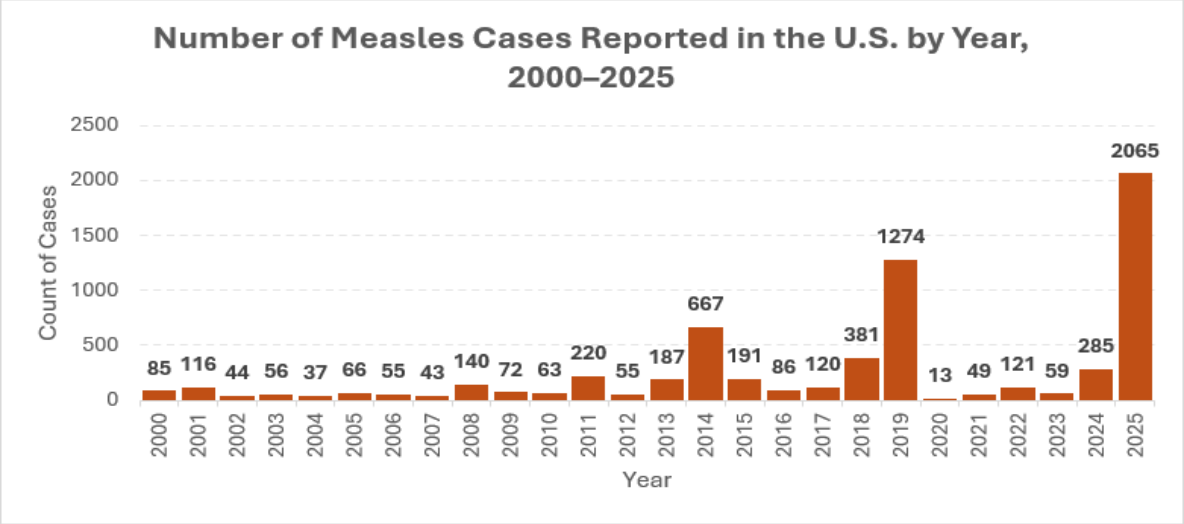


Figure 4: The number of measles cases reported in the U.S. by year, from 2000 to 2025.[51]

1.3 Vaccine Mandates and Trust

With a few exceptions, peer nations do not have childhood vaccination mandates. They have shown that transparent and trustworthy public health authorities can achieve very high voluntary vaccination rates while preserving informed consent (Table 1). The U.S. is among a minority of peer nations with childhood vaccine mandates (enacted by individual U.S. states) for school entry (Table 2). Education is critical to the development of children, and among other things is highly correlated with health and income. Many children lost over a year of schooling during the COVID-19 pandemic, with negative impacts on their academic performance.[52]

	Measles		Rubella	DTP		Polio		Hib	PCV	HPV girls	HPV boys	
dose:	1st	2nd	1st	1st	3rd	1st	3rd	3rd	3rd	1st	1st	**Average**
Many Vaccine Mandates	**93%**	**91%**	**93%**	**96%**	**94%**	**96%**	**94%**	**94%**	**91%**	**65%**	**59%**	**88%**
Australia (13 vaccines)	91%	92%	91%	93%	93%	93%	94%	93%	95%	73%	70%	89%
France (11)	95%	93%	95%	99%	96%	99%	96%	96%	96%	48%	37%	86%
Italy (10)	95%	84%	95%	94%	94%	94%	94%	95%	90%	66%	59%	87%
United States (# varies by state)	92%	95%	92%	98%	94%	97%	93%	92%	84%	74%	70%	89%
No Vaccine Mandates	**93%**	**89%**	**93%**	**96%**	**94%**	**96%**	**94%**	**94%**	**89%**	**74%**	**71%**	**89%**
Austria	90%	84%	90%	95%	85%	95%	85%	85%	..	53%	42%	80%
Denmark	94%	93%	94%	97%	96%	97%	96%	96%	96%	89%	87%	94%
Finland	94%	92%	94%	97%	91%	97%	91%	91%	87%	71%	63%	88%
Greece	91%	71%	91%	98%	95%	98%	95%	99%	90%	..	..	92%
Ireland	90%	90%	90%	93%	92%	93%	92%	92%	84%	73%	69%	87%
Japan	95%	96%	95%	99%	99%	98%	98%	96%	91%	39%	..	91%
Netherlands	89%	81%	89%	91%	91%	91%	91%	89%	88%	63%	59%	84%
New Zealand	89%	87%	89%	94%	89%	99%	97%	89%	60%	53%	52%	82%
Norway	96%	94%	96%	99%	97%	99%	97%	97%	95%	93%	92%	96%
Portugal	99%	96%	99%	99%	99%	99%	99%	99%	98%	91%	88%	97%
Spain	97%	92%	97%	98%	94%	98%	94%	94%	92%	90%	83%	94%
Sweden	93%	92%	93%	97%	96%	97%	95%	95%	94%	91%	87%	94%
Switzerland	96%	93%	96%	97%	96%	97%	96%	95%	91%	78%	64%	91%
United Kingdom	89%	85%	89%	92%	92%	92%	92%	92%	89%	75%	70%	87%
Partial Vaccine Mandates												
Belgium (only polio)	96%	82%	96%	98%	97%	99%	98%	97%	94%	80%	73%	92%
Canada (2/10 provinces)	92%	79%	92%	92%	92%	92%	92%	90%	85%	86%	81%	88%
Germany (only measles)	96%	92%	96%	97%	89%	97%	88%	88%	75%	68%	46%	85%

Table 1: WHO/UNICEF estimates of national immunization coverage (WUENIC) for some core vaccines in 2024. No estimates available for the other core vaccines, nor for PCV/Austria, HPV/Greece or HPV/boys/Japan. For HPV the percentages are for the vaccination program coverage, that is, the percent of the target population that received the vaccine that year. Note that, if vaccination rates are declining, the uptake of a second or third dose can sometimes be higher than the first dose.[53,54]

It is generally considered contrary to basic medical ethics to coerce or require a medical intervention, and informed consent is a cornerstone of medical care in the U.S. and abroad.[55] In its Code of Medical Ethics, the American Medical Association states that *"Informed consent in medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making."*[56] In its Public Health Code of Ethics, the American Public Health Association asserts that *"the effective and ethical practice of public health depends upon social and cultural conditions of respect for personal autonomy, self-determination, privacy, and the absence of domination in its many interpersonal and institutional forms."*[57]

Some peer countries have recognized that each additional vaccine may erode trust in the entire childhood immunization schedule, resulting in lower uptake of consensus childhood vaccines. Danish health authorities have specifically expressed concerns about adding vaccines to the routine childhood immunization schedule when the opportunity for benefit in non-high-risk populations is low and/or when the disease does not pose a mortality or long-term disability risk.[58] For example, when deciding not to recommend the hepatitis B (HepB) vaccine for all children, the Danish public health authority stated that *"if one includes a vaccine which some consider less important, it could negatively affect the view of vaccines in general. The result of this could be that the current [vaccination] program would have lower uptake,"* and that *"A prerequisite for a successful vaccination program with high uptake has been, in other words, that [the vaccine] is seen as an attractive offer."*[59]

Another key aspect of medicine is mutual trust between patients and physicians.[60] In the U.S., health insurers incentivize physicians with financial bonuses tied to vaccination rates of their patient population,[61] which can encourage coercive vaccination experiences. This can create both distrust in the vaccination schedule and a medical culture which may be reluctant to question vaccine safety. Some children from families who do not consent to certain vaccines have difficulty obtaining medical care because many pediatricians dismiss children from their practice if the parents refuse to have their children vaccinated.[62]

The concomitant administration of multiple separate (not combined into one multivalent product) childhood vaccines on the same day, has raised concerns among some parents about following the recommended vaccines schedules,[63] as there is limited post-market epidemiological research on interaction effects between vaccines in the same schedule.[64] Denmark has managed to minimize the concomitant administration of multiple vaccines by giving a pentavalent (with 5 diseases-targeted-in-one vaccine) three times in the first year of life; separating administration of the MMR and DTaP vaccines into different visits; and vaccinating children for fewer diseases.[65] Without resorting to vaccine mandates, Denmark has achieved consistently high rates of uptake for the consensus recommended vaccines and a lack of serious disease outbreaks.[66,67]

A new U.S. childhood schedule that removes the routine recommendation for non-consensus vaccines could lessen coercion and increase public trust.

A successful childhood vaccination program requires mutual trust between patients/parents and physicians/public health authorities. This is built on four pillars:

1. Scientific honesty about vaccines, including what is known and not known.
2. Informed consent; not coercion.
3. A vaccine approval process using evidence-based science and thorough post-licensure evaluation of vaccine safety and risks.
4. Recommendations that take account of the experience of peer nations.

2. Knowledge Gaps

A 2013 report from the Institute of Medicine (IOM) stated that *"vaccines—like all drugs or medical interventions—are neither 100 percent risk-free nor 100 percent effective."*[68] It is hence essential to have a robust science-based system to detect potential risks, using both pre-licensure placebo-controlled randomized trials and post-licensure observational pharmacovigilance studies. If there is a problem that is not detected in pre-licensure trials, it needs to be detected as soon as possible.[69,70] A robust clinical trial and safety surveillance system is critical to ensure trust in the recommended childhood vaccine schedule.

2.1 State of the Evidence for Childhood Vaccinations

Given the growing distrust that the American people have in the current childhood vaccine schedule, there is a need for more and better science, including gold standard placebo-controlled randomized trials.[71] This could help address knowledge gaps about potential side effects and risk/benefit profiles. Until more studies are completed, the childhood vaccination recommendations must be based on the best available evidence, however limited, and the best practices of peer, developed nations.

To establish a solid scientific basis for the childhood vaccine schedule and to inform global best practices for childhood vaccinations, HHS agencies should fund gold standard science to assess overall health outcomes related to both consensus and non-consensus vaccines, the interaction effects between different vaccines, as well as other aspects of the vaccine schedule. Placebo-controlled randomized trials can be done in an ethical manner by, for example, randomizing the age of vaccination, with the control group getting a placebo at the earlier age but the vaccine at a later time[72] or by studying vaccines for which there is no international consensus about the recommendation.

Those who are convinced that vaccines are safe will welcome randomized, placebo-controlled trials, as they will show that the vaccines are safe if they are safe. Those who are concerned about potential side effects of vaccines will also welcome these trials, as they will detect

problems if problems exist. Prior to completion of these studies, HHS should continue to make determinations about childhood vaccination recommendations based on the best available evidence and the best practices of peer, developed nations.

2.2 Vaccine Safety Surveillance Systems

Safety surveillance systems need to be very robust, minimize bias, and large enough to adequately detect risks which could tip the benefit-risk ratio in a direction that is unfavorable to the vaccine. Number needed to vaccinate (NNV) and number needed to harm (NNH) calculations should be performed for low- and high-risk children for each vaccination on an ongoing basis as harms are identified and as new information is obtained about efficacy against severe disease. These should inform CDC recommendations on an ongoing basis.

The U.S. has a limited post-licensure infrastructure focused on monitoring potential adverse reactions that occur within a few days or weeks after vaccination. This includes the Vaccine Adverse Event Reporting System (VAERS),[73] CDC's Vaccine Safety Datalink (VSD)[74] and FDA's Biologics Effectiveness and Safety (BEST) System.[75] Within a year of vaccine approval, these systems have confirmed serious harm, including intussusception after rotavirus vaccines,[76,77] febrile seizures after the MMRV vaccine,[78] and anaphylaxis[79] and myocarditis[80] after the mRNA COVID-19 vaccines.

However, these systems have serious shortcomings in that they have been underutilized, including for evaluating long-term effects of vaccines and the effect of various combined aspects of the vaccine schedule. Vaccines may cause adverse reactions that occur or are diagnosed months or years after vaccination. For example, a 2023 study from CDC's VSD found that children receiving more aluminum adjuvants had higher rates of persistent asthma, with an estimated hazard ratio of 1.19 per mg of aluminum (95% CI: 1.14-1.25).[81] When comparing mean aluminum exposure to no exposure, this corresponds to a hazard ratio of 2.0 (95% CI: 1.7-2.5), a doubling of the risk. However, this is an exception, and adequate studies of the association between vaccines and long-term health outcomes, including asthma, allergies, auto-immune diseases, neurological disorders, ear infections, or other infectious diseases, have not been performed.[82]

2.3 The Vaccine Schedule

As the childhood vaccination schedule has expanded over the past four decades, the effects of the overall schedule have never been fully evaluated and published by a major institution. The Institute of Medicine (IOM) has called for such studies to be completed.[83,84] A 2013 IOM report recommended that HHS *"incorporate study of the safety of the overall childhood immunization schedule into its processes for setting priorities for research, recognizing stakeholder concerns,*

and establishing the priorities on the basis of epidemiological evidence, biological plausibility, and feasibility." and *"continue to fund and support the Vaccine Safety Datalink project to study the safety of the recommended immunization schedule."*[85] While some important studies have been conducted, on for example the above-mentioned relationship between vaccine adjuvants and asthma,[86] progress has been slow. There are many knowledge gaps, and only a few of the many studies that the IOM sought and deemed feasible have been conducted.

2.4 Filling the Knowledge Gap

In addition to randomized placebo-controlled vaccine trials, HHS should increase and strengthen the use of large population-based observational studies and data to evaluate the safety of vaccines. Any changes in the vaccination schedule should be accompanied by scientific research to evaluate the short- and long-term impact of the updated immunization schedule on the targeted infectious diseases, other infectious diseases, acute adverse reactions and chronic conditions such as asthma, allergies, auto-immune diseases, developmental disorders (including ADHD, developmental delay, learning disabilities, intellectual disabilities, speech disorders, and tics), neurological disorders, seizures, diabetes, fertility issues, and eczema. Some important priorities include observational cohort studies comparing health outcomes between vaccinated and unvaccinated children, and if issues are identified, drilling down to evaluate the ideal number of doses, the timing and order of childhood vaccines; interaction effects of administering multiple vaccines on the same day; multivalent versus monovalent vaccines for the same diseases; vaccine adjuvants; and different immunization schedules.

In order to assess the long-term impacts of vaccines on chronic conditions, both retrospective and prospective cohort study designs should be utilized, with sufficient sample size and follow-up.

Sophisticated statistical methods for large population-based samples can be effectively used to minimize bias in observational studies. Examples include different forms of propensity score matching[87,88] and inverse probability weighting,[89] which can improve the covariate balance between exposed and unexposed groups. Self-control methods are another way to reduce bias in observational vaccine studies, by removing any between person confounding.[90]

With a large sample size, it may also be possible to identify specific population groups that are at increased risk for adverse events, as long as such analyses are carefully and systematically done.

A successful childhood immunization program must be built on solid scientific evidence. This means:

1. Approvals of new vaccines designed for mass uptake should be based on double-blind placebo-controlled randomized trials. This has seldom been the case.
2. For new vaccines, there must be a post-market system in place to quickly detect unexpected adverse reactions.
3. In addition to acute adverse reactions, we must evaluate long-term effects on the immune system, such as asthma, auto-immune diseases, neurological disorders, and non-targeted infections. We have parts of the infrastructure in place to this, but it has been underutilized.
4. In addition to individual vaccines, we must thoroughly evaluate the safety of the immunization schedule, including cumulative effects, vaccine types and ingredients, the timing and order of vaccines, and interaction effects. The IOM has long called for such studies, but progress has been slow.

3. International Comparison of Childhood Immunization Schedules

Table 2 compares the U.S. childhood vaccination schedule[91] to those of 20 peer nations: Australia,[92] Austria,[93] Belgium,[94] Canada,[95] Denmark,[96] Finland,[97] France,[98] Germany,[99] Greece,[100] Ireland,[101] Italy,[102] Japan,[103] Netherlands,[104] New Zealand,[105] Norway,[106] Portugal,[107] Spain,[108] Sweden,[109] Switzerland,[110] and the United Kingdom.[111]

Universal Vaccine Recommendations Funded by the Government	Age at 1st Vaccine (months)	Rotavirus	Diphteria	Tetanus	Pertussis	Polio	Hib	Tuberculosis	Japanese Encephalitis	Hepatitis A	Hepatitis B	Pneumococcal	Measles	Mumps	Rubella	Varicella	HPV	Meningococcal	Influenza	Covid-19	# Vaccine Doses	# Diseases	# Mandated
Australia	0	2	6	6	6	4	4	..	..	..	4	3	2	2	2	1	1	2	5-6	..	50-51	15	13
Austria	2	2-3	5	5	5	5	3	..	..	..	4	3	2	2	2	..	2	1	17-18	..	58-60	14	0
Belgium	2	..	6	6	6	5	4	..	..	..	4	3	2	2	2	..	2	1	..	..	43	12	1
Canada	2	2-3	6	6	6	5	4	..	..	..	2-3	3-4	2	2	2	2	1	2	18-19	..	64-68	15	0
Denmark	3	..	4	4	4	4	3	..	..	..	..	3	2	2	2	..	2	..	..	..	30	10	0
Finland	2	3	5	5	5	4	3	..	..	..	..	3	2	2	2	2	2	..	6-7	..	44-45	13	0
France	2	2-3	5	5	5	5	3	..	..	..	3	3	2	2	2	..	2	6	..	..	45-46	13	11
Germany	1.5	2-3	5	5	5	4	3	..	..	..	3	3	2	2	2	2	2	4	..	..	44-45	14	1
Greece	2	2-3	6	6	6	4-5	4	..	..	2	3	3	2	2	2	2	2	5	5-6	..	56-58	16	0
Ireland	2	2	6	6	6	5	4	..	..	..	4	3	2	2	2	1	1	5	16	..	65	15	0
Italy	3	2	5	5	5	5	3	..	..	..	3	3	2	2	2	2	2	6	..	..	47	14	10
Japan	2	2-3	5	5	4	4	4	1	4	..	3	4	2	..	2	2	2-3	..	..	..	44-46	14	0
Netherlands	1.5	2	6	6	5	5	4	..	..	..	4	3	2	2	2	..	2	2	..	..	45	13	0
New Zealand	1.5	2	5	5	5	4	4	..	..	..	3	3	2	2	2	1	2	3	..	..	43	14	0
Norway	1.5	2	5	5	5	5	3	..	..	..	3	3	2	2	2	..	2	..	..	..	39	12	0
Portugal	0	..	6	6	5	5	4	..	..	..	3	3	2	2	2	..	2	4	..	..	44	12	0
Spain	2	2-3	5	5	4	4	3	..	..	..	3	3	2	2	2	2	1	6	4-5	..	48-50	15	0
Sweden	1.5	2-3	5	5	5	4	3	..	..	..	3	3	2	2	2	..	2	..	..	..	38-39	12	0
Switzerland	2	2	5	5	5	4	3	..	..	..	3	3	2	2	2	2	2	6	..	..	46	14	0
United Kingdom	2	2	6	6	5	6	4	..	..	..	4	2	2	2	2	2	1	4	14	..	62	15	0
# Recommended		17	20	20	20	20	20	1	1	1	18	20	20	19	20	12	20	15	8	0			
# Mandated		1	3	3	3	4	3	0	0	0	3	2	4	3	3	2	0	2	0	0			
USA 2024	0	2-3	6	6	6	4	3-4	..	..	2	3	4	2	2	2	2	2	2	18-19	18-19	84-88	17	12
USA Suggested	2	A	6	6	6	4	3-4	..	..	A	A	4	2	2	2	2	1	A	A	A	38-39	11	0

Table 2: The number of vaccines recommended for all children in peer nations, not including monoclonal antibodies. The number of vaccine doses is more than the number of injections or diseases covered. For example, the MMR shot contains three vaccine doses, one each for measles, mumps and rubella. Red indicates that the vaccine is mandated for e.g. school,[112] and dark green that it is recommended for all children and covered by insurance. For the U.S., "A" means that it should be available through health insurance for all children. In Canada, provincial recommendations may differ for some vaccines, and there are school vaccine mandates in Ontario and New Brunswick. In the U.S., the mandated vaccines vary by state; shown is New York State. The rotavirus vaccine can come in either 2 or 3 doses. For the influenza and COVID-19 vaccines, 2 doses are sometimes given the first time and 1 dose each subsequent year. If it is recommended annually from age 6 months, some children get it 17 times and others 18 times before their 18th birthday. For U.S. infants also receiving the RSV monoclonal antibody injection, the total number of diseases for which protection was provided in 2024 was 18.

In 2024, the U.S. recommended more childhood vaccines than any peer nation, and more than twice as many doses as some European nations. At the lower end is Denmark, which immunizes children against 10 diseases with a total of 30 doses. By using multivalent vaccines, Denmark's schedule only requires 11 vaccine injections/shots/needles: 3 x (diphtheria + tetanus + pertussis + Hib + polio), 1 x (diphtheria + tetanus + pertussis + polio), 3 x pneumococcal, 2 x (measles + mumps + rubella) and 2 x HPV.[113]

By contrast, in 2024 the U.S. recommended routine vaccination against 17 diseases with 84 to 88 vaccine doses, depending on vaccine product and date of birth. Depending on the number of multivalent vaccines used, this required between 57 and 71 vaccine injections, of which the 2 or 3 for rotavirus are oral. For infants also receiving the RSV monoclonal antibody injection, the total number of injections could be 72 to provide protection against 18 diseases.[114]

Many considerations are relevant as countries develop their vaccination recommendations. However, if disease prevalences are comparable and children without underlying risk factors face similar risks from the target disease, variations in practice in terms of doses, number of diseases, and timing of vaccinations often reflects valid uncertainties as to what is the best practice. Such uncertainties and disagreements within the medical community are known as *"clinical equipoise."*[115]

Each disease addressed by the U.S. child immunization schedule poses a health risk, but the level of risk varies widely by disease and sometimes by individual underlying risk factors. Yet the mere existence of a vaccine does not automatically make it appropriate for every child, nor does it necessarily justify routine vaccination.

While a set of consensus vaccines are consistently recommended in all peer countries, several vaccines currently included in the childhood immunization schedule in the U.S. (hepatitis A, varicella, influenza, rotavirus and meningococcal vaccines) are limited in their recommendation or excluded in some other developed countries (Table 2). Another stark difference is that most countries maintain high vaccination rates through trust in public health authorities rather than vaccine mandates (red in Table 2).

There is global variation in the universal use and timing of numerous childhood vaccines. Although these differences sometimes reflect the unique epidemiology of diseases in each region, they more often arise from uncertain science and knowledge gaps, which lead to inadequately informed assessments of risks and benefits that are subject to differing interpretations. Disagreement among states and professional societies[116] in the U.S. further underscores the need and opportunity for a more adaptable childhood immunization schedule.

Countries differ in terms of both disease exposure and health care system. The U.S. provides health care access for children through a combination of private insurance, state Medicaid programs, the Children's Health Insurance Program (CHIP), and the Vaccines for Children (VFC) program.

Broad insurance coverage of both consensus and non-consensus immunizations should remain in effect following the updates to the immunization schedule. Identifying the consensus vaccines on the schedule would help Americans make informed decision while making all vaccines available

for parents also opting for their child to receive non-consensus immunizations. Through proper vaccine research, it is important to improve our understanding of populations who are most likely to benefit from individual vaccines as well as situations where vaccination may not be needed.

A successful childhood vaccination program can learn from successful peer nations. In particular:

1. The U.S. has been an international outlier in the number of vaccines given, and uptake of consensus vaccinations has decreased.
2. One way to restore trust in the U.S. childhood immunization schedule is to better align the country with consensus vaccine components of the schedules of peer nations, while not restricting anyone's access to other immunizations.

4. Recommended Childhood Immunization Schedule

To increase trust, public health agencies should be honest regarding knowledge gaps about vaccines. Without placebo-controlled randomized trials with sufficient sample size and follow-up time for thorough safety evaluation, and post-marketing cohort studies comparing exposed and unexposed populations with long follow-up, we do not have the basic data needed to assess potential vaccine harms. Childhood vaccination recommendations must therefore be based on the best available evidence and the best practices of peer, developed nations. If there is a clear benefit of the vaccine, as for measle vaccines, the risks will need to be more substantial to outweigh the benefit. On the other hand, if the benefits are limited, as for the hepatitis A vaccine, even a small risk will tip the balance, where harms outweigh the benefits. For such vaccines, it is prudent to adopt a more conservative approach. Many peer countries have chosen to limit their core vaccines to diseases where the potential for benefit is understood to be the largest. There can be honest disagreements about where to draw the line, and different countries have made different decisions.

As with all medical procedures, vaccine decisions should never involve coercion but instead should always be the result of informed consent and with the final decision resting with the patient/parents. Coercion renders informed consent invalid and undermines this basic right.

4.1 Immunization Categories

Immunizations Recommended for All Children: These are vaccines, such as the measles vaccine, for which there is consensus among peer nations that all children should receive them. These vaccines should be covered by all forms of health insurance without cost sharing.

Immunizations Recommended for Certain High-Risk Groups or Populations: Like all medical products, vaccines have different risk-benefit profiles for different people. This can either be because of underlying comorbidities, unusual exposure to the disease, or the risk of disease transmission to others. For example, the hepatitis A vaccine when children travel internationally to an endemic area or the birth dose of the hepatitis B vaccine for infants born to mothers that are hepatitis B positive. This document has not assessed and does not propose any changes in vaccine recommendations for high-risk populations. These vaccines should be covered by all forms of health insurance without cost sharing.

Immunizations Based on Shared Clinical Decision-Making: Shared clinical decision-making recommendations are individually based and informed by a discussion between the health care provider and the patient or parent/guardian.[117] It is not always possible for public health to clearly define who will benefit from a vaccine, who has relevant risk factors, or who are at risk of exposure. Parents and physicians, who know the child, may be better placed to make that judgement. With shared clinical decision-making, the characteristics of the individual are considered, including their likelihood of being exposed to the diseases, their risks of morbidity and mortality if contracting the diseases, their likelihood of benefitting from the vaccine, their likelihood of vaccine adverse reactions, and their risk of transmitting the disease to others. Sometimes, it is also important to consider personal and family preferences, beliefs, and knowledge, including when a patient presents specific information regarding the pre-and-post licensure safety data of a vaccine or presents specific familial experience with a vaccine.

While these immunizations are not routinely recommended for all children, they should be available for anyone who wants them and they should be covered by Medicaid, CHIP, the Vaccine for Children (VFC) Program, and private health insurance, without cost sharing. This is in contrast to some peer nations, where such vaccines must be purchased out-of-pocket.[118]

Not Recommended Immunizations: No currently recommended vaccines should be moved into this category. Some vaccines are not recommended for anyone, either because a lack of efficacy, known side effects, or low disease prevalence in the U.S. For example, while the BCG tuberculosis vaccine is used in many countries, it is not recommended for children in the U.S.[119] If approved by FDA, these vaccines may be available for purchase, but they are not covered by Medicaid, the Children's Health Insurance Program (CHIP), or the Vaccine for Children (VFC) Program.

4.2 Immunizations Recommended for All Children

Measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib and pneumococcal disease vaccines (MMR, DTaP, IPV, Hib, and PCV): These are consensus vaccines that are part of the recommended childhood immunization schedules for all 20 peer nations, with the

exception of mumps in Japan (Table 2). As consensus vaccines, they should remain on the immunization schedule in the U.S. as vaccines recommended for all children. While the safety/risk profiles are not fully understood, and in need of further study, there is consensus among peer nations that they provide material benefits against the target disease. Focusing on these vaccines is more likely to reverse the declining uptake[120] of these vaccines.

HPV: There is also international consensus on the HPV vaccine, and it should continue to be recommended for all children/adolescents, but with one dose instead of two. Vaccination with one dose is as or nearly as effective as two doses.[121,122,123,124] Australia, Canada, Ireland, Spain, and the United Kingdom have already updated their recommendations to one dose (Table 2).[125,126,127]

Varicella: The varicella zoster virus causes chickenpox (typically in children), and, for those infected, can reemerge as shingles (typically in adults). The uncertainty of its long-term consequences on adults is one reason why some countries have been cautious about adding the varicella vaccine to the childhood schedule,[128] but similar caution may be warranted regarding a removal once there has been widespread use of this vaccine.[129] The rate of two dose vaccination for varicella among American children is estimated at 92%.[130] Partial population varicella vaccination (60-80% for two doses) could increase the average age at which the population naturally gets chickenpox when this disease could cause more complications, and hence there is a consensus among peer nations that once vaccination for chicken pox has become widespread, stopping use of this vaccine could cause certain complications.[131,132] For these reasons, the varicella vaccine should remain recommended for all children.

4.3 Immunizations Recommended for Certain High-Risk Groups or Populations

Respiratory syncytial virus (RSV) monoclonal antibodies, and Hepatitis A, Hepatitis B, Meningococcal B, Meningococcal ACWY, and Dengue vaccines: This document does not contain an assessment of which high-risk groups and populations should receive which immunizations, and hence, it does not propose any changes to such recommendations.

4.4 Immunizations Based on Shared Clinical Decision-Making

Hepatitis A: There are two FDA approved hepatitis A vaccines: Havrix since 1995 and Vaqta since 1996. At that time, the primary candidates for vaccination were *"travelers to regions of endemic disease, children living in high prevalence areas, homosexual males, users of illicit intravenous drugs, persons working directly with nonhuman primates or hepatitis A virus, patients older than 30 years of age with chronic liver disease, and persons who have received a liver transplant or are awaiting one."*[133] For children, the vaccine was originally only

recommended in high endemic communities. Those had disappeared in the U.S. by 2006, at which time a 2-dose regiment at age 12 to 23 months was added to the universally recommended childhood immunization schedule. In 2006, the annual incidence rate of hepatitis A was very low at around 1 per 100,000 and it remains similarly low. The annual mortality rate is 1 per 10 million, with the highest rate among older men.[134,135,136]

There has been one randomized trial (n=40,119) for Havrix in young children, which used the Engerix-B vaccine for hepatitis B as the control group.[137] For Vaqta, the phase 3 randomized trial for children (n=1037) gave an aluminum and mercury containing diluent to the control group.[138] Hence, without a proper placebo-controlled randomized trial, reliable safety data is limited.

Among peer nations, Greece is the only one with a routine childhood vaccine recommendation (Table 2). Given the low U.S. incidence and mortality, and the lack of randomized placebo-controlled safety data, the benefit-risk ratio is at best very low for most children. There is a clear benefit, but still undefined risk, for children travelling to high endemic countries in the developing world.[139]

The Hep A vaccine should not be recommended for all children, but it should be available for all children whose parents want it through shared clinical decision making, and it should be covered by insurance without cost sharing.

Hepatitis B: Together with hepatitis B immune globulin, infants should be administered the hepatitis B vaccine at birth if the mother is HBsAg-positive or status is unknown. If the mother tests negative, only two of the 20 peer nations recommend universal vaccination at birth: Australia and Portugal, while two countries do not recommend it at all (Table 2). At their December 2025 meeting, the Advisory Committee on Immunization Practices followed the majority of peer nations and voted to no longer recommend the birth dose if the mother tested negative. Instead, it recommended shared clinical decision-making, taking the risk profile of each unique child into account.[140]

Rotavirus: Rotavirus is a common infection, and prior to the rotavirus vaccine, nearly every child would be infected, both in the U.S. and abroad.[141]In the developing world, many children die from dehydration after catching the virus, and there is greater opportunity for benefit from vaccination.[142]

In the U.S., it can cause hospitalization for gastroenteritis, but the virus poses almost no risk of either mortality or chronic morbidity. Data from CDC indicate that among all U.S. children <15 years of age, there were an average of 3.3 deaths per year with the rotavirus diagnostic code listed on the death certificate between 1999 and 2005.[143] This was after the RotaShield vaccine

was withdrawn from the market in 1999 and before the RotaTeq vaccine was approved in 2006. Another vaccine, Rotarix, was approved in 2008. After these vaccines were recommended for all children, there were 1.6 deaths per year from 2009 to 2020.[144] There may be many reasons for this very small decrease in mortality that are unrelated to the vaccine, including improved medical care, changes in diagnostic practices or random fluctuations.

RotaShield was removed from the market due to an excess risk of intussusception.[145] The newer current vaccines have a lower intussusception risk, at around 1 or 2 per 100,000 vaccinated children.[146]

Reasonable people can reach different conclusions about recommending the rotavirus vaccine for all children. Among peer nations, Belgium, Denmark and Portugal do not recommend it. Denmark has cited the very low risk of mortality and chronic morbidity to nearly all children in their rationale for not adding the vaccine to their childhood immunization schedule,[147]

The rotavirus vaccine should not be a consensus vaccine recommended for all children, but it should be available for all children whose parents want it through shared clinical decision making, and it should be covered by insurance without cost sharing.

Meningococcal Disease: Among peer nations, 15 recommend meningococcal vaccination for all children while five limit it to high-risk groups (Table 2). The incidence of meningococcal disease has declined during the past decades, both in countries with and without the routine vaccine recommendations for children, and the magnitude of the decline appears to be independent of vaccination policy (Table 3). The current incidence in the U.S. is 0.12/100,000 or about one case per million per year.

Countries Recommending Menigococcal Vaccine for All Children			
	Incidence 1998-2002	Incidence 2023-2024	Change in Incidence (%)
Australia	2.31	0.52	-78%
Austria	1.02	0.17	-83%
Belgium	3.75	0.72	-81%
Canada	0.76	0.26	-65%
France	0.84	0.86	2%
Germany	0.91	0.36	-61%
Greece	2.13	0.29	-86%
Ireland	12.41	1.01	-92%
Netherlands	3.73	0.73	-80%
Portugal	2.57	0.36	-86%
Spain	2.87	0.64	-78%
Switzerland	2.08	0.42	-80%
United Kingdom	1.36	0.71	-48%
United States	0.83	0.12	-85%
Average	**2.68**	**0.51**	**-72%**
Countries Not Recommending Menigococcal Vaccine for All Children			
Denmark	2.91	0.49	-83%
Finland	1.00	0.14	-86%
Norway	2.10	0.27	-87%
Sweden	0.66	0.37	-44%
Average	**1.67**	**0.32**	**-75%**

Table 3: Annual incidence rates per 100,000 population of meningococcal disease in the U.S. and peer countries, and percent change from 1998-2002 to 2023-2024. International population estimates were obtained from the U.S. Census Bureau, International Programs Center, International Database.[148] *Because historical meningococcal surveillance data are not harmonized across countries, data sources varied by country and time period. To calculate the IR for the U.S., 1998-2002, 2019, and 2024 data were collected from Centers for Disease Control and Prevention.*[149,150] *In the remaining instances, 1998–2002 data were primarily obtained from the European Commission, Health and Consumers Directorate, European Community Health Indicators: Meningococcal Disease report; for Sweden, there existed a probable data error from the source for 2001's count of case reports that resulted in an exclusion of this data point, therefore, the 1998-2002 incidence was calculated as a four-year average with the remaining data points.*[151] *For Australia, 1998–2001 data were compiled from national surveillance publications by The Australian Meningococcal Surveillance Programme and another academic source, with a four-year IR average calculated due to 2002 data unavailability.*[152,153] *For Denmark, 2023-2024 data were from Statens Serum Institut.*[154] *2020-2024 incidence data are reported cases of invasive meningococcal*

disease collected annually through the WHO/UNICEF Joint Reporting Form on Immunization (JRF).[155] *Reliable incidence rates were not found for Italy, New Zealand or Japan.*

In a 2011 position paper, the World Health Organization (WHO) recommended that countries with more than 2 cases per 100,000 population/year maintain a *"large scale meningococcal vaccination program,"* while only vaccinating the high-risk population in countries with lower rates.[156] In the U.S., the current incidence of 0.1 per 100,000,[157] is much lower than the WHO suggested cut-off.

The current meningococcal vaccines recommended for all children (Menveo, Menquadfi, and Penbraya) were not evaluated in large-scale double-blind placebo-controlled randomized trials before FDA approval.[158,159,160]

Considering the low incidence of meningococcal disease in the U.S., the meningococcal vaccine should not be part of the consensus recommended vaccine schedule. High-risk children and adolescents, such as children with certain types of immune deficiencies, may have a greater chance of benefiting from the vaccine, and it should be available and covered by insurance for all children and adolescents through shared-clinical decision making.

Influenza: The primary purpose of the childhood influenza vaccine in children is to reduce hospitalizations and mortality in children, as well as transmission to the elderly, who are of higher risk for death but there are no randomized controlled trials demonstrating these benefits.[161,162,163] There are some randomized placebo-controlled trials for the influenza vaccine. The most comprehensive review was done in 2018 by the Cochrane Collaboration.[164] They found that *"in children aged between 3 and 16 years, live influenza vaccines probably reduce influenza (moderate-certainty evidence)"* infections while *"inactivated vaccines also reduce influenza (high certainty evidence)."* Only a few of the trials evaluated school and parental work absenteeism, not finding a statistically significant reduction. There was no evidence about reduced transmission. The trials could not evaluate differences in hospitalizations or mortality, as there were none or few in either group, so they provide no evidence that the vaccines reduce hospitalization or deaths. There was not much information about children under 2 years old.

The conclusion of the Cochrane systematic review of randomized trials in children was that *"Decision-makers' attention to the vaccination of very young children is not supported by the evidence summarised in our review. Although there is a growing body of evidence showing the impact of influenza on hospitalisations and deaths of children, at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza."*[165]

There have been some observational studies with mixed results. A test-negative case-control study claimed to show that childhood influenza vaccine reduces hospitalization,[166] but that is a notoriously biased study design,[167] with highly implausible results.[168]

While there is a scarcity of reliable safety data, the influenza vaccines are not without risk. The seasonal vaccine has been linked to Guillain Barré syndrome.[169] During the 2009/2010 H1N1 influenza pandemic, the Pandemrix pandemic vaccine was found to cause narcolepsy among vaccinated children and adolescents.[170,171] The Cochrane systematic review, noted that *"the lack of safety data for inactive vaccines in younger children is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA and Canada"* and that *"the manufacturers' refusal to release all safety outcome data from trials carried out in young children, together with obvious reporting bias and inconsistencies in the primary studies, does not bode well for a fair assessment of the safety of live attenuated vaccines."*[172]

Considering the evidence, and lack of evidence, it is understandable that public health agencies in different countries have come to different conclusions about the influenza vaccine for children. Among the 20 peer countries, only Austria and Canada recommend an annual influenza vaccine for all children >6 months and all adolescents. Another six recommend the shot for all children in selected age ranges. The remaining twelve peer nations do not recommend the influenza vaccine for all children in any age group (Table 2).

Based on both the evidence and uncertainties, the influenza vaccine should not be recommended for all children, but it should be available through insurance for all children >6 months old, through shared-clinical decision making.

COVID-19: In 2022, Denmark became the first peer nation to remove its universal recommendation of the COVID-19 vaccine for children, with the director of its public health authority recognizing that there was little benefit in giving this vaccine to children.[173] Since then, all other peer nations have followed (Table 2). At their September 2025 meeting, the Advisory Committee on Immunization Practices voted that shared clinical decision-making should be applied to the COVID-19 vaccine for U.S. children and adolescents.[174] This means that insurance continues to cover this vaccine for all children in the U.S., unlike many peer nations, where insurance only pays for recommended vaccines.

To ensure a successful childhood vaccination program, the proposed updated schedule:

1. Recommends for all children all the vaccines for which there is consensus among peer nations.
2. Allows for more flexibility and choice, with less coercion, by reassigning non-consensus vaccines to certain high-risk groups and populations and/or based on shared clinical decision-making.
3. Ensures that all the diseases covered by the prior immunization schedule would still be available to anyone who wants them through their private health insurance, Medicaid, the Children's Health Insurance Program (CHIP), and/or the Vaccine for Children (VFC) Program. Among peer nations, the U.S. would continue to offer the greatest number of childhood vaccines for free to those who want them.
4. Is accompanied by a strengthening of vaccine research by launching double-blind placebo controlled randomized trials if appropriate and more observational studies to evaluate long-terms effects of individual vaccines and the vaccine schedule.

5. Next Steps

While closely monitoring vaccine safety and risks, vaccine uptake and infectious disease rates, the CDC and its Advisory Committee on Immunization Practices should continue its work revising recommendations based on the latest vaccine developments and scientific research. For example, they should fine-tune the schedule with recommendations for certain populations for those vaccines that are no longer routinely recommended for all children.

HHS should work with states and physician groups to educate parents and physicians on changes to the CDC childhood immunization schedule.

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EXHIBIT 20

IMMUNIZATIONS RECOMMENDED FOR ALL CHILDREN

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20–23 mos	2–3 yrs	4–6 yrs	7 yrs	8 yrs	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Diphtheria, tetanus, acellular pertussis (DTaP < 7 yrs)			1st dose	2nd dose	3rd dose				4th dose					5th dose											
Tetanus, diphtheria, acellular pertussis (Tdap ≥ 7 yrs)																			1st dose						
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	3rd dose			3rd / 4th dose																	
Pneumococcal conjugate (PCV15, PCV20)			1st dose	2nd dose	3rd dose			4th dose																	
Inactivated poliovirus (IPV < 18 yrs)			1st dose	2nd dose	3rd dose									4th dose											
Measles, mumps, rubella (MMR)								1st dose						2nd dose											
Varicella (VAR)								1st dose						2nd dose											
Human papillomavirus (HPV)																			1 dose						

Some children should get a dose at this age depending on the vaccine brand.

IMMUNIZATIONS RECOMMENDED FOR CERTAIN HIGH-RISK GROUPS OR POPULATIONS

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20–23 mos	2–3 yrs	4–6 yrs	7 yrs	8 yrs	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Respiratory syncytial virus (RSV–mAb) [1]	1 dose																								
Respiratory syncytial virus (RSV–mAb) [2]	1 dose						2nd dose																		
Hepatitis B (HepB) [3]	1st dose	2nd dose			3rd dose																				
Dengue [4]																	3 dose series								
Meningococcal ACWY [5]			2, 3 or 4 dose series																						
Meningococcal B [6]																		1 dose							
Hepatitis A (HepA) [7]					1 dose																				

[1] All children whose mother did not have the vaccine should get one dose.
[2] High-risk children, such as those with chronic lung disease, should receive a second dose at ages 8 to 19 months.
[3] Vaccination recommended for infants born to women who tested positive for the hepatitis B virus or whose status is unknown.
[4] Recommended ONLY if living in areas with endemic dengue AND with a laboratory confirmation of previous dengue infection.
[5] For high-risk groups (e.g., those with anatomic or functional asplenia or HIV infection), those traveling to countries with hyperendemic or epidemic meningococcal disease, and first-year college students living in residential housing, vaccination is recommended.
[6] Recommended for high-risk groups, e.g., with anatomic or functional asplenia, and during outbreaks.
[7] Vaccination recommended for international travel to areas with high or intermediate hepatitis A endemicity.

IMMUNIZATIONS BASED ON SHARED CLINICAL DECISION-MAKING

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20–23 mos	2–3 yrs	4–6 yrs	7 yrs	8 yrs	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Rotavirus (RV): RV1 (2-dose series), RV5 (3-dose series)			1st dose	2nd dose	3rd dose																				
COVID-19 (1vCOV-mRNA, 1vCOV-aPS)					2 doses first year, then 1 dose annually								1 dose annually												
Influenza (IIV3, cellV3) OR					2 doses first year, then 1 dose annually								OR						1 dose annually						
Influenza (LAIV3)													2 doses first year, then 1 dose annually						1 dose annually						
Hepatitis A (HepA)								2-dose series																	
Hepatitis B (HepB) [1]			1st dose	2nd dose	3rd dose																				
Meningococcal ACWY																			1st dose					2nd dose	
Meningococcal B																								2 or 3 doses	

Some children should get a dose at this age depending on the vaccine brand.

[1] For parents deciding whether to vaccinate for HepB in infants born to women who tested negative for the hepatitis B virus, it is suggested that the initial dose is administered no earlier than 2 months of age.

EXHIBIT 21

AMENDMENT
to the
CHARTER
of the
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES

Advisory Committee's Official Designation.

Advisory Committee on Immunization Practices (ACIP).

Authority.

The ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C. §2l7a), as amended. The Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. § 1001 et seq.), as amended.

The ACIP has been given statutory roles under subsections 1928(c)(2)(B)(i) and 1928(e) of the Social Security Act (42 U.S.C. § 1396s(c)(2)(B)(i) and 1396s(e)) and subsection 2713(a)(2) of the Public Health Service Act (42 U.S.C. § 300gg-13(a)(2)).

Objective and Scope of Activities.

The Secretary, Department of Health and Human Services (HHS), and by delegation the Director, Centers for Disease Control and Prevention (CDC), are authorized under Section 311 and Section 317 of the Public Health Service Act, [42 U.S.C. §243 and 42 U.S.C. §247b], as amended, to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs.

The ACIP shall provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States. Recommendations made by the ACIP are reviewed by the CDC Director, and if adopted, are published as official CDC/HHS recommendations in the *Morbidity and Mortality Weekly Report (MMWR)*. The CDC Director informs the Secretary, HHS, and the Assistant Secretary for Health, of immunization recommendations. Upon the licensure of any vaccine or any new indication for a vaccine, the Committee shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting. If the Committee does not make a recommendation at the Committee's first regularly scheduled meeting, the Committee shall provide an update on the status of such for the Committee's review.

Description of Duties.

The Committee shall provide advice for the control of diseases for which a vaccine is licensed in the U.S. The guidance will address use of vaccines and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling a disease for which a vaccine is available. Guidance for use of unlicensed vaccines may be developed if circumstances warrant. For each vaccine, the Committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The Committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. The Committee also may provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents, use of specific antibody products for prevention of infectious diseases, and special situations or populations that may warrant modification of the routine recommendations.

Committee deliberations on use of vaccines to control disease in the U.S. shall include consideration of disease epidemiology and burden of disease, vaccine safety, vaccine efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues. The Committee may revise or withdraw their recommendation(s) regarding a particular vaccine as new information on disease epidemiology, vaccine effectiveness or safety, economic considerations, or other data become available.

In accordance with Section 1928 of the Social Security Act, the ACIP also shall establish and periodically review and, as appropriate, revise the list of vaccines for administration to children and adolescents eligible to receive vaccines through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric vaccines. The Secretary, and as delegated the CDC Director, shall use the list established by the ACIP for the purpose of the purchase, delivery, and administration of pediatric vaccines in the Vaccines for Children Program.

Further, under provisions of the Affordable Care Act (Section 2713 of the Public Health Service Act, as amended), immunization recommendations of the Committee that have been adopted by the Director of the Centers for Disease Control and Prevention must be covered by applicable health plans.

Agency or Official to Whom the Committee Reports.

The Committee reports to the Director, CDC. The CDC Director informs the Secretary, HHS and the Assistant Secretary for Health, HHS, of immunization recommendations.

Support.

Management and support services shall be provided by the Office of the Director, National Center for Immunization and Respiratory Diseases, CDC.

Estimated Annual Operating Costs and Staff Years.

Estimated annual cost for operating the Committee, including compensation and travel expenses for members, but excluding staff support, is $409,922. Estimate of annual person-years of staff support required is 9.40, at an estimated annual cost of $1,760,637.

Designated Federal Officer.

CDC will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (DFO) to attend each committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting policies and agendas, call all of the committee and subcommittee meetings, adjourn any meeting when the DFO deems adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the committee reports. The DFO or his/her designee shall be present at all meetings of the full committee and subcommittees. In the event that the DFO cannot fulfill the assigned duties of the Committee, one or more full-time or permanent part-time employees will be assigned as DFO and carry out these duties on a temporary basis.

Estimated Number and Frequency of Meetings.

Meetings shall be held approximately three times per year at the call of the DFO, in consultation with the Chair.

Meetings shall be open to the public except as determined otherwise by the Director, CDC, or other official, to whom the authority has been delegated, in accordance with the Government in the Sunshine Act (5 U.S.C. § 552b(c)) and Section 10(d) of the Federal Advisory Committee Act ((5 U.S.C. § 1009(d)). Notice of all meetings shall be given to the public.

Duration.

Continuing.

Termination.

Unless renewed by appropriate action, the ACIP will terminate two years from the date this charter is filed.

Membership and Designation.

The Committee shall consist of up to 19 Special Government Employees, including the Chair and Vice Chair. Members shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety. The Committee shall include a person or persons knowledgeable about consumer perspectives and/or social and community aspects of immunization programs. Members shall be deemed Special Government Employees.

The Committee also shall consist of six non-voting ex-officio members from the Health Resources and Services Administration; the Food and Drug Administration; Centers for Medicare and Medicaid Services; National Institutes of Health; Indian Health Service; and the Office of Infectious Disease and HIV/AIDS Policy, HHS; or their designees.

If fewer than a quorum of ACIP members are eligible to vote due to absence or a financial or other conflict of interest, the DFO, or designee, shall have the authority to temporarily designate the ex-officio members as voting members.

There also shall be non-voting liaison representatives from the American Academy of Family Physicians; American Academy of Pediatrics; American Academy of Physician Associates; American College Health Association; American College of Nurse Midwives; American College of Obstetricians and Gynecologists; American College of Physicians; American Geriatrics Society; America's Health Insurance Plans; American Immunization Registry Association; American Medical Association; American Nurses Association; American Osteopathic Association; American Pharmacists Association; Association of Immunization Managers; Association for Prevention Teaching and Research; Association of State and Territorial Health Officials; Biotechnology Innovation Organization; Council of State and Territorial Epidemiologists; Canadian National Advisory Committee on Immunization; Infectious Diseases Society of America; International Society of Travel Medicine; National Association of County and City Health Officials; National Association of Pediatric Nurse Practitioners; National Foundation for Infectious Diseases; National Medical Association; Pediatric Infectious Diseases Society; Pharmaceutical Research and Manufacturers of America; Society for Adolescent Health and Medicine; Society for Healthcare Epidemiology of America and such other non-voting liaison representatives as the Secretary deems necessary to effectively carry out the functions of the Committee. Liaisons shall be deemed representatives.

Members, including the Chair and Vice Chair, shall be selected by the Secretary and shall be invited to serve for overlapping terms of up to four years, except that any member appointed to fill a vacancy for an unexpired term shall be appointed for the remainder of that term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

Subcommittees.

Subcommittees composed, in part, of members of the parent committee and other subject matter experts may be established with the approval of the Secretary, HHS, or his/her designee. The subcommittees must report back to the parent committee and do not provide advice or work products directly to the agency. The Department Committee Management Officer will be notified upon establishment of each subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

Recordkeeping.

The records of the committee, established subcommittees, or other subgroups of the committee, shall be managed in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. §552.

Filing Date.

April 1, 2026

Amended Filing Date.

Approved:

12/3/2025
Date

Robert F. Kennedy, Jr.

EXHIBIT 22

Plaintiffs' Federal Rule of Evidence 1006 Summary Exhibit

PCV13 in Adults from Routine Use to Shared Clinical Decision-Making

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	ACIP Vote & Recommendation	
1. Prevnar 13 (PCV13, Wyeth Pharmaceuticals), authorized by FDA on December 30, 2011[1]			
2. Prevnar 13 (PCV13, Wyeth Pharmaceuticals), recommended by ACIP, adopted by CDC for specific population groups	**February 24, 2011**[2] - Introduction[3] - Safety and Immunogenicity of PCV13 in Adults[4]	**June 20, 2012**[27] ACIP recommended routine use of PCV13 for adults aged ≥19 years with immunocompromising conditions, functional or	**October 12, 2012**[30] "The evidence for the benefits and risk of PCV13 vaccination of adults with immunocompromising conditions was evaluated using

[1] Archive of letter from Wellington Sun, Ctr. for Biologics Evaluation and Research to Wyeth Pharma. Inc. by Archive-It, *December 30, 2011 Approval Letter — Prevnar 13* (Dec. 30, 2011), https://wayback.archive-it.org/7993/20170723031317/https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm285434.htm (archived on July 23, 2017).
[2] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *February 23–24*, *2011*, *Atlanta*, *Georgia*, 3 (May 17, 2012), https://stacks.cdc.gov/view/cdc/76513.
[3] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *February 23–24*, *2011*, *Atlanta*, *Georgia*, 153 (May 17, 2012), https://stacks.cdc.gov/view/cdc/76513.
[4] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *February 23–24*, *2011*, *Atlanta*, *Georgia*, 153-160 (May 17, 2012), https://stacks.cdc.gov/view/cdc/76513.
[27] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 20–21*, *2012*, *Atlanta*, *Georgia*, 32-38 (Sept. 18, 2012), https://stacks.cdc.gov/view/cdc/76509.
[30] Nancy M. Bennett, et al., CDC, *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions*: *Recommendations of the Advisory Committee on Immunization Practices* (*ACIP*), 61 Morb. Mortal. Wkly. Rep. 816, 816-819 (Oct.12, 2012), https://stacks.cdc.gov/view/cdc/20844.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	**ACIP Vote & Recommendation**	
	- Cost-Effectiveness of PCV13 Vaccination of Adults ≥50 Years of Age[5] - Public Health and Economic Impact of PCV13 in U.S. Adults ≥50 Years of Age[6] **June 23, 2011[7]** - Introduction[8] - Public Health and Economic Impact of PCV13 in US Adults ≥50 Years of Age[9] - Current Epidemiology of Pneumococcal Disease in Adults[10] - Considerations for PCV13 Use Among Adults: Summary of	anatomic asplenia, cerebrospinal fluid leak, or cochlear implants GRADE Summary of Evidence Table[28] **Votes: Recommendations for Pneumococcal Vaccine use among Immunocompromised Adults: 14 in favor to 1 abstained[29]** In favor: 14 Opposed: 0 Abstained: 1	the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework and designated as a Category A recommendation."[31] "The ACIP decision to recommend PCV13 use among adults aged ≥65 years was deferred until data became available on 1) the impact of PCV13 use in children on disease in adults (i.e., indirect effects) and 2) the efficacy of PCV13 against noninvasive

[5] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *February 23–24*, *2011*, *Atlanta*, *Georgia*, 160-164 (May 17, 2012), https://stacks.cdc.gov/view/cdc/76513.
[6] *Id.*
[7] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *2011 June 22–23*, *Atlanta*, *Georgia*, 3 (Oct.17, 2011), https://stacks.cdc.gov/view/cdc/76512.
[8] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *2011 June 22–23*, *Atlanta*, *Georgia*, 132-133 (Oct.17, 2011), https://stacks.cdc.gov/view/cdc/76512.
[9] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *2011 June 22–23*, *Atlanta*, *Georgia*, 133-138 (Oct.17, 2011), https://stacks.cdc.gov/view/cdc/76512.
[10] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *2011 June 22–23*, *Atlanta*, *Georgia*, 138-140 (Oct.17, 2011), https://stacks.cdc.gov/view/cdc/76512.
[28] ACIP, *Grading of Recommendations*, *Assessment*, *Development*, *and Evaluation* (*GRADE*) *for Pneumococcal Vaccines for Immunocompromised Adults* (Sept. 9, 2024), https://www.cdc.gov/acip/grade/pneumo-immuno-adults.html.
[29] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 20–21*, *2012*, *Atlanta*, *Georgia*, 38 (Sept. 18, 2012), https://stacks.cdc.gov/view/cdc/76509.
[31] Nancy M. Bennett, et al., CDC, *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine for Adults with Immunocompromising Conditions*: *Recommendations of the Advisory Committee on Immunization Practices* (*ACIP*), 61 Morb. Mortal. Wkly. Rep. 816, 816 (Oct.12, 2012), https://stacks.cdc.gov/view/cdc/20844.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	ACIP Vote & Recommendation	
	Immunogenicity and Efficacy; Cost-Effectiveness Studies[11] **October 26, 2011**[12] - Introduction[13] - Immunogenicity of PCV13 in Adults: Results of Phase III Studies[14] - Considerations for PCV13 Use Among Adults with Immunocompromising Conditions: Results of Immunogenicity and Efficacy Studies[15] **February 22, 2012**[16]		pneumococcal pneumonia among adults."[32]

[11] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *2011 June 22–23*, *Atlanta*, *Georgia*, 140-146 (Oct.17, 2011), https://stacks.cdc.gov/view/cdc/76512.
[12] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *October 25–26*, *2011*, *Atlanta*, *Georgia*, 3 (January 27, 2012), https://stacks.cdc.gov/view/cdc/76514.
[13] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *October 25–26*, *2011*, *Atlanta*, *Georgia*, 129 (January 27, 2012), https://stacks.cdc.gov/view/cdc/76514.
[14] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *October 25–26*, *2011*, *Atlanta*, *Georgia*, 130-136 (January 27, 2012), https://stacks.cdc.gov/view/cdc/76514.
[15] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *October 25–26*, *2011*, *Atlanta*, *Georgia*, 137-141 (January 27, 2012), https://stacks.cdc.gov/view/cdc/76514.
[16] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *February 22–23*, *2012*, *Atlanta*, *Georgia*, 2 (May 17, 2012), https://stacks.cdc.gov/view/cdc/76510.
[32] Sara Tomczyk, et al., CDC, *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥ 65 Years*: *Recommendations of the Advisory Committee on Immunization Practices* (*ACIP*), 63 Morb. Mortal. Wkly. Rep. 823, 823 (Sept. 19, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	ACIP Vote & Recommendation	
	- 13-valent Pneumococcal Conjugate Vaccine for Adults (PCV13)[17] - Considerations for Age-Based Recommendations for Pneumococcal Conjugate Vaccine for Adults: GRADE of Evidence[18] - 13-valent Pneumococcal Conjugate Vaccine use in Adults with Immunocompromising Conditions: GRADE of Evidence[19] **June 20, 2012[20]** - 13-valent Pneumococcal Conjugate Vaccine for Adults[21] - Current Recommendations for Pneumococcal Polysaccharide Vaccine for Immunocompromised Adults: GRADE of Evidence[22]		

[17] Nancy M. Bennett, ACIP, *13-Valent Pneumococcal Conjugate Vaccine for Adults* (*PCV13*) (Feb. 22, 2012), https://stacks.cdc.gov/view/cdc/78591.
[18] Tamara Pilishvili, ACIP, *Considerations for Age-based Recommendations for Pneumococcal Conjugate Vaccine for Adults*: *GRADE of Evidence* (Feb. 22, 2012), https://stacks.cdc.gov/view/cdc/78592.
[19] Kathleen Dooling, ACIP, *13-Valent Pneumococcal Conjugate Vaccine Use in Adults with Immunocompromising Conditions*: *GRADE of Evidence* (Feb. 22, 2012), https://stacks.cdc.gov/view/cdc/78593.
[20] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 20–21*, *2012*, *Atlanta*, *Georgia* (Sept. 18, 2012), 2, https://stacks.cdc.gov/view/cdc/76509.
[21] Nancy M. Bennett, ACIP, *13-Valent Pneumococcal Conjugate Vaccine for Adults* (June 20, 2012), https://stacks.cdc.gov/view/cdc/78435.
[22] Tamara Pilishvili, ACIP, *Current Recommendations for Pneumococcal Polysaccharide Vaccine for Immunocompromised Adults*: *GRADE of Evidence* (June 20, 2012), https://stacks.cdc.gov/view/cdc/78436.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	ACIP Vote & Recommendation	
	- 13-valent Pneumococcal Conjugate Vaccine Use in Adults with Immunocompromising Conditions[23] - 13-valent Pneumococcal Conjugate Vaccine Use in Adults with Immunocompromising Conditions: GRADE of Evidence[24] - Cost-Effectiveness of PCV13 for Adults with Immunocompromising Conditions[25] - Recommendations for PCV13 Use Among Immunocompromised Adults[26]		
3. Prevnar 13 (PCV13, Wyeth Pharmaceuticals), recommended by	**February 26, 2014[33]**	**August 13, 2014** ACIP votes to recommended routine use of PCV13 among	**September 19, 2014[48]** "In June 2014, the results of a randomized placebo-controlled

[23] Kathleen Dooling, ACIP, *13-Valent Pneumococcal Conjugate Vaccine Use in Adults with Immunocompromising Conditions* (June 20, 2012), https://stacks.cdc.gov/view/cdc/78437.
[24] Kathleen Dooling, ACIP, *13-Valent Pneumococcal Conjugate Vaccine Use in Adults with Immunocompromising Conditions*: *GRADE of Evidence* (Feb. 22, 2012), https://stacks.cdc.gov/view/cdc/78593.
[25] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 20–21*, *2012*, *Atlanta*, *Georgia*, 27-31 (Sept. 18, 2012), https://stacks.cdc.gov/view/cdc/76509.
[26] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 20–21*, *2012*, *Atlanta*, *Georgia*, 32-38 (Sept. 18, 2012), https://stacks.cdc.gov/view/cdc/76509.
[33] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *February 26–27*, *2014*, 1 (Feb. 26, 2014), https://stacks.cdc.gov/view/cdc/59210.
[48] Sara Tomczyk, et al., CDC, *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years*: *Recommendations of the Advisory Committee on Immunization Practices* (*ACIP*), 63 Morb. Mortal. Wkly. Rep. 822, 822–825 (Sept. 19, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	ACIP Vote & Recommendation	
ACIP, adopted by CDC for routine use among adults ≥65	- 13-valent Pneumococcal Conjugate Vaccine[34] **June 26, 2014[35]** - 13-valent Pneumococcal Conjugate Vaccine[36] - PCV13 Efficacy Among Adults: Results of CAPiTA Study[37] - Incremental Cost-Effectiveness of Modifying PPSV and PCV Recommendations for Adults Age 50 and Over[38] - Considerations for Age-Based Recommendations for	adults aged ≥65 years. "PCV13 should be administered in series with the 23-valent pneumococcal polysaccharide vaccine (PPSV23 [Pneumovax23, Merck & Co., Inc.]), the vaccine currently recommended for adults aged ≥65 years."[45] GRADE Table 4: Summary of Evidence for 13-valent Pneumococcal Conjugate Vaccine in Adults aged ≥65 years[46] **Votes: 13 to 2[47]** In favor: 13 Opposed: 2 Abstain: 0	trial evaluating efficacy of PCV13 for preventing community-acquired pneumonia among approximately 85,000 adults aged ≥65 years with no prior pneumococcal vaccination history (CAPiTA trial) became available and were presented to ACIP (*1*). The evidence supporting PCV13 vaccination of adults was evaluated using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) framework and determined to be type 2 (moderate level of evidence); the recommendation was

[34] Nancy M. Bennett, ACIP, *13-Valent Pneumococcal Conjugate Vaccine* (Feb. 26, 2014), https://stacks.cdc.gov/view/cdc/62197.
[35] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *June 25–26*, *2014*, 2 (June 25, 2014), https://stacks.cdc.gov/view/cdc/59209.
[36] Nancy M. Bennett, ACIP, *13-Valent Pneumococcal Conjugate Vaccine* (June 26, 2014), https://stacks.cdc.gov/view/cdc/62011.
[37] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *June 25–26*, *2014*, 2 (June 25, 2014), https://stacks.cdc.gov/view/cdc/59209.
[38] Charles Stoecker, Tul. Sch. Pub. Health and Tropical Med., *Incremental Cost-Effectiveness of Modifying PPSV and PCV Recommendations for Adults Age 50 and Over* (June 25, 2014), https://stacks.cdc.gov/view/cdc/62012.
[45] Sara Tomczyk, et al., ACIP, *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years*: *Recommendations of the Advisory Committee on Immunization Practices* (*ACIP*), 63 Morb. Mortal. Wkly. Rep. 822, 822 (Sept. 19, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm.
[46] ACIP, *Grading of Recommendations*, *Assessment*, *Development*, *and Evaluation* (*GRADE*) *for Pneumococcal Vaccines for Adults Aged ≥65 Years*, tbl. 4 (Sept. 9, 2024), https://www.cdc.gov/acip/grade/pneumo-vac-adult.html.
[47] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *August 13*, *2014*, *Atlanta*, *Georgia*, 29 (Oct. 20, 2014), https://stacks.cdc.gov/view/cdc/45918.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	ACIP Vote & Recommendation	
	Pneumococcal Conjugate Vaccine for Adults[39] **August 13, 2014[40]** - 13-valent Pneumococcal Conjugate Vaccine[41] - Routine PCV13 Use Among Adults >65 Years Old: Summary of Evidence, Cost-Effectiveness, and GRADE Conclusions[42] - Considerations for Pneumococcal 13-valent Conjugate and 23-valent Polysaccharide Vaccine Use Among Adults[43] - Recommendations for PCV13 Use Among Adults[44]		categorized as a Category A recommendation (*2*)."[49]

[39] Tamara Pilishvili, ACIP, *Considerations for Age-Based Recommendations for Pneumococcal Conjugate Vaccine for Adults* (June 26, 2014), https://stacks.cdc.gov/view/cdc/62013.
[40] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *August 13*, *2014*, 1 (July 28, 2014), https://stacks.cdc.gov/view/cdc/59208; ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *August 13*, *2014*, *Atlanta*, *Georgia*, 7-29 (Oct. 20, 2014), https://stacks.cdc.gov/view/cdc/45918.
[41] Nancy M. Bennett, ACIP, *13-Valent Pneumococcal Conjugate Vaccine* (Aug. 13, 2014), https://stacks.cdc.gov/view/cdc/61847.
[42] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *August 13*, *2014*, *Atlanta*, *Georgia*, 9–15 (Oct. 20, 2014), https://stacks.cdc.gov/view/cdc/45918.
[43] Tamara Pilishvili, ACIP, *Considerations for Pneumococcal 13-Valent Conjugate and 23-Valent Polysaccharide Vaccine Use Among Adults* (Aug. 13, 2014), https://stacks.cdc.gov/view/cdc/61848.
[44] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *August 13*, *2014*, *Atlanta*, *Georgia*, 29 (Oct. 20, 2014), https://stacks.cdc.gov/view/cdc/45918.
[49] Sara Tomczyk, et al., CDC, *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥65 Years*: *Recommendations of the Advisory Committee on Immunization Practices* (*ACIP*), 63 Morb. Mortal. Wkly. Rep. 822, 822 (Sept. 19, 2014), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6337a4.htm.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	ACIP Vote & Recommendation	
4. Prevnar 13 (PCV13, Wyeth Pharmaceuticals) recommended by ACIP, adopted by CDC to downgrade from routine to shared-clinical decision-making	**June 2015**[50] - Pneumococcal Vaccines[51] - Intervals Between PCV13 and PPSV23: Supporting Evidence and Rationale for Change[52] - Proposed Recommendations[53] **October 20, 2016**[54] - Pneumococcal Vaccines[55] - Changes in Invasive Pneumococcal Disease (IPD) Following 5 Years of 13-valent Pneumococcal Conjugate Vaccine Use in the US[56]	**June 26, 2019**[92] "ACIP votes to remove the recommendation for routine PCV13 use among adults aged ≥65 years and to recommend administration of PCV13 based on shared clinical decision-making for adults aged ≥65 years who do not have an immunocompromising condition,† cerebrospinal fluid (CSF) leak, or cochlear implant, and who have not previously received PCV13"[93]	**November 22, 2019**[99] "During 2016–2019, using the Evidence to Recommendations Framework, (https://www.cdc.gov/vaccines/acip/recs/grade/PCV13-etr.html) the ACIP Pneumococcal Vaccines Work Group reviewed relevant scientific evidence regarding the benefits and harms of PCV13 use among adults aged ≥65 years without an immunocompromising condition, CSF leak, or cochlear

[50] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 24–25*, *2015*, *Atlanta*, *Georgia*, 3 (Nov. 6, 2015), https://stacks.cdc.gov/view/cdc/45772.
[51] Nancy M. Bennett, ACIP, *Pneumococcal Vaccines* (June 25, 2015), https://stacks.cdc.gov/view/cdc/60975.
[52] Miwako Kobayashi, ACIP, *Intervals Between PCV13 and PPSV23 Vaccines*: *Evidence Supporting Currently Recommended Intervals and Proposed Changes* (June 25, 2015), https://stacks.cdc.gov/view/cdc/60976.
[53] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 24–25*, *2015*, *Atlanta*, *Georgia*, 129-133 (Nov. 6, 2015), https://stacks.cdc.gov/view/cdc/45772.
[54] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *October 19–20*, *2016*, 2 (Oct. 14, 2016), https://stacks.cdc.gov/view/cdc/59283.
[55] Allison Kempe, ACIP, *Pneumococcal Vaccines* (Oct. 20, 2016), https://stacks.cdc.gov/view/cdc/82076.
[56] Tamara Pilishvili, ACIP, *Changes in Invasive Pneumococcal Disease* (*IPD*) *Following 5 Years of 13-Valent Pneumococcal Conjugate Vaccine Use in the U.S.* (Oct. 20, 2016), https://stacks.cdc.gov/view/cdc/82077.
[92] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*, *June 26–27*, *2019*, *Atlanta*, *Georgia*, 46–64 (June 26-27, 2019), https://stacks.cdc.gov/view/cdc/82365.
[93] Almea Matanock, et al., CDC, *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Among Adults Aged ≥ 65 Years*: *Updated Recommendations of the Advisory Committee on Immunization Practices*, 68 Morb. Mortal. Wkly. Rep. 1069, 1069 (Nov. 22, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm.
[99] Almea Matanock, et al., CDC, *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Amond Adults Aged ≥ 65 Years*: *Updated Recommendations of the Advisory Committee on Immunization Practices*, 68 Morb. Mortal. Wkly. Rep. 1069, 1069-1074 (Nov. 22, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	**ACIP Vote & Recommendation**	
	- Outline of Research Agenda to Inform Potential Policy Reconsideration in 2018 for PCV13 Use Among Adults[57] - Impact of PCV13 Use Among Adults With and Without Indication for PCV13 Use[58] **October 26, 2017[59]** - Pneumococcal Vaccines[60] - US Adult Pneumococcal Colonization Study: Preliminary Findings[61] - Invasive Pneumococcal Disease in the US, 2008-2016[62] - Progress of the Research Agenda to Inform Potential Policy	GRADE Summary of Evidence Table[94] Evidence to Recommendation Framework[95] **Votes 1: Continue to Recommend PCV13 for All Adults ≥65 Years of Age Not Previously Vaccinated with PCV13: 6 to 8[96]** In favor: 6 Opposed: 8 Abstain:0 **Vote #2: No Longer Recommend PCV13 for All Adults ≥65 Years of Age Not**	implant, in the context of >5 years of pediatric PCV13 use. The Work Group evaluated the quality of evidence for PCV13 efficacy, effectiveness, safety, and population-level impact on pneumococcal-related disease using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (https://www.cdc.gov/vaccines/acip/recs/grade/PCV13.html). A systematic review of scientific literature published from January 1, 2014, to July 3, 2018, was conducted to identify studies evaluating direct and indirect effects of vaccination with

[57] Tamara Pilishvili, ACIP, *Outline of Research Agenda to Inform Potential Policy Reconsideration in 2018 for PCV13 Use Among Adults* (Oct. 20, 2016), https://stacks.cdc.gov/view/cdc/82079.
[58] Sana Shireen Ahmed et al., ACIP, *Impact of PCV13 Use Among Adults With And Without Indications for PCV13 Use* (Oct. 20, 2016), https://stacks.cdc.gov/view/cdc/82078.
[59] ACIP, *Meeting of the Advisory Committee on Immunization Practices* (*ACIP*), *October 25–26*, *2017*, *Summary Minutes*, 150-165 (Nov. 1, 2017), https://stacks.cdc.gov/view/cdc/157578; ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *October 25–26*, *2017*, 2 (Oct. 19, 2017), https://stacks.cdc.gov/view/cdc/57579.
[60] Arthur Reingold, ACIP, *Pneumococcal Vaccines* (Nov. 27, 2017), https://stacks.cdc.gov/view/cdc/57590.
[61] Fernanda C. Lessa, ACIP, *US Adult Pneumococcal Colonization Study*: *Preliminary Findings* (Nov. 27, 2017), https://stacks.cdc.gov/view/cdc/57592.
[62] Almea Matanock, Nat'l Ctr. for Disease Control, *Invasive Pneumococcal Disease in the U.S.–2008–2016* (Oct. 26, 2017), https://stacks.cdc.gov/view/cdc/57593.
[94] ACIP, *Grading of Recommendations Assessment*, *Development and Evaluation* (*GRADE*) *for Use of PCV13 Among Adults ≥65 Years Old* (July 23, 2024), https://www.cdc.gov/acip/grade/PCV13.html.
[95] ACIP, *Evidence to Recommendations for PCV13 Use Among Adults ≥65 Years Old* (Sept. 5, 2024), https://www.cdc.gov/acip/evidence-to-recommendations/PCV13-etr.html.
[96] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*, *June 26–27*, *2019*, *Atlanta*, *Georgia*, 61 (June 26–27, 2019), https://stacks.cdc.gov/view/cdc/82365.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	**ACIP Vote & Recommendation**	
	Reconsideration in 2018 for PCV Use Among Adults[63] **February 12, 2018[64]** - Pneumococcal Vaccines[65] - PCV13 Effectiveness: Case Control Study[66] - PCV13 Direct and Indirect Effects among Adults ≥65 Year Old[67] - Pneumococcal Vaccine Effectiveness Against Invasive Disease Among Adults 65 Years or Older[68] - Estimating Burden of Pneumococcal Pneumonia Among Adults in the US: Progress of the Research Agenda to Inform Potential Policy Change[69]	**Previously Vaccinated with PCV13: 1 to 13[97]** In favor: 1 Opposed: 13 Abstained: 0 **Vote #3: Recommend Shared Clinical Decision-Making for PCV13 for Adults ≥65 Years of Age Not Previously Vaccinated with PCV13: 13 to 1[98]** In favor: 13 Opposed: 1 Abstained: 0	PCV13 on invasive pneumococcal disease (IPD), pneumonia (PCV13-type,¶ all pneumococcal, and all-cause), and mortality (pneumococcal or all-cause). In addition, PCV13 safety was evaluated by looking for severe adverse events, including death, occurring after receipt of PCV13 in adults aged ≥65 years. Title and abstract screening yielded 364 studies for in-depth review. Of these, 344 did not use PCV13 or did not include an outcome or population of interest. Observational studies with <20% adult PCV13 coverage and studies conducted in settings

[63] Tamara Pilishvili, ACIP, *Progress of Research Agenda to Inform Potential Policy Reconsideration in 2018 for PCV13 Use Among Adults* (Oct. 26, 2017), https://stacks.cdc.gov/view/cdc/57594.
[64] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *February 21–22*, *2018*, 2 (Feb. 12, 2018), https://stacks.cdc.gov/view/cdc/58983.
[65] Grace Lee, ACIP, *Pneumococcal Vaccines* (Feb. 22, 2018), https://stacks.cdc.gov/view/cdc/60029.
[66] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *February 21–22*, *2018*, 2 (Feb. 12, 2018), https://stacks.cdc.gov/view/cdc/58983.
[67] Tamara Pilishvili, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Estimating PCV13 Direct and Indirect Effects on IPD Among Adults ≥65 Years* (Feb. 22, 2018), https://stacks.cdc.gov/view/cdc/60027.
[68] Tamara Pilishvili, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Pneumococcal Vaccine Effectiveness Against Invasive Disease Among Adults 65 years or Older* (Feb. 22, 2018), https://stacks.cdc.gov/view/cdc/60026.
[69] Almea Matanock, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Estimating Pneumococcal Pneumonia Burden Among U.S. Adults and Progress on the Research Agenda for Potential Policy Change* (Feb. 22, 2018), https://stacks.cdc.gov/view/cdc/60028.
[97] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*, *June 26–27*, *2019*, *Atlanta*, *Georgia*, 63 (June 26–27, 2019), https://stacks.cdc.gov/view/cdc/82365.
[98] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 26–27*, *2019*, *Atlanta*, *Georgia*, 64 (Nov. 4, 2019), https://stacks.cdc.gov/view/cdc/82365.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
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	June 21, 2018[70] - Pneumococcal Vaccines[71] - Safety of 13-valent Pneumococcal Conjugate Vaccine (PCV13) in Adults Aged ≥65 Years Old[72] - Pneumonia Incidence in the US[73] - Pneumococcal Carriage and Disease in Native Americans in the Era of Routine Use of PCV13[74] - Incidence of Invasive Pneumococcal Disease (IPD) by Race, United States, 2008–2016[75] - Preliminary Evidence to Recommendations for the Ongoing Review of the PCV13 Recommendation for Adults ≥65 Years Old[76]		with low pediatric PCV13 coverage were excluded, as were studies evaluating PCV13 safety if PCV13 was administered with another vaccine, because severe adverse events could not be attributed to PCV13. The remaining 20 studies were included in the GRADE tables. The policy question considered was whether PCV13 should be administered routinely to all immunocompetent** adults aged ≥65 years in the context of indirect effects from pediatric PCV use experienced to date."[100]

[70] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *June 20–21*, *2018*, 2 (June 13, 2018), https://stacks.cdc.gov/view/cdc/59282.
[71] Grace M. Lee, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Pneumococcal Vaccines* (June 21, 2018), https://stacks.cdc.gov/view/cdc/60493.
[72] Tom T. Shimabukuro, Nat'l Ctr. for Emerging and Zoonotic Infectious Diseases, *Safety of 13-Valent Pneumococcal Conjugate Vaccine* (*PCV13*) *in Adults Aged ≥65 Years Old* (June 21, 2018), https://stacks.cdc.gov/view/cdc/60494.
[73] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *June 20–21*, *2018*, 2 (June 13, 2018), https://stacks.cdc.gov/view/cdc/59282.
[74] Laura Hammitt, Ctr. for Am. Indian Health, *Pneumococcal Carriage and Disease in Native Americans in the Era of Routine Use of PCV13* (June 21, 2018), https://stacks.cdc.gov/view/cdc/60496.
[75] Almea Matanock, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Incidence of Invasive Pneumococcal Disease* (*IPD*) *by Race*, *United States*, *2008–2016* (June 21, 2018), https://stacks.cdc.gov/view/cdc/60495.
[76] Almea Matanock, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Preliminary Evidence to Recommendations for the Ongoing Review of the PCV13 Recommendation for Adults≥ 65 Years Old* (Oct. 24, 2018), https://stacks.cdc.gov/view/cdc/61453.
[100] Almea Matanock, et al., CDC, *Use of 13-Valent Pneumococcal Conjugate Vaccine and 23-Valent Pneumococcal Polysaccharide Vaccine Amond Adults Aged ≥ 65 Years*: *Updated Recommendations of the Advisory Committee on Immunization Practices*, 68 Morb. Mortal. Wkly. Rep. 1069, 1069-1070 (Nov. 22, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6846a5.htm.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
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	October 24, 2018[77] - Pneumococcal Vaccines[78] - Impact of PCV13 on Invasive Pneumococcal Disease (IPD) Burden and the Serotype Distribution in the U.S.[79] - Estimating Impact of 13-valent Pneumococcal Conjugate Vaccine (PCV13) on Pneumococcal Pneumonia Among U.S. Adults[80] - Economic Analysis of Sustaining the Current Recommendation for PCV13 Use Among Adults 65 Years or Older in the Context of Continued Indirect Effects from the Pediatric PCV13 Program[81] **February 28, 2019**[82] - Pneumococcal Vaccines[83]		

[77] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *October 24–25*, *2018*, 1 (Oct. 16, 2018), https://stacks.cdc.gov/view/cdc/59885/.
[78] Grace M. Lee, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Pneumococcal Vaccines* (Oct. 24, 2018), https://stacks.cdc.gov/view/cdc/61448.
[79] Tamara Pilishvili, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Impact of PCV13 on Invasive Pneumococcal Disease* (*IPD*) *Burden and the Serotype Distribution in the U.S.* (Oct. 24, 2018), https://stacks.cdc.gov/view/cdc/61449.
[80] Ryan Gierke, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Estimating Impact of 13-Valent Pneumococcal Conjugate Vaccine* (*PCV13*) *on Pneumococcal Pneumonia Among U.S. Adults* (Oct. 24, 2018), https://stacks.cdc.gov/view/cdc/61450.
[81] Charles Stoecker, Tul. Sch. Pub. Health and Tropical Med., *Economic Analysis of Sustaining the Current Recommendation for PCV13 Use Among Adults 65 Years or Older in the Context of Continued Indirect Effects from the Pediatric PCV13 Program* (Oct. 24, 2018), https://stacks.cdc.gov/view/cdc/61452.
[82] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *February 27–28*, *201*, 2 (Feb. 25, 2019), https://stacks.cdc.gov/view/cdc/76045.
[83] Grace M. Lee, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Pneumococcal Vaccines* (Feb. 28, 2019), https://stacks.cdc.gov/view/cdc/78090.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	ACIP Vote & Recommendation	
	- PCV13 Direct and Indirect Effects on Serotype 3 Disease[84] - PCV13 Direct Effects on Pneumonia Hospitalizations in Adults[85] - Overview of Three Economic Analyses of Pneumococcal Vaccinations at Age 65[86] - Evidence to Recommendations and GRADE for PCV13 Use Among Immunocompetent Adults ≥65 Years Old[87] **June 26, 2019[88]** - Pneumococcal Vaccines[89] - Considerations for PCV13 Use Among Adults ≥65 Years Old and a Summary of the Evidence to Recommendations Framework[90]		

[84] Tamara Pilishvili, Nat'l Ctr. for Immunizations and Respiratory Diseases, *13-Valent Pneumococcal Conjugate Vaccine* (*PCV13*) *Effects on Disease Caused by Serotype 3* (Feb. 28, 2019), https://stacks.cdc.gov/view/cdc/78091.
[85] ACIP, [*Agenda*]: *Meeting of the Advisory Committee on Immunization Practices*, *February 27–28*, *2019*, 2 (Feb. 25, 2019), https://stacks.cdc.gov/view/cdc/76045.
[86] Andrew J. Leidner, Berry Technology Solutions, *Overview of Three Economic Analysis of Pneumococcal Vaccinations at Age 65* (Feb. 28, 2019), https://stacks.cdc.gov/view/cdc/78093.
[87] Almea Matanock, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Evidence to Recommendations and GRADE for PCV13 Use Among Immunocompetent Adults ≥65 Years Old* (Feb. 28, 2019), https://stacks.cdc.gov/view/cdc/78094.
[88] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 26–27*, *2019*, *Atlanta*, *Georgia*, 46–64 (Nov. 4, 2019), https://stacks.cdc.gov/view/cdc/82365.
[89] Grace M. Lee, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Pneumococcal Vaccines* (June 26, 2019), https://stacks.cdc.gov/view/cdc/80461.
[90] Almea Matanock, Nat'l Ctr. for Immunizations and Respiratory Diseases, *Considerations for PCV13 Use Among Adults ≥65 Years Old and a Summary of the Evidence to Recommendations Framework* (June 26, 2019), https://stacks.cdc.gov/view/cdc/80462.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing ACIP Vote	ACIP Vote & Recommendation	
	- Proposed Policy Options[91]		

[91] ACIP, *Advisory Committee on Immunization Practices* (*ACIP*) *Summary Report*: *June 26–27*, *2019*, *Atlanta*, *Georgia*, 61-64 (Nov. 4, 2019), https://stacks.cdc.gov/view/cdc/82365.

EXHIBIT 23

Plaintiffs' Federal Rule of Evidence 1006 Summary Exhibit

HepB

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
1. Hepatitis B vaccine considered by ACIP prior to FDA approval, double blind, placebo-controlled clinical trial data reviewed	**October 14, 1981** • CDC Collaborative Trial of Hepatitis B Virus Vaccine (Oct. 14, 1981)[1] • Hepatitis B Virus Vaccine (Oct. 14, 1981)[2]	**NONE**	**NONE**
2. Merck Hepatitis B Vaccine (Heptavax-B) approved by FDA in November 1981[3]	**NONE**	**NONE**	**NONE**
3. ACIP considered draft HBV vaccine recommendations	**May 20, 1982** • "The Committee will consider the draft of the recommendations for use of hepatitis B vaccine, and will address the issues of screening techniques for hepatitis B susceptibility, measures to handle carriers, cost-benefit of vaccination in groups with varying prevalences of hepatitis B,	**NONE**	**NONE**

[1] https://stacks.cdc.gov/view/cdc/77095
[2] https://stacks.cdc.gov/view/cdc/77095
[3] *See* Maugh Thomas, *FDA approves hepatitis B vaccine*, 214 Science 1113, 1113 (Dec 4, 1981) https://pubmed.ncbi.nlm.nih.gov/7302582/.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
	and description of the groups at highest risk to benefit from the vaccine."[4]		
4. First ACIP recommendation on HBV vaccine published in MMWR			**June 25, 1982[5]** Risk-Based recommendation published in MMWR: "Primary adult vaccination consists of 3 intramuscular doses of 1.0 ml of vaccine (20 ug/1.0 ml) each. The second and third doses should be given 1 and 6 months, respectively, after the first. For patients undergoing hemodialysis, and for other immunosuppressed patients, 3 2-ml doses (40 ug) should be used. For children under 10 years of age, 3 similarly spaced doses of 0.5 ml (10 ug) are sufficient. Vaccine doses administered at longer intervals than those stipulated provide equally satisfactory protection, but optimal protection is not conferred until after the third dose. Since HBV vaccine is an inactivated (non-infective)

[4] Advisory Committee on Immunization Practices, *Minutes of Meeting*, 2 (May 20, 1982) https://stacks.cdc.gov/view/cdc/77091.
[5] *Recommendation of the Immunization Practices Advisory Committee (ACIP) Inactivated Hepatitis B Virus Vaccine*, 31 *Morbidity & Mortality Weekly Rep.* 317 https://www.cdc.gov/mmwr/preview/mmwrhtml/00001116.htm.

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			product, it is presumed that there will be no interference with other simultaneously administered vaccine(s). The duration of protection and the need for booster doses have not yet been determined. . . . "Screening in groups with the highest risk of HBV infection (e.g., users of illicit injectable drugs, homosexually active males, and institutionalized mentally retarded persons) will be cost effective unless testing costs are extremely high. For groups at intermediate risk (e.g., health-care workers with an expected prevalence of 8%-20%), cost effectiveness of screening may be marginal, and vaccination programs may or may not utilize screening. For groups with a low expected prevalence of HBV serologic markers (e.g., entering health professionals) screening will not be cost effective. . . . "Persons at substantial risk of HBV infection who are demonstrated or judged likely to be

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			susceptible should be vaccinated. They include: Health-Care Workers--Health-care workers (medical, dental, laboratory, and support groups) have varied risks of exposure to HBV depending on their jobs. Those workers for whom vaccine is recommended should be vaccinated as soon as possible after beginning work in a high-risk environment, ideally during their period of training. Hospital Staff--Hospital staff are at increased risk of HBV infection because of contact with blood and blood products. The risk for hospital personnel can vary both among hospitals and within hospitals. In developing specific immunization strategies, hospitals should use available published data about the risk of infection (8-10) and, in addition, may wish to evaluate their own clinical and institutional experience with hepatitis B. Studies in urban centers have indicated that occupational groups with frequent exposure to blood and/or needles have a substantial risk of acquiring HBV infection. The highest

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			risk is for individuals with frequent blood exposure, including the following groups: medical technologists, operating room staff, phlebotomists and intravenous therapy nurses, surgeons and pathologists, and oncology and dialysis unit staff. Other groups that have been shown to be at increased risk in some hospitals include: emergency room staff, nursing personnel, and physicians. To quantitate HBV risks among workers, groups can be ranked according to their frequency of blood/needle exposure. Additional information can be obtained from employee health records, serologic prevalence surveys, and estimates of HBsAg prevalence among patients. Other Health-Care Workers--Other health workers, based outside of hospitals, who have frequent contact with blood or blood products are at increased risk of acquiring HBV infection. These include dental professionals (dentists, oral surgeons, dental hygienists), laboratory and blood bank technicians, dialysis center staff, morticians, and

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			similar professionals. Clients and Staff of Institutions for the Mentally Retarded--Susceptible clients and selected staff of institutions for the mentally retarded should be vaccinated. Risks for staff are comparable to those for health-care personnel in other high-risk environments. However, the risk in institutional environments is associated not only with blood exposure, but is also consequent to bites and contact with skin lesions, saliva, and other infective secretions. Hemodialysis Patients--Numerous studies have established the high risk of HBV virus transmission in hemodialysis units. While recent data have shown a decrease in the rate of HBV infection in hemodialysis units following introduction of environmental control measures, vaccination is recommended for susceptible patients. Homosexually Active Males--Susceptible homosexually active males should be vaccinated regardless of their age or duration of their homosexual practices. It is important to vaccinate persons as soon as

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			possible after their homosexual activity begins. Homosexually active females do not appear to be at increased risk of sexually transmitted HBV infection. Illicit Injectable Drug Users--All users of illicit injectable drugs who are susceptible to HBV should be vaccinated as early as possible after their drug use begins. Recipients of Certain Blood Products--Although screening of all blood donors for HBsAg has decreased the incidence of transfusion-related HBV infection, patients with clotting disorders who receive factor VIII or IX concentrates have an elevated risk of HBV infection. Vaccination is recommended for these persons, and should be initiated at the time their specific clotting disorder is identified. Screening is recommended for patients who have already received multiple infusions of these products. Household and Sexual Contacts of HBV Carriers--Household contacts of HBV carriers are at high risk of HBV infection. Sexual contacts appear to be at greatest risk. Vaccination of

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			susceptible household contacts of carriers is recommended. At present, most carriers are identified through routine screening of donated blood, diagnostic testing in hospitals, or through other screening programs among high-risk groups. As part of expanded HBV control programs, additional screening to identify HBV carriers may be warranted. Other Contacts of HBV Carriers--Persons in contact with carriers at schools, offices, etc., are at minimal risk of contracting HBV, and vaccine is not routinely recommended for them. However, classroom contacts of deinstitutionalized mentally retarded HBV carriers who behave aggressively or have special medical problems that increase the risk of exposure to their blood or serous secretions may be at risk. In such situations, vaccine may be offered to classroom contacts. Special High-Risk Populations--Some American populations, such as Alaskan Eskimos, and immigrants and refugees from areas with highly endemic disease (particularly eastern Asia

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
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			and sub-Saharan Africa) have high HBV infection rates and deserve special attention. Depending on specific epidemiologic and public health considerations, more extensive vaccination programs may be warranted. Inmates of Long-Term Correctional Facilities--The prison environment may provide a favorable setting for the transmission of HBV because of the frequent use of illicit injectable drugs and homosexual practices. In such institutions, prison officials may elect to undertake screening and vaccination programs. Post-Exposure Vaccination Infants Born to HBsAg-Positive Mothers--Pregnant women who are HBsAg positive should be informed about the risk of transmission to their infants. Infants born to these women should receive HBIG (5,11). Infants whose mothers are chronic carriers will be continuously exposed to HBV throughout their childhood; therefore these infants should receive vaccine. The optimum timing for vaccination in conjunction with HBIG

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			administration has not been established. Pending additional information, it is recommended that vaccination begin at 3 months of age or shortly thereafter. Studies to determine the immunogenicity and efficacy of vaccine at birth, with or without HBIG, are currently under way. Sexual and Household Contacts of Acute Hepatitis B Cases and Health Workers Who Receive Needle Sticks from HBsAg-Positive Patients--Possible alternatives for post-exposure prophylaxis include HBIG, immunoglobulin (IG), HBV vaccine, or a combination of vaccine and an immune globulin. Recommendations for immune globulin use have already been published (5). Studies are currently under way to evaluate the use of vaccine in some of these settings. No recommendations can be made at this time for post-exposure use of HBV vaccine."

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
5. HBV Vaccine Discussed at ACIP Meeting	**January 24, 1983** • Donald Francis, Presentation on reported adverse reactions to HBV vaccine and lack relationship of the Acquired Immune Deficiency Syndrome (AIDS) to vaccine recipients (Committee concluded no serious reactions appeared to be related to HBV vaccine) (Jan. 24, 2983).[6]	**NONE**	**NONE**
6. HBV Vaccine Discussed at ACIP Meeting	**October 18, 1983** • Presentation on a survey that finds there is no data suggesting a causal relationship between AIDS and HBV vaccine.[7]	**NONE**	**NONE**
7. HBV Vaccine Discussed at ACIP Meeting	**February 7, 1984** • Multiple presentations and discussion on post-exposure prophylaxis, antibody persistence, vaccine safety, perinatal transmission, and draft statements post-exposure prophylaxis from the Committee.[8]	**NONE**	**NONE**

[6] https://stacks.cdc.gov/view/cdc/77090
[7] https://stacks.cdc.gov/view/cdc/77089
[8] https://stacks.cdc.gov/view/cdc/77087

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
8. HBV Vaccine Discussed at ACIP Meeting	**April 5, 1984** • Kane, Review revised draft statement on post-exposure prophylaxis, discuss cost effectiveness of antigen screening of pregnant women.[9] • Cladd Stevens, Recent data from recent studies on HBV vaccine use.[10]	**NONE**	**September 28, 1984**[11] The estimated lifetime risk of acquiring HBV infection in the United States is approximately 5% for the population as a whole but may approach 100% for the highest risk groups. Annually, an estimated 100,000 symptomatic cases of hepatitis B disease occur in the United States, leading to approximately 10,000 hospitalizations and 190 fulminant cases. Three fourths of persons with fulminant disease die. In 1982, 88% of hepatitis B cases for which patient age was known occurred in persons 20 years of age or older. Between 6% and 10% of adults with HBV infection become carriers. The United States currently has 4 0 0 ,0 0 0 -8 0 0 ,0 0 0 carriers. Chronic active hepatitis occurs in 25% of carriers. Each year in the United States, approximately 4 ,0 0 0 persons die of

[9] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Apr. 5-6, 1984) https://stacks.cdc.gov/view/cdc/77086/cdc_77086_DS1.pdf.
[10] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Apr. 5-6, 1984) https://stacks.cdc.gov/view/cdc/77086/cdc_77086_DS1.pdf.
[11] Morbidity and Mortality Weekly Report (MMWR): Supplement, 33 *Morbidity & Mortality Weekly Rep.* 1S, 22S https://stacks.cdc.gov/view/cdc/13291.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
			HBVrelated cirrhosis, and 800, of HBV-related liver cancer. Hepatitis B vaccine A series of three 1 -ml IM doses of HB vaccine, each containing 20 /ug/ml of HBsAg protein, provides protective antibody in over 90% of healthy adult recipi-ents and is 80% -95% effective in preventing infection for at least 2 years. The first two doses should be given 1 month apart, and the third dose, 5 months af-ter the second. The duration of vaccine-induced protection and the need for booster doses are not yet known. For susceptible hemodialysis patients, three 2-m l doses given at the above inter-vals are recommended. Because the prevalence of HBV varies widely among various popula-tion groups, serologic screening to detect susceptible individuals before vaccination may or may not be cost effective. Cost effec-tiveness depends on the known or perceived risk of infection, the cost of screening, and the cost of HB vaccine.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
9. HBV Vaccine Discussed at ACIP Meeting	**January 31, 1985** • James Maynard, low seroconversion rates in HBV vaccine recipients.[12] • Stephen Hadler, Harry Guess, response to vaccination in various bodily regions.[13] • Stephen Hadler, Updated draft of "Recommendations on Immune Globulins for Pre- and Post-Exposure Protection Against Viral Hepatitis."[14]	**NONE**	**NONE**
10. HBV Vaccine Discussed at ACIP Meeting	**April 15, 1985** • Stephen Hadler, Disccussion and review of draft recommendations for Pre- and Post-Exposure Against Viral Hepatitis.[15]	**NONE**	**NONE**
11. HBV Vaccine Discussed at ACIP Meeting, updated recommendation to be drafted	**May 12, 1986** • Stephen Hadler, Duration of protection and need for booster doses of HBV vaccine.[16]	Recommendation for vaccination for hemodialysis patients, persons who received initial vaccine in the buttock, and other groups with low response to vaccine series.[19]	**ACIP members begin to prepare a draft recommendation on post-vaccination of HBV vaccine to be discussed at next ACIP meeting.[20]**

[12] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Jan. 31, 1985) https://stacks.cdc.gov/view/cdc/77084/cdc_77084_DS1.pdf.
[13] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Jan. 31, 1985) https://stacks.cdc.gov/view/cdc/77084/cdc_77084_DS1.pdf.
[14] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Jan. 31, 1985) https://stacks.cdc.gov/view/cdc/77084/cdc_77084_DS1.pdf.
[15] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Apr. 15, 1985) https://stacks.cdc.gov/view/cdc/77082/cdc_77082_DS1.pdf.
[16] Advisory Committee on Immunization Practices, *Minutes of Meeting* (May 12, 1986) https://stacks.cdc.gov/view/cdc/77079/cdc_77079_DS1.pdf.
[19] Advisory Committee on Immunization Practices, *Minutes of Meeting* (May 12, 1986) https://stacks.cdc.gov/view/cdc/77079/cdc_77079_DS1.pdf.
[20] Advisory Committee on Immunization Practices, *Minutes of Meeting* (May 12, 1986) https://stacks.cdc.gov/view/cdc/77079/cdc_77079_DS1.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
	• Stephen Hadler, Considerations for booster-dose strategy: Effectiveness in cost, feasibility, and acceptability.[17] • Cladd Stevens, Antibody data from studies at 5 years in HBV vaccine recipients; infectious in homosexual men who responded to Merck HBV vaccine; antibody to HBsAg response following primary immunization with plasma-derived HBV vaccine and a subsequent booster dose of yeast recombinant HBV vaccine 5 to 7 years later; and immunogenic effect of a booster dose of HBV vaccine administered 6 years after initial immunization.[18]		
12. Merck Hepatitis B Vaccine (Recombivax) approved by FDA on July 23, 1986[21]	**NONE**	**NONE**	**NONE**
13. HBV Vaccine Discussed at ACIP Meeting, updated	**October 28, 1987**		**ACIP members to make necessary modifications in the draft update "Prevention of**

[17] Advisory Committee on Immunization Practices, *Minutes of Meeting* (May 12, 1986) https://stacks.cdc.gov/view/cdc/77079/cdc_77079_DS1.pdf.
[18] Advisory Committee on Immunization Practices, *Minutes of Meeting* (May 12, 1986) https://stacks.cdc.gov/view/cdc/77079/cdc_77079_DS1.pdf.
[21] *Product Details for: Recombivax, Recombivax Hb*, Purple Book Database of Licensed Biological Products (July 23, 1986) https://purplebooksearch.fda.gov/productdetails?query=101066.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
recommendation to be drafted	• Mark Kane, Overview of why screening of women at high risk of HBsAg should be undertaken, introduced universal screening of pregnant women for HBsAg, citing complexity and lack of sensitivity of the current strategy.[22]		**Perinatal HBV Transmission" (presented at the February 5-6, 1987 meeting) and reintroduce it at the next meeting. The committee suggested that coordinated efforts regarding testing should be made with the Academy of Pediatrics and the American College of Obstetrics and Gynecology (ACOG).[23]**
14. HBV Vaccine Discussed at ACIP Meeting, ACIP voted to recommend universal screening of pregnant women	**February 10, 1988** • Mark Kane, Reintroduced "Prevention of Perinatal HBV Transmission", discussed why routine prenatal screening of all pregnant women should be undertaken.[24] • A number of investigators expressed concern that many health care providers are not obtaining sexual and drug histories necessary to identify nigh risk patients. Recent studies in several large inner city hospitals, where all pregnant women were tested for HBsAg, have found that only about 35%-65% of HBsAg-positive mothers would have	The ACIP voted to approve universal screening of pregnant women.[26]	

[22] https://stacks.cdc.gov/view/cdc/77078
[23] https://stacks.cdc.gov/view/cdc/77078
[24] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 10, 1988) https://stacks.cdc.gov/view/cdc/77074/cdc_77074_DS1.pdf.
[26] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 10, 1988) https://stacks.cdc.gov/view/cdc/77074/cdc_77074_DS1.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	**ACIP Vote & Recommendation**	
	been identified by following the ACIP guidelines. Recent studies also indicate that the costs and benefits of universal testing of mothers are comparable to those encountered in other widely implemented programs of prenatal screening and of blood donor screening. The cost of an HBsAg test ranges from an estimated $3.50 per test in blood bank laboratories to $21.00 per test charged by private commercial laboratories.[25]		
15. HBV Vaccine Discussed at ACIP Meeting	**October 11, 1988** • Three issues discussed: the need for booster doses, alternative low-dose strategies for vaccination, and the impending licensure of a new HBV vaccine.[27]	**NONE**	**NONE**
16. HBV Vaccine Discussed at ACIP Meeting	**May 10, 1989** Stephen Hadler, Discussion on changes to draft recommendation.[28]	**Members discussed that the HBV vaccine recommendation will be published by the fall of 1989.[29]**	**NONE**
17. GlaxoSmithKline Biologicals Hepatitis B vaccine	**NONE**	**NONE**	**NONE**

[25] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 10, 1988) https://stacks.cdc.gov/view/cdc/77074/cdc_77074_DS1.pdf.
[27] https://stacks.cdc.gov/view/cdc/77075
[28] Advisory Committee on Immunization Practices, *Minutes of Meeting* (May 10, 1989) https://stacks.cdc.gov/view/cdc/77071/cdc_77071_DS1.pdf.
[29] Advisory Committee on Immunization Practices, *Minutes of Meeting* (May 10, 1989) https://stacks.cdc.gov/view/cdc/77071/cdc_77071_DS1.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
(Engerix-B) approved by FDA on August 28, 1989[30]			
18. HBV Vaccine Discussed at ACIP Meeting	**September 26, 1989** • Draft recommendation reviewed, two specific issues discussed: vaccine cost and intradermal vaccination.[31]	**NONE**	**NONE**
19. HBV Vaccine Discussed at ACIP Meeting	**February 28, 1990** • Discussion covered duration of efficacy of the vaccine in infants, immunization of high-risk populations and the difficulty of reaching them, particularly Asian children, and simultaneous administration with other childhood vaccines.[32]	**NONE**	**NONE**
20. HBV Vaccine Discussed at ACIP Meeting	**June 5, 1990** • Dean Mason, Perinatal Hepatitis B Grants, Proposal for elimination of perinatal HBV transmission via screening pregnant women and vaccinating infants born to seropositive women.[33]	**NONE**	**NONE**

[30] *Product Details for: Engerix-B*, Purple Book Database of Licensed Biological Products (August 28, 1989) https://purplebooksearch.fda.gov/productdetails?query=103239.
[31] https://stacks.cdc.gov/view/cdc/77070
[32] https://stacks.cdc.gov/view/cdc/76609
[33] Advisory Committee on Immunization Practices, *Minutes of Meeting* (June 5, 1990) https://stacks.cdc.gov/view/cdc/76608/cdc_76608_DS1.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
21. HBV Vaccine Discussed at ACIP Meeting, Universal Recommendation Considered	**October 16, 1990** • Harold Margolis, Universal Immunization Against Hepatitis, Has the Time Come?[34]	**"Members of the ACIP made it clear that the Committee is leaning toward a recommendation of universal infant immunization against HBV . . . ."[35]**	
22. Universal Recommendation for HBV vaccine unanimously passed by ACIP	**June 2, 1991** • Harold Margolis, ACIP Hepatitis Statement.[36]	**"ACIP voted unanimously to recommend universal immunization for infants, children, and adolescents, with the caveats that the emphasis is primarily on achieving universal coverage of infants . . . ."[37]**	**November 22, 1991** **A comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)[38]** "Immunization with hepatitis B vaccine is the most effective means of preventing HBV infection and its consequences. In the United States, most infections occur among adults and adolescents. The recommended strategy for preventing these infections has been the selective

[34] https://stacks.cdc.gov/view/cdc/77069
[35] https://stacks.cdc.gov/view/cdc/77069
[36] https://stacks.cdc.gov/view/cdc/76605
[37] https://stacks.cdc.gov/view/cdc/76605
[38] Samuel L. Katz et al., *Hepatitis B Virus: A Comprehensive Strategy for Eliminating Transmission in the United States Through Universal Childhood Vaccination: Recommendations of the Immunization Practices Advisory Committee (ACIP)*, 40 *Morbidity & Mortality Weekly Rep.* 1 (Nov. 22, 1991) https://www.cdc.gov/mmwr/preview/mmwrhtml/00033405.htm.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
			vaccination of persons with identified risk factors. However, this strategy has not lowered the incidence of hepatitis B, primarily because vaccinating persons engaged in high-risk behaviors, life-styles, or occupations before they become infected generally has not been feasible. In addition, many infected persons have no identifiable source for their infections and thus cannot be targeted for vaccination. Preventing HBV transmission during early childhood is important because of the high likelihood of chronic HBV infection and chronic liver disease that occurs when children less than 5 years of age become infected. Testing to identify pregnant women who are hepatitis B surface antigen (HBsAg)-positive and providing their infants with immunoprophylaxis effectively prevents HBV transmission during the perinatal period. Integrating hepatitis B vaccine into childhood vaccination schedules in populations with high rates of childhood infection (e.g., Alaskan Natives and Pacific

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
			Islanders) has been shown to interrupt HBV transmission. This document provides the rationale for a comprehensive strategy to eliminate transmission of HBV and ultimately reduce the incidence of hepatitis B and hepatitis B-associated chronic liver disease in the United States. The recommendations for implementing this strategy include making hepatitis B vaccine a part of routine vaccination schedules for infants."
23. ACIP revisited and assessed existing HBV vaccine recommendations	**February 24, 1994** • Margolis, Action Plan for Eliminating HBV transmission: 1) universal screening of pregnant women; 2) universal immunization of infants; and 3) catch-up immunization of adolescents and high-risk children and selected high-risk adults.[39] • Mahoney, Update on Current status of infant immunization program.[40] • Margolis, Phase 3 of Eliminating HBV Transmission: Adolescent Issues[41]	**NONE**	**NONE**

[39] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76599/cdc_76599_DS1.pdf.
[40] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76599/cdc_76599_DS1.pdf.
[41] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76599/cdc_76599_DS1.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
24. ACIP revisited and assessed existing HBV vaccine recommendations	**June 29, 1994** • Cladd Stevens, Review of a series of studies in high-risk, mostly Asian-American infants.[42] • Margolis, Revised HBV Recommendation.[43] • Margolis, Technical updates regarding long-term protection.[44] • Frank Mahoney, Data from several studies identifying risk factors for nonresponse to vaccination among adults.[45] • Fancisco Averholf, Risk factors for nonresponse to HBV vaccines.[46] • Margolis, Epidemiology of HBV infection among adolescents.[47] • Formation of two additional working groups: Adolescent HBV immunization; Adult HBV immunization.[48]	**ACIP voted to revise the age range for HBV vaccinations within the Vaccines for Children Program, and to include a contraindication for us of HBV vaccine in the Vaccines for Children program.**	**NONE**
25. ACIP expanded Universal Recommendation to older children	**October 19, 1994**	**ACIP voted to expand recommendation to older children by recommending catch-up vaccinations**	**August 4, 1995** **Notice to Readers Update: Recommendations to Prevent**

[42] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76598/cdc_76598_DS1.pdf.
[43] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76598/cdc_76598_DS1.pdf.
[44] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76598/cdc_76598_DS1.pdf.
[45] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76598/cdc_76598_DS1.pdf.
[46] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76598/cdc_76598_DS1.pdf.
[47] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76598/cdc_76598_DS1.pdf.
[48] Advisory Committee on Immunization Practices, *Minutes of Meeting* (Feb. 24, 1994) https://stacks.cdc.gov/view/cdc/76598/cdc_76598_DS1.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	**ACIP Vote & Recommendation**	
	• Hasley, Recommend hepatitis B vaccination catch-up during adolescence[49]	**for children who have not received HBV vaccination**	**Hepatitis B Virus Transmission -- United States[50]** In October 1994, the Advisory Committee on Immunization Practices (ACIP) approved recommendations expanding the vaccination strategy to eliminate hepatitis B virus (HBV) transmission in the United States. These recommendations include: 1. Vaccination of all unvaccinated children aged less than 11 years who are Pacific Islanders or who reside in households of first-generation immigrants from countries where HBV is of high or intermediate endemicity. 2. Vaccination of all 11-12-year-old children who have not previously received hepatitis B vaccine. Reported by: Epidemiology and Surveillance Div, National Immunization Program;

[49] https://stacks.cdc.gov/view/cdc/76600/

[50] *Notice to Readers Update: Recommendations to Prevent Hepatitis B Virus Transmission -- United States*, 44 *Morbidity & Mortality Weekly Rep.* 574 (Aug. 4, 1995) https://www.cdc.gov/mmwr/preview/mmwrhtml/00038437.htm.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
			Hepatitis Br, Div of Viral and Rickettsial Diseases, National Center for Infectious Diseases, CDC.
26. ACIP assessed and revised existing HBV vaccine recommendations	**February 9, 1995** • Margolis, Recommendations for HBV vaccine.[51]	**ACIP voted on and passed the following:** All individuals not previously vaccinated with hepatitis B vaccine should be vaccinated at eleven to twelve years of age with the age appropriate dose of vaccine. The vaccination schedule should take into account the feasibility of delivering three doses of vaccine to this age group.[52]	**NONE**
27. HBV Vaccine Discussed at ACIP Meeting, Began to consider combination HBV vaccines	**October 23, 1996** • Presentation and discussion on combination HBV vaccines, and updating recommendations once combination vaccines are made available.[53]	**NONE**	**NONE**
28. ACIP expanded recommendation to all unvaccinated	**October 23, 1997**	**ACIP voted to harmonize recommendations for HBV vaccine between existing ACIP**	**January 22, 1999[56]**

[51] https://stacks.cdc.gov/view/cdc/76596
[52] https://stacks.cdc.gov/view/cdc/76596
[53] https://stacks.cdc.gov/view/cdc/76571
[56]Notice to Readers Update: Recommendations to Prevent Hepatitis B Virus Transmission -- United States, 48 *Morbidity & Mortality Weekly Rep.* 33 (Jan. 22, 1999) https://www.cdc.gov/mmwr/preview/mmwrhtml/00056293.htm.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
children aged 0-18 years	• Halsey, ACIP Adolescent Hepatitis B Recommendations (Oct. 23, 1997)[54]	**recommendations and conflicting Vaccines for Children Program resolutions, resulting in a simplified recommendation for "All unvaccinated children 18 and under."[55]**	**Notice to Readers Update: Recommendations to Prevent Hepatitis B Virus Transmission -- United States** In October 1997, the Advisory Committee on Immunization Practices (ACIP) expanded its hepatitis B vaccination recommendations to include all unvaccinated children aged 0-18 years and made hepatitis B vaccine available through the Vaccines for Children program (VFC) for persons aged 0-18 years who are eligible for VFC. ACIP priorities for hepatitis B vaccination of children remain unchanged and include all infants; children in populations at high risk for hepatitis B virus (HBV) infection (e.g., Alaska Natives, Pacific Islanders, and children who reside in households of first-generation immigrants from countries where HBV infection is moderately or highly endemic); previously unvaccinated children aged 11-12 years; and older

[54] https://stacks.cdc.gov/view/cdc/76568
[55] https://stacks.cdc.gov/view/cdc/76568

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
			adolescents and adults in defined risk groups.
29. SmithKline Beecham Biologicals Hepatitis B combination vaccine (Pediarix) approved by FDA on December 13, 2002[57]	**NONE**	**NONE**	**NONE**
30. Dynavax Hepatitis B vaccine (HEPLISAV-B) approved by FDA on November 9, 2017[58]	**NONE**	**NONE**	**NONE**
31. MCM Vaccine Company Hepatitis B combination vaccine (VAXELIS) approved by FDA on December 21, 2018[59]	**NONE**	**NONE**	**NONE**
32. VBI Vaccines Hepatitis B vaccine	**NONE**	**NONE**	**NONE**

[57] U.S. Food and Drug Administration, *BLA Approval Letter for Pediarix* (Dec. 13, 2002) https://wayback.archive-it.org/7993/20170723144348/https://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm103183.htm.
[58] U.S. Food and Drug Administration, *BLA Approval Letter for HEPLISAV-B* (Nov. 9, 2017) https://www.fda.gov/media/108828/download?attachment.
[59] U.S. Food and Drug Administration, *BLA Approval Letter for VAXELIS* (Dec. 21, 2018) https://www.fda.gov/media/119466/download.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
(PreHevBrio) approved by FDA on November 30, 2021[60]			
33. ACIP votes to adjust HBV vaccine recommendation to shared clinical decision-making for infants born to HBV-negative people	**December 4, 2025** • Robert Malone, Hepatitis B – Recap.[61] • Vicky Pebsworth, Hepatitis B Virus Vaccine Birth Dose.[62] • C Nevison, Burden of disease.[63] • Mark Blaxill, Safety Review of Hepatitis B Birth Dose Vaccination.[64] • C. Robinson, M. Goveia, A. Chit, Hepatitis B Vaccine Manufacturer Presentation.[65] • Vicky Pebsworth, Childhood/Adolescent Schedule Workgroup Hepatitis B Virus Vaccine Birth Dose.[66] • Jeanne Santoli, VFC Resolution Update: Hepatitis B Vaccine.[67]	**December 5, 2025** **VOTE:** **8 Favored** **3 Opposed** **0 Abstained** For infants born to HBsAg-negative women: ACIP recommends individual-based decision-making, in consultation with a health care provider, for parents deciding when or if to give the HBV vaccine, including the birth dose.[1] Parents and health care providers should consider vaccine benefits, vaccine risks, and infection risks. For those	Adopted via CDC Press release;[69] no accompanying publication in MMWR.

[60] U.S. Food and Drug Administration, *BLA Approval Letter for PreHevBrio* (Nov. 30, 2021) https://www.fda.gov/media/154560/download?attachment.
[61] https://www.cdc.gov/acip/meetings/presentation-slides-december-04-05-2025.html
[62] https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/01-Pebsworth-hepatitis-b-508.pdf.
[63] https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/02-nevison-Hepatitis-B-508.pdf
[64] https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/03-blaxill-Hepatitis-B-508.pdf
[65] https://www.cdc.gov/acip/meetings/presentation-slides-december-04-05-2025.html
[66] https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/04-pebsworth-hepatitis-b-508.pdf
[67] https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/05-santoli-hepatitis-b-508.pdf
[69] CDC, *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus* (Dec. 16, 2025) https://www.cdc.gov/media/releases/2025/2025-hepatitis-b-immunization.html.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	**ACIP Vote & Recommendation**	
	• Tracy Beth Høeg, Evolution of the Childhood/Adolescent Vaccination Schedule in the U.S. and Vaccine Schedule Comparison: U.S. and other Developed Countries.[68]	not receiving the HBV birth dose, it is suggested that the initial dose is administered no earlier than 2 months of age. 1. Parents and health care providers should also consider whether there are risks, for example, such as a household member is HBsAg-positive or when there is frequent contact with persons who have emigrated from areas where Hepatitis B is common. **VOTE:** **6 Favored** **4 Opposed** **1 Abstained** When evaluating the need for a subsequent HBV vaccine dose in children, parents should consult with health care providers to determine if a post-vaccination anti-HBs serology testing should be offered. Serology results should determine whether the established protective anti-HBs titer threshold of ≥10 mIU/mL has been achieved. The	

[68] https://www.cdc.gov/acip/downloads/slides-2025-12-04-05/01-Hoeg-Danish-vax-schedule-508.pdf

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing Hepatitis B Vaccine ACIP Vote	ACIP Vote & Recommendation	
		cost of this testing should be covered by insurance.	
34. Recommendations for all Hepatitis B vaccines changed to "Recommended for certain high-risk groups or populations"[70]	A "Scientific Assessment"[71] was published on January 5, 2026, but never reviewed by, nor presented to ACIP.	**No ACIP vote was taken on any of the changes to the pediatric immunization schedule announced on January 5, 2026.**	The changes to the pediatric immunization schedule announced on January 5, 2026 were effective immediately.[72]

[70] *CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule* (Jan. 5, 2026) https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html; Jay Bhattacharya, Mehmet Oz, Mart Makary, *DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule* (Jan. 5, 2026) https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf.
[71] Tracy Beth Høeg, Martin Kulldorff, *Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries* (Jan. 2, 2026) https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf.
[72] *CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule* (Jan. 5, 2026) https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html; Jay Bhattacharya, Mehmet Oz, Mart Makary, *DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule* (Jan. 5, 2026) https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf.

EXHIBIT 24

Plaintiffs' Federal Rule of Evidence 1006 Summary Exhibit

RSV

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing RSV Monoclonal Antibody ACIP Vote	ACIP Vote & Recommendation	
1. Sanofi and AstraZeneca Respiratory Syncytial Virus (RSV) monoclonal antibody (nirsevimab) approved by FDA on July 17, 2023[1]	•		
2. Sanofi and AstraZeneca RSV monoclonal antibody (nirsevimab) recommended by ACIP	**February 23, 2022** • Jones, Jefferson, *Draft Interim Clinical Considerations: Nirsevimab* (February 23, 2023).[2] • Munjal, Iona, *Safety and efficacy of bivalent RSV prefusion F vaccine in vaccinated mothers and their infants* (February 23, 2022).[3]	**August 3, 2023** ACIP votes to recommend the Sanofi and AstraZeneca RSV monoclonal antibody for all infants aged <8 months who are born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk for	**August 25, 2023[23]** Relevant evidence used in MMWR • Since October 2021, the Advisory Committee on Immunization Practices (ACIP) Maternal and Pediatric RSV Work Group has reviewed evidence on the safety and

[1] *FDA Approves New Drug to Prevent RSV in Babies and Toddlers* (July 17, 2023) https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-prevent-rsv-babies-and-toddlers.
[2] https://stacks.cdc.gov/view/cdc/125145
[3] https://stacks.cdc.gov/view/cdc/125146
[23] Jefferson M. Jones et al., *Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023*, 72 *Morbidity & Mortality Weekly Rep.* 920, 921 (Aug. 25, 2023) https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7234a4-H.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing RSV Monoclonal Antibody ACIP Vote	**ACIP Vote & Recommendation**	
	• Hutton, David W., *Economic analysis of Nirsevimab in pediatric populations* (February 23, 2022).[4] • Ortega-Sanchez, Ismael R., *Economics of preventing respiratory syncytial virus lower respiratory tract infections (RSVLRTI) among US infants with Nirsevimab : a summary report comparing models from: Sanofi and University of Michigan and CDC* (February 23, 2022).[5] **June 23, 2022** • Felter, C., *Nirsevimab for the prevention of RSV in all infants* (June 23, 2022).[6] • Thornburg, Natalie J., *RSV virion and vaccine products* (June 23, 2022).[7] **October 20, 2022** • Felter, C., *Nirsevimab for the prevention of RSV in all infants* (Oct. 20, 2022).[8]	severe RSV disease and are entering their second RSV season.[21] **Votes: 10–0**[22] 10 Favored 0 Opposed 0 Abstained	efficacy of nirsevimab among infants and young children. • The Work Group has conducted a systematic literature search and reviewed available evidence regarding the efficacy and safety of nirsevimab (*2*,*3*). The Work Group considered a priori outcomes that were critical or important to policy decisions.[§] For infants born during or entering their first RSV season, evidence regarding efficacy and safety was derived from multicountry trials[¶] that randomized infants, in a 2:1 ratio, to receive nirsevimab or placebo; a phase 2b trial that enrolled 1,453 preterm infants born at 29–34 weeks' gestation (phase 2b trial) (*17*); and a

[4] https://stacks.cdc.gov/view/cdc/125142
[5] https://stacks.cdc.gov/view/cdc/125143
[6] https://stacks.cdc.gov/view/cdc/118595
[7] https://stacks.cdc.gov/view/cdc/118592
[8] https://stacks.cdc.gov/view/cdc/122373
[21] Jefferson M. Jones et al., *Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023*, 72 *Morbidity & Mortality Weekly Rep.* 920, 920 (Aug. 25, 2023) https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7234a4-H.pdf.
[22] ACIP, *Meeting of The Advisory Committee on Immunization Practices (ACIP)*, August 3, 2023 Meeting Summary (Aug. 3, 2023) https://www.cdc.gov/acip/downloads/minutes/summary-2023-08-03-508.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing RSV Monoclonal Antibody ACIP Vote	ACIP Vote & Recommendation	
	• Long, Sarah S., *Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group* (October 20, 2022).[9] • Jones, Jefferson, *Next steps for the ACIP Maternal & Pediatric RSV Work Group* (October 20, 2022).[10] **February 23, 2023** • Long, Sarah S., *Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group* (February 23, 2023).[11] • Jones, Jefferson, *Evidence to Recommendations Framework: Nirsevimab* (February 23, 2023).[12] **June 22, 2023** • Long, Sarah S., *Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group* (June 22, 2023).[13] • Jones, Jefferson, *Clinical considerations for RSV maternal vaccine and nirsevimab* (June 22, 2023).[14]		phase 3 trial that enrolled 3,012 late preterm and term infants born at ≥35 weeks' gestation (phase 3 trial) (*18*).** For children at increased risk for severe disease entering their second RSV season, evidence regarding efficacy and safety was obtained from a multicountry trial that randomized children to receive nirsevimab or palivizumab (*19*). The Work Group used the GRADE approach to assess the certainty of evidence for outcomes related to nirsevimab, rated on a scale of very low to high certainty (*2*,*3*). The Work Group then used the EtR Framework to guide its deliberations on recommendation of nirsevimab, reviewing data on the public health problem, benefits and harms, value to the target

[9] https://stacks.cdc.gov/view/cdc/122372
[10] https://stacks.cdc.gov/view/cdc/122374
[11] https://stacks.cdc.gov/view/cdc/125141
[12] https://stacks.cdc.gov/view/cdc/125144
[13] https://stacks.cdc.gov/view/cdc/130018
[14] https://stacks.cdc.gov/view/cdc/130156

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing RSV Monoclonal Antibody ACIP Vote	ACIP Vote & Recommendation	
	• Hutton, David W., *Economics of Pfizer maternal RSVpreF vaccine* (June 22, 2023).[15] • Hutton, David W., *Economics of combined use of Pfizer maternal RSVpreF vaccine and nirsevimab* (June 22, 2023).[16] **August 3, 2023** • Long, Sarah S., *Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group* (August 3, 2023).[17] • Jones, Jefferson, *Evidence to Recommendations Framework: Nirsevimab Updates* (August 3, 2023).[18] • Jones, Jefferson, *Proposed Clinical Consideration Updates for Nirsevimab* (August 3, 2023).[19] • Peacock, Georgina, *Nirsevimab: Implementation Considerations* (August 3, 2023).[20]		population, acceptability to key stakeholders, feasibility, resource use, and equity (*4*,*5*). **August 10, 2023** • Jatlaoui, Tara C., Joseph, Naima T., *Clinical Vaccination Guidance for Pregnant People* (August 10, 2023).[24] **October 18, 2023** • Fleming-Dutra, Katherine E. (2023). *Recommendations and Clinical Guidance for Use of RSV Vaccines in Older Adults and Pregnant People and Use of Nirsevimab in Infants and Young Children* (Oct. 18, 2023).[25] • CDC's Vaccines for Children Program Addendum: Special

[15] https://stacks.cdc.gov/view/cdc/130019
[16] https://stacks.cdc.gov/view/cdc/130021
[17] https://stacks.cdc.gov/view/cdc/131585
[18] https://stacks.cdc.gov/view/cdc/131586
[19] https://stacks.cdc.gov/view/cdc/131588
[20] https://stacks.cdc.gov/view/cdc/131587
[24] https://stacks.cdc.gov/view/cdc/131929
[25] https://stacks.cdc.gov/view/cdc/149779

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing RSV Monoclonal Antibody ACIP Vote	ACIP Vote & Recommendation	
			Considerations for Nirsevimab (Oct. 18, 2023).[26] **March 27, 2024** • Frequently Asked Questions About RSV Immunization with Monoclonal Antibody for Children 19 Months and Younger (March 27, 2024).[27]
3. Merck Respiratory Syncytial Virus (RSV) monoclonal antibody (clesrovimab) approved by FDA on June 9, 2025[28]			

[26] https://stacks.cdc.gov/view/cdc/134195
[27] https://stacks.cdc.gov/view/cdc/154507
[28] *U.S. FDA Approves Merck's ENFLONSIA™ (clesrovimab-cfor) for Prevention of Respiratory Syncytial Virus (RSV) Lower Respiratory Tract Disease in Infants Born During or Entering Their First RSV Season* (June 9, 2025) https://www.merck.com/news/u-s-fda-approves-mercks-enflonsia-clesrovimab-cfor-for-prevention-of-respiratory-syncytial-virus-rsv-lower-respiratory-tract-disease-in-infants-born-during-or-entering-their-fir/; Center for Drug Evaluation and Research, *Approval Package for: Application Number: 761432Orig1s000* (June 9, 2025) https://www.accessdata.fda.gov/drugsatfda_docs/nda/2025/761432Orig1s000Approv.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing RSV Monoclonal Antibody ACIP Vote	ACIP Vote & Recommendation	
4. Merck RSV monoclonal antibody (clesrovimab) recommended by ACIP	**June 28, 2024** (Note: All ACIP members present at the June 28, 2024 meeting would be removed by Secretary Kennedy prior to the June 25, 2025 vote on clesrovimab) • Payne, Amanda, *Summary of effectiveness of nirsevimab in infants* (June 28, 2024).[29] • Moro, Pedro, *Maternal RSV vaccine safety surveillance* (June 28, 2024).[30] • Stokley, Shannon, *Implementation and Uptake of Nirsevimab and Maternal Vaccine* (June 28, 2024).[31] • Jones, Jefferson, *Maternal/Pediatric RSV Work Group Considerations* (June 28, 2024).[32] • Long, Sarah S., *Maternal/Pediatric Respiratory Syncytial Virus (RSV) Work Group* (June 28, 2024).[33] **June 25, 2025**	**June 25, 2025** **Votes: 5–2**[41] 5 Favored 2 Opposed 0 Abstained	**August 4, 2025** ACIP recommends infants aged < 8 months born during or entering their first RSV season who are not protected by maternal vaccination receive one dose of clesrovimab. There is no preferential recommendation between nirsevimab and clesrovimab. This recommendation was adopted by the CDC Director on August 4, 2025, and is now an official recommendation of the CDC.[42] **August 28, 2025** ACIP recommends that all infants be protected against RSV-associated LRTI through one of three product options: 1) maternal RSV vaccination during

[29] https://stacks.cdc.gov/view/cdc/157872
[30] https://stacks.cdc.gov/view/cdc/157873
[31] https://stacks.cdc.gov/view/cdc/157874
[32] https://stacks.cdc.gov/view/cdc/157871
[33] https://stacks.cdc.gov/view/cdc/157875
[41] ACIP, *Meeting of The Advisory Committee on Immunization Practices (ACIP)*, June 25, 2025 Meeting Summary https://www.cdc.gov/acip/downloads/minutes/summary-2025-06-25-26-508.pdf.
[42] CDC, *ACIP Recommendations* (Aug. 8, 2025) https://www.cdc.gov/acip/vaccine-recommendations/index.html.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing RSV Monoclonal Antibody ACIP Vote	ACIP Vote & Recommendation	
	• MacNeil, A, *Maternal/Pediatric Respiratory Syncytial Virus (RSV) Session* (June 25, 2025).[34] • Peacock, Georgina, *Implementation and Uptake of Nirsevimab and Maternal Vaccine for Infant Protection from RSV* (June 25, 2025).[35] • MacNeil, A, *Effectiveness and impact of RSV prevention products in infants during the 2024–2025 RSV season* (June 25, 2025).[36] • DeSilva, Malini, *Prenatal RSVpreF Vaccine Safety 2023–2024 Respiratory Season The Vaccine Safety Datalink* (VSD) (June 25, 2025).[37] • Daley, Matthew F., *Monitoring the Safety of Nirsevimab in Infants Birth through* (June 25, 2025).[38] • MacNeil, A, *Evidence to Recommendation Framework: Clesrovimab* (June 25, 2025).[39]		pregnancy; 2) infant receipt of the long-acting RSV monoclonal antibody, nirsevimab; or 3) infant receipt of the long-acting RSV monoclonal antibody, clesrovimab (Table). Health care providers should select which product to use based on parent preference, product availability, and timing relative to the RSV season, with an understanding of relative advantages and disadvantages.[43] Relevant evidence used in the MMWR: • During September 2024–June 2025, the ACIP Maternal/ Pediatric RSV Work Group met monthly to review evidence regarding the safety and efficacy of

[34] https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/01-MacNeil-Mat-Peds-RSV-508.pdf
[35] https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/02-Peacock-Mat-Peds-RSV-508.pdf
[36] https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/03-MacNeil-Mat-Peds-RSV-508.pdf
[37] https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04a-DeSilva-Mat-Peds-RSV-508.pdf
[38] https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04b-Daley-Mat-Peds-RSV-508.pdf
[39] https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/05-MacNeil-Mat-Peds-RSV-508.pdf
[43] Danielle L. Moulia et al., *Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus– Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025*, 74 *Morbidity & Mortality Weekly Rep.* 508, 510 (Aug. 28, 2025) https://www.cdc.gov/mmwr/volumes/74/wr/pdfs/mm7432a3-H.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing RSV Monoclonal Antibody ACIP Vote	ACIP Vote & Recommendation	
	• MacNeil, A, *Work group considerations and clinical considerations for clesrovimab* (June 25, 2025).[40]		clesrovimab and determined the quality of this evidence using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach (12). The Evidence to Recommendations (EtR) framework was used to guide the work group's deliberations and develop RSV prevention product recommendations for infants and children (13); the work group provided input on voting language. The work group conclusions regarding evidence for the use of clesrovimab in infants were presented to ACIP at public meetings on October 16, 2024; April 24, 2025; and June 25, 2025 (14–16).[44]

[40] https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/06-MacNeil-Mat-Peds-RSV-508.pdf

[44] Danielle L. Moulia et al., *Use of Clesrovimab for Prevention of Severe Respiratory Syncytial Virus– Associated Lower Respiratory Tract Infections in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025*, 74 *Morbidity & Mortality Weekly Rep.* 508, 509 (Aug. 28, 2025) https://www.cdc.gov/mmwr/volumes/74/wr/pdfs/mm7432a3-H.pdf.

Event Summary	ACIP MEETINGS		CDC Adoption & MMWR Publication
	Presentations During ACIP Meetings Informing RSV Monoclonal Antibody ACIP Vote	ACIP Vote & Recommendation	
5. Recommendations for both RSV monoclonal antibodies (nirsevimab and clesrovimab) changed to "Recommended for certain high-risk groups or populations"[45]	A "Scientific Assessment"[46] was published on January 5, 2026, but never reviewed by, nor presented to ACIP.	**No ACIP vote was taken on any of the changes to the pediatric immunization schedule announced on January 5, 2026.**	The changes to the pediatric immunization schedule announced on January 5, 2026 were effective immediately.[47]

[45] *CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule* (Jan. 5, 2026) https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html; Jay Bhattacharya, Mehmet Oz, Mart Makary, *DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule* (Jan. 5, 2026) https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf.

[46] Tracy Beth Høeg, Martin Kulldorff, Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries (Jan. 2, 2026) https://www.hhs.gov/sites/default/files/assessment-of-the-us-childhood-and-adolescent-immunization-schedule-compared-to-other-countries.pdf.

[47] *CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule* (Jan. 5, 2026) https://www.hhs.gov/press-room/cdc-acts-presidential-memorandum-update-childhood-immunization-schedule.html; Jay Bhattacharya, Mehmet Oz, Mart Makary, *DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule* (Jan. 5, 2026) https://www.hhs.gov/sites/default/files/decision-memo-adopting-revised-childhood-adolescent-immunization-schedule.pdf.

EXHIBIT 25

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF GEORGES C. BENJAMIN, M.D.

I, Georges C. Benjamin, MD, declare pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am the Executive Director of the American Public Health Association ("APHA"). I have served in this role since December 2002. I make this statement based on personal knowledge and if called as a witness could and would testify competently thereto. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction. I am over the age of 18 and make this declaration based on my personal knowledge and in my official capacity as Executive Director of APHA.

2. The actions taken by the Department of Health and Human Services ("HHS"), Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary"), and Jim O'Neill, Acting Director of the Centers for Disease Control and Prevention ("CDC"), during the Secretary's tenure have caused immediate, ongoing, and compounding harm to the American

Public Health Association ("APHA"), its members, the public health system and the public's health they are charged with protecting. These actions including, the Secretary's May 19, 2025 Directive reclassifying COVID-19 vaccination for children as Shared Clinical Decision-Making ("SCDM") and removing the recommendation for vaccination during pregnancy (the "May 19 Directive"); the September 2025 downgrade of Covid-19 vaccination for adults under age 65 from routine to SCDM (the "September Schedule Change"); the January 5, 2026 issuance of a revised CDC Childhood Immunization Schedule accompanied by inconsistent and unsupported decision documents (the "January 5 Childhood Schedule Change"); and the Secretary's appointment of unqualified individuals to the Advisory Committee on Immunization Practices ("ACIP"), represent a sustained departure from the evidence-based processes that anchor the nation's public health system. Together, these actions are injecting chaos and confusion into public health practice and clinical care, forcing APHA and its members into perpetual crisis-response mode and compelling the diversion of limited resources away from disease prevention and toward damage control.

3. Unless the May 19 Directive, the September Schedule Change, the January 5 Childhood Schedule Change, and the February 25–26, 2026 ACIP meetings are enjoined, the resulting harm to APHA, its members, and the health of the public will continue to escalate. The public health system that APHA and its members are dedicated to building and protecting is already under severe strain, and the challenged actions threaten to further destabilize a system that depends on prevention, trust, and scientific integrity to function. Defendants have set the public health infrastructure on fire, and the current ACIP pours gasoline on that fire.

4. I am a graduate of the Illinois Institute of Technology and the University of Illinois College of Medicine. I am licensed to practice medicine in Maryland and the District of Columbia.

5. I am board-certified in internal medicine and a Master of the American College of Physicians, a fellow of the National Academy of Public Administration, a fellow emeritus of the American College of Emergency Physicians, an elected member of the National Academy of Medicine (formally the Institute of Medicine) of the National Academies of Sciences, Engineering and Medicine, an honorary fellow of the Faculty of Public Health, and an honorary fellow of the Royal Society of Public Health.

6. Following graduation from medical school, I entered active duty in the Army where I completed a residency in internal medicine at the Brooke Army Medical Center in San Antonio, Texas. Upon completion of my residency in 1981, I was assigned to Madigan Army Medical Center in Tacoma, Washington and served as faculty and staff in the Department of Emergency Medicine. At Madigan Army Medical Center, I managed a 72,000-patient per year ambulatory care service as chief of the Acute Illness Clinic and was an attending physician within the Department of Emergency Medicine. I was reassigned in 1983 and from then until the spring of 1987, I served as Chief of Emergency Medicine at the Walter Reed Army Medical Center.

7. Following my discharge from the United States Army in 1987, I was appointed as Chair of the Department of Community Health and Ambulatory Care at the District of Columbia General Hospital, serving in that post until December of 1990. From January 1990 to the fall of 1991, I was the Acting Commissioner for Public Health for the District of Columbia, and the Acting Director of the Emergency Ambulance Bureau in the District of Columbia Fire Department. I returned to serve as the Interim Director of the Emergency Ambulance Bureau from the fall of 1994 to the spring of 1995.

8. I served as the Secretary of the Maryland Department of Health and Mental Hygiene from April 1999 to December 2002, following four years as its Deputy Secretary for Public Health Services.

9. In April 2016, I was appointed by President Obama to the National Infrastructure Advisory Council. In that role, I served as a health sector representative to advise the President on how best to assure the security of the nation's critical infrastructure. I served in this capacity until December 2020.

10. The APHA was founded in 1872, at a time when scientific advances were helping to reveal the causes of communicable diseases. These discoveries laid the foundation for the public health profession and for the infrastructure to support APHA' s work. From its inception, APHA has been dedicated to improving the health of all U.S. residents. From its early days, two of APHA's most crucial functions have been advocacy for adoption by the government of the most current scientific advances relevant to public health, and professional and public education on how to improve community health.

11. APHA's mission is to: "Build public health capacity and promote effective policy and practice." APHA members include more than 23,000 individual public health professional members, as well as state, local, tribal, and territorial health departments, organizations interested in health, and health-related businesses. APHA also coordinates with state and regional APHA affiliates across the nation. APHA members work in every discipline of public health, in every state, and in countries across the globe. APHA and APHA members utilize and rely on the CDC immunization schedule as an authoritative national benchmark governing vaccine practice, outbreak, prevention, and the standard of care. It also drives financial reimbursement requirements for vaccine services by federal law. Sudden and unsupported changes to the CDC immunization

schedule creates confusion and increases distrust of vaccine safety and efficacy. This immediately increases the risk of preventable infectious disease outbreaks, alters real-world clinical and public health operations, and exposes practitioners and agencies to increased legal, ethical, and professional risk.

12. APHA's mission requires it to work in constant coordination with its members to sustain, protect, and improve the operationalization of the public health system in the United States, the nationwide infrastructure that prevents disease, detects emerging threats, and safeguards communities at scale. One pillar of America's public health system is the federal vaccine evaluation and recommendation system that has historically operated as a safeguard to protect the public from preventable infectious disease outbreaks and, reduce the risk of serious illness and death. The public health system in the United States is a coordinated, multi-level infrastructure designed to protect health and well-being, prevent disease before it occurs, detect emerging health threats early, and respond rapidly to protect population health at scale. It operates through an interdependent network of federal, state, local, tribal, and territorial health departments; clinicians and health systems; surveillance and laboratory networks; and community-based prevention programs. This system functions effectively when there are stable, evidence-based, national standards that allow prevention, preparedness, and response to operate across jurisdictions. APHA and its members (who include professionals that serve as state and local health officers, epidemiologists, physicians, nurses, experts in infectious disease, public health program administrators, health educators, health lawyers and emergency-preparedness officials, just to name a few) are integral to this system. They are the public safety individuals who are responsible for identifying when a disease threat exists in a community, evaluating its risk, crafting strategies to reduce that risk, and controlling it. Think of them as the nation's disease detectives. Public health

is regulated and managed primarily at the state and local level, but the federal government provides national guidance and consistency because many diseases, especially infectious diseases, do not honor geographic boundaries.

13. The APHA as well as its members, state and local health officials and practitioners, policy makers and the public in general rely on the federal government's health processes to ensure therapeutics like vaccines are safe and effective. They rely on the evidence and science-based evaluations done first by the FDA and its advisory committee the Vaccines and Related Biological Products Advisory Committee (VRBPAC) and then the CDC and its Advisory Committee on Immunization Practices (ACIP) to properly and expertly review and make recommendations for the safe and effective use of vaccines. The nongovernmental public health community then translates federal public health guidance into real-world infectious disease prevention strategies that fuel programs resulting in both individual and population protection from preventable diseases. The impact of their work when done properly, using evidence-based and proven scientific principles protect millions of people every day. The CDC immunization schedule is embedded throughout this infrastructure as the authoritative national benchmark that governs vaccine timing, specific vaccine coverage and required reimbursement; the CDC immunization schedule produced from the evidence-based framework has been the backbone of infectious disease management in the United States.

14. The CDC immunization schedule has historically been anchored in the Advisory Committee on Immunization Practices ("ACIP"), a statutorily recognized body composed of independent, highly qualified, scientific, and clinical experts in infectious disease, immunology, epidemiology, pediatrics, obstetrics, internal medicine, and public health. It was first established in 1964 by the Surgeon General of the U.S. Public Health Service and became an official federal

advisory committee in 1972. ACIP's composition and mandate are central to the integrity of the federal immunization framework. Its role is not advisory in the abstract, but structural: ACIP serves as the scientific gatekeeper for national vaccine policy by conducting rigorous, unbiased evaluations of the evidence using proven standardized and transparent methodologies such as the GRADE approach and the Evidence-to-Recommendations ("EtR") framework. Using a robust, evidence-based framework, the ACIP systematically assesses vaccine safety, effectiveness, population-level benefit, equity, feasibility, and resource use, openly addresses uncertainty, and issues clear recommendations grounded in expert scientific consensus.

15. No individual clinician, hospital system, or local or state health department can independently replicate this level of evidence synthesis across every vaccine and pathogen. The ACIP evidence-based framework exists precisely because modern and competent public health depends on centralized, expert, methodologically rigorous review to function at scale. When the ACIP process is bypassed, degraded, or supplanted by unsupported directives, and when the CDC immunization schedule is altered without that evidentiary foundation, scientific review, and clear explanation, the public health system destabilizes immediately. Prevention programs fragment, outbreak preparedness erodes, clinical counseling becomes inconsistent, and trust (the essential currency of public health) is lost in ways that cannot be quickly restored once disease transmission accelerates.

16. Clinicians and public health practitioners' reliance on the appointment of qualified ACIP members and the integrity of the evidence-based framework is foundational to the modern and competent public health system in the United States. This reliance allows clinicians to counsel patients with confidence and enables public health agencies and health systems to design vaccination programs, plan surveillance and preparedness strategies, allocate resources, and

respond effectively to emerging and reemerging infectious threats. Trust in these federal processes and the CDC immunization schedule has historically been earned through qualified expert participation, methodological rigor, administrative practices that foster transparency, and consistency over time.

17. For decades, APHA and its members have relied on this federal framework for vaccine recommendations as the nation's authoritative mechanism for evaluating vaccine safety, effectiveness, and population-level need. Under this structure, ACIP conducts its systematic evidence review using GRADE and EtR, and the CDC publishes ACIP's scientific rationale through the Morbidity and Mortality Weekly Report ("MMWR"). This creates a transparent, nationally uniform evidentiary foundation on which professional and nonprofessional stakeholders rely to determine the standard of care. Because this framework anchors clinical and public health practice, sudden and drastic changes to the CDC immunization schedule is harmful across the entire medical, legal, public health, financial, policy and operational landscape.

18. The CDC immunization framework is embedded in public health systems at every level. Because infectious diseases spread across state borders, a uniform national benchmark is necessary to ensure that individuals receive vaccinations at evidence-based ages and intervals regardless of where they live. This consistency is critical to maintaining herd immunity, preventing outbreaks, and protecting the public health nationwide, and it is ingrained in the care that APHA members provide to their patients and communities. Herd-immunity is the mechanism by which enough people are vaccinated or otherwise protected in a community so that disease spread is interrupted.

19. APHA members, particularly those serving in state, local, tribal and territorial health departments, federally qualified health centers, community clinics and public hospital

systems, operate on the front lines of the nation's public health system. Their work depends on clear, stable, and scientifically grounded federal vaccine guidance to inform the design of vaccination programs, allocate staff and resources, counsel patients, conduct disease surveillance, and prevent outbreaks before they occur. APHA and its members have relied on the CDC immunization schedule recommendations and ACIP's robust, scientific, evidence-based review process as the backbone of their outbreak prevention strategies, clinical protocols, and public health guidance.

20. A "routine" recommendation on the CDC immunization schedule serves a distinct and essential public-health function that is materially different from a recommendation designated for Shared Clinical Decision-Making ("SCDM"). A "routine" recommendation conveys ACIP's expert determination, based on rigorous, unbiased review using proven standardized and transparent methodologies (such as the GRADE approach and EtR framework), that a vaccine's benefits clearly outweigh its risks for a defined population, and that widespread, timely administration is necessary to prevent disease at the population level. Routine recommendations establish the default standard of care, promote high and consistent vaccine uptake, and sustain the herd-immunity thresholds required to suppress transmission before outbreaks occur. By contrast, shifting a vaccine from routine status to SCDM represents a material weakening of the recommendation and necessarily requires additional guidance to ensure consistent and appropriate implementation. SCDM is a term which means different things to different people and is a false distinction from informed consent which is always inherent in any therapeutic encounter.[1] When

[1] *See* Centers for Disease Control and Prevention, Advisory Committee on Immunization Practices, ACIP Shared Clinical Decision-Making Recommendations (Jan. 7, 2025), https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html ("Unlike routine, catch-up, and risk-based recommendations, shared clinical decision-making vaccinations are not recommended for everyone in a particular age group or everyone in an identifiable risk group. Rather, shared clinical decision-making recommendations are individually based and

vaccinations are recommended, the accompanying MMWR guidance published by the CDC provides the critical framework that explains how clinicians, health systems, payers, and public-health authorities should specifically apply the recommendation in practice. That guidance preserves trust in the immunization schedule and prevents misinterpretation of the recommendation's evidentiary basis. Here, however, routine recommendations were downgraded to SCDM without the corresponding clear MMWR and related guidance material necessary to operationalize that shift. Because SCDM is implemented across diverse clinical and public-health settings, the absence of clear guidance on the new SCDM designation predictably results in inconsistent application, conflicting messaging, and confusion across the public health system in America. This combination, a weakened recommendation coupled with the failure to follow and provide the frameworks on which that SCDM designation relies, fractures prevention efforts and contributes to the Secretary's shift of the public-health system from proactive disease control into reactive outbreak response, at which point infections, hospitalizations, and deaths are already occurring and cannot be undone through later intervention.

21. The May and September Covid Schedule Changes and the January 5 Childhood Schedule Change represent a historic and destabilizing break from that settled federal process for changing CDC immunization schedule recommendations. These actions were issued without use of an evidence-based, proven standardized transparent methodology (such as the GRADE approach and EtR framework) and without explanatory guidance in the MMWR that ordinarily accompanies changes to the schedule. As a result, APHA members have been left without any

informed by a decision process between the health care provider and the patient or parent/guardian. The key distinction … is the default decision to vaccinate … For shared clinical decision-making recommendations, there is no default—the decision about whether or not to vaccinate may be informed by the best available evidence of who may benefit from vaccination; the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered.")

scientific explanation for why vaccines long deemed routinely recommended for population-level protection are suddenly downgraded. This absence of process and transparency in changing the schedule has injected confusion directly into public health administration and clinical care provided by APHA and APHA members, undermined prevention efforts and materially harmed APHA members' ability to perform their professional duties.

22. The harm is magnified because the January 5 Childhood Schedule Change did not affect a single vaccine in isolation. Instead, it simultaneously downgraded multiple routine childhood vaccines, including hepatitis B, rotavirus, RSV, and meningococcal disease, each of which had been embedded for decades in coordinated prevention and outbreak-control strategies. This forced APHA members, including state and local health officers, epidemiologists, immunization program directors, and preparedness officials, to immediately reassess outbreak risk across multiple diseases, revise vaccination guidance, retrain staff, adjust surveillance priorities, and prepare contingency response plans, all while confronting widespread confusion among clinicians and families about which vaccines remain universally recommended. This shift in federal policy from prevention to anticipatory outbreak response is occurring now, not prospectively, and diverts limited resources away from stable vaccination programs toward emergency planning for diseases that were previously controlled.

23. When multiple vaccine recommendations are weakened simultaneously, the resulting harm increases exponentially. Herd-immunity thresholds erode across diseases at the same time, increasing the likelihood of concurrent outbreaks, and magnifying morbidity and mortality in ways that are costly to be controlled or extinguished both in dollars and human health. APHA and APHA members are thus forced into crisis response as preventable infections occur, hospitalizations increase, and lives are lost.

24. **Hepatitis B** provides a concrete and particularly grave example. Universal hepatitis B birth-dose vaccination was adopted as a routine CDC recommendation in 1991 following rigorous evidence-based review demonstrating that screening-only or a risk-based strategy failed in the United States' fragmented health-care system. Inconsistent prenatal care, lack of insurance, false-negative tests, failures in follow-up, and exposure from caregivers other than the mother rendered reliance on maternal screening inadequate. Before universal birth-dose recommendations, tens of thousands of U.S. babies were infected annually by mothers, other family members and others who did not know they carried the virus. Maternal screening only screens the mother and not everyone that interacts with the newborn or the child later in life. Ninety percent of infected infants develop chronic infection. Chronic infection dramatically increases lifetime risk of cirrhosis, liver failure and hepatocellular carcinoma (As much as 25%), harms that often-manifest decades later. In December 2025, ACIP voted on changes to hepatitis B vaccination in a manner that departed materially from an evidence-based standardized and transparent review process (methodologies such as the GRADE approach and EtR framework were not followed). The vote language was ambiguous, and ACIP members openly expressed uncertainty regarding whether they were altering the strength, universality, or timing of the recommendation. The January 5 Childhood Schedule Change then adopted this unclear vote to remove the routine birth-dose recommendation for non-high-risk populations without any EtR-based rationale. APHA members now lack an evidentiary record to interpret or implement this change while responding in real time to parental questions and preparing outbreak-response strategies.

25. **Rotavirus** provides a clear example of the immediate and irreversible harm resulting from the January 5 Childhood Schedule change. Rotavirus is a highly contagious viral infection causing severe diarrhea, vomiting, dehydration, abdominal pain, and hospitalization of

many infants and young children. There is no antiviral therapy. Rotavirus vaccination is the primary means of preventing this disease in infants. Vaccination must occur within a narrow age window; otherwise, the vaccine is ineffective. Downgrading rotavirus vaccination to SCDM (without any evidentiary basis for doing so) causes confusion during patient consultations and can lead parents to delay or decline vaccination, permanently increasing vulnerability among infants who are unvaccinated. Prior to routine vaccination, rotavirus was a leading cause of emergency department visits and pediatric hospitalization in the United States causing an estimated 2.7 million cases a year. After routine vaccination, emergency department visits and hospitalizations declined dramatically nationwide. It is estimated that each year, the vaccine prevents 280,000 clinic visits, 62,000 emergency department visits and 45,000 hospitalizations.[2] By weakening this recommendation, the public health system predictably reverses those gains, increasing emergency-department visits, pediatric hospital admissions, and preventable morbidity and mortality, which are harms that cannot be undone once community transmission increases. This harm is compounded by Defendants' failure to follow the rigorous, evidence-based process that has governed rotavirus Childhood Schedule recommendations since 1997. APHA and its members rely on the ACIP's rigorous, evidence-based process to understand the scientific basis, strength, and practical meaning of CDC schedule recommendations and to plan vaccination strategies, communicate consistently with clinicians and the public, and make operational decisions such as vaccine ordering and resource allocation. The absence of the evidence-based framework leaves APHA and its members without any scientific basis or implementation guidance to understand, apply, or explain the rotavirus Childhood Schedule change, preventing effective vaccination

[2] *See* CDC, Rotavirus, *Pink Book,* ch. 19 (14th ed. Apr. 25, 2024), https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-19-rotavirus.html

planning and communication at the very moment when delay results in permanent loss of protection for infants.

26. APHA members report that, within days of the January 5 announcement changing the CDC childhood immunization schedule APHA members were immediately required to review and when needed, revise counseling practices, educational materials, and public-facing guidance to explain the conflicts with well accepted evidenced based guidance with the new flawed federal recommendations. State, local, tribal, and territorial health departments staffed by APHA members are now reallocating resources to address confusion created by the revised schedule. These diversions are occurring during peak respiratory-virus season and amid ongoing and growing measles, influenza, and pertussis outbreaks. Such efforts divert resources for other critical public health functions.

27. APHA members who provide vaccinations are also experiencing immediate financial and logistical harm as a direct result of the January 5 childhood immunization schedule changes because it has disrupted vaccine procurement decisions already made months earlier in reliance on routine CDC immunization recommendations. APHA members who are public health agencies and physician practices purchase pediatric vaccines, including combination vaccines, well in advance based on established recommended schedules and historical experience based on need. APHA members report that the sudden and nonevidence based downgrade of component vaccines, including hepatitis B, has rendered previously purchased combination vaccines unusable when parents decline a single component, forcing agencies to discard doses purchased with federal and state funds. This is a waste of taxpayer dollars for governmental employees who are charged with protecting taxpayer resources. Public health practitioners including APHA members have ordered, received, and are administering vaccines according to the previous recommended federal

vaccine schedule and their state, local or territorial laws and regulations. APHA members have already printed materials, scheduled clinics, and existing outreach campaigns that are in process and will be negatively impacted by this abrupt change. Changing federal guidance during the peak in the influenza season has required APHA members and others to alter clinics, train staff on the implications of the altered guidance and patient eligibility and respond to public confusion.

28. **Meningococcal disease** progresses rapidly and carries a high fatality rate (10-15%), with many survivors experiencing permanent disability. APHA members have also long relied on routine meningococcal vaccination recommendations to protect adolescents and college-bound students in congregate housing. The January 5 Childhood Schedule Change introduced confusion just as students return to dormitories nationwide, forcing APHA members to devote substantial time to addressing questions from parents, clinicians, and school administrators. Any delay or reduction in meningococcal vaccination during this period materially increases outbreak risk. The average cost to investigate and manage even a small outbreak of meningococcal disease can be as much as $300,000.[3] This is in addition to the significant clinical impact of a single case.

29. The January 5 Childhood Schedule Change is further compounded by a decision memorandum and assessment that are affirmatively misleading. These documents rely on undefined, non-scientific concepts such as "consensus vaccines" and selectively invoke international comparisons, such as Denmark, without disclosing that those countries operate centralized health systems with integrated surveillance, high baseline trust, and universal access to care, robust social support systems that bear no resemblance to the United States. By stripping these comparisons of necessary context, the memorandum falsely signals that downgraded

[3] *See* Andrea Anonychuk et al., The Cost of Public Health Burden of Invasive Meningococcal Disease Outbreaks: A Systematic Review, 31 Pharmacoeconomics 563 (2013), https://pmc.ncbi.nlm.nih.gov/articles/PMC3691489/

recommendations are scientifically validated, fueling vaccine hesitancy by implying that children in the United States have been receiving unnecessary vaccines. For APHA members tasked with translating federal guidance into real-world vaccination policy and practice this misinformation forces an immediate shift from prevention to crisis management when a vaccine preventable outbreak occurs. As a result of the May Directive, September Schedule Change, and January 5 Childhood Schedule Change, APHA clinician members report compromised standards of care for Covid-19 vaccination for pregnant individuals, children, and adults under 65, and for routine childhood vaccinations including hepatitis B, rotavirus, RSV, meningococcal disease, and influenza. APHA clinician members are forced to choose between following the best available science or complying with federal guidance that lack evidentiary grounding, placing their professional judgment, licensure, and credibility at risk. APHA clinician members also report now substantially more unreimbursed time correcting misinformation and explaining vaccine safety without the support of the transparent, robust evidence-based framework that they have relied on.

30. The May 19 Directive, September Schedule Change, and January 5 Childhood Schedule Change are immediately harming APHA itself by compelling the organization to abandon planned mission-critical work and operate in a constant crisis-response mode. APHA leadership, scientific staff, and communications teams are now spending hours each day responding to misinformation, correcting federal pronouncements, and briefing members on the internally inconsistent CDC materials. APHA has been forced to divert staff and expert contributors to review its flagship publications, including the Control of Communicable Diseases Manual, because those works have utilized the evidence-based ACIP framework that the Defendants have abandoned. At the same time, the CDC's unexplained departure from established scientific processes has damaged APHA's credibility as a reliable disseminator of evidence-based

guidance, because of the confusion, misinformation and disinformation caused by the abrupt unscientific change in federal guidance. This requires APHA to expend additional resources to ensure trust with members, partners, and the public. These compelled diversions of resources are concrete, ongoing, and unrecoverable.

31. If the February 25–26, 2026 ACIP meeting proceeds as scheduled, it will immediately compound the harms already inflicted on APHA, its members, and the public health system. The current ACIP, constituted and operating outside the qualified-expert, evidence-based framework that historically anchors vaccine policy, has been a national megaphone for misinformation, confusion, and instability. If this ACIP, with its current members and using its recently used dysfunctional and nontransparent process; holds another meeting, frontline clinicians and public health professionals will be forced, yet again, to divert substantial time, expertise, and organizational resources away from patient care, disease prevention, surveillance, and outbreak preparedness to address confusion and erosion of trust generated by illegitimate federal guidance. Each additional ACIP meeting and each vote taken by this body inflicts new and compounding injury. APHA clinician members must counsel patients amid uncertainty created by unstable and unexplained federal recommendations. They must devote increasing amounts of unreimbursed time explaining changes to the CDC immunization schedule that were not produced through an established, evidence-based review framework. APHA's agency and public health professional members must revise guidance, outreach materials, and preparedness plans that are built around the CDC immunization schedule as the national benchmark for preventing infectious disease. APHA itself must continue redirecting staff, scientific expertise, and funding from other important public health activities to address these manufactured threats to the public's health. These harms occur when false or misleading information is disseminated at a public ACIP meeting, when this

ACIP votes to endorse or ratify changes to the CDC immunization schedule and when it is then approved by an acting CDC director with no health or scientific expertise. Once an ACIP public meeting is held, vaccine votes are taken, and guidance approved, the resulting damage to clinical reliance and coordinated public health infrastructure is immediate and cannot be fully reversed through later litigation, post-hoc agency explanations, or retrospective reconsideration. Absent immediate injunctive relief, APHA and its members will remain trapped in perpetual crisis-response mode, sustaining ongoing and irreparable injuries to their missions, their professional integrity, and the health of the communities they serve.

32. These harms to APHA and APHA members are occurring now, and will continue, as a direct result of the May 19 Directive, the September Schedule Change, and the January 5 Childhood Schedule Change, all of which departed from the ACIP's qualified-expert, evidence-based framework that has long anchored the public health system. For APHA and its members, the harm is immediate, compounding, and irreversible: vaccination confidence has eroded, routine prevention systems have fractured, and public health professionals have been forced from proactive disease prevention into reactive crisis response. Allowing the February 25–26, 2026 ACIP meeting to proceed would further exacerbate and legitimize these existing harms by amplifying confusion, deepening the erosion of trust on which coordinated public health action depends, and further destabilizing a stressed public health system. Once these systems fail and preventable disease spreads, no later remedy can restore the lives lost as a result. Preventable infectious diseases and their downstream harms are not, and should never be treated as, "the cost of doing business."[4] Immediate injunctive relief is therefore necessary to halt further injury and

[4] *See* Top CDC Official Says Measles Surge Is the "Cost of Doing Business," U.S. News & World Report (Jan 23, 2026), https://www.usnews.com/news/health-news/articles/2026-01-23/top-cdc-official-says-measles-surge-is-the-cost-of-doing-business

preserve what remains of the evidence-based public health system before the damage becomes permanent and unrepairable.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Washington D.C., that the foregoing is true and correct.

Executed on January 25, 2026, in Washington, D.C.

Georges C. Benjamin, MD

Georges C. Benjamin, MD
Executive Director, American Public Health Association

EXHIBIT 26

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF JAMES LEWIS, MD, MPH

I, James Lewis, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I have personal knowledge of the facts stated herein. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction

2. I reside in Everett, Washington.

3. I earned a Master of Public Health degree from the University of North Carolina and a Doctor of Medicine degree from the University of Arkansas for Medical Sciences. I am board certified in Internal Medicine, Infectious Diseases, and Preventive Medicine. I am an adjunct Clinical Assistant Professor at the University of Washington in the Division of Allergy and Infectious Diseases.

4. I am the Health Officer for the Snohomish County Health Department in Washington State.

5. I am a member of the American Public Health Association ("APHA").

6. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025, and have read the related May 19 "Secretarial Directive" ("Directive") confirming what the Secretary said in the video.

7. I am aware that on June 9, 2025, all sitting Advisory Committee on Immunization Practices ("ACIP") were terminated and slowly replaced with non-experts.

8. I am aware that this newly reconstituted ACIP met from September 18 and 19 and that at this meeting the Committee discussed recommending the COVID-19 vaccine through Shared Clinical Decision Making ("SCDM") for essentially all patients.

9. I am aware that Centers for Disease Control and Prevention's ("CDC") adopted the new ACIP's recommendation for SCDM for essentially all patients under the age of 65 for COVID-19 vaccinations. I have also reviewed the CDC's immunization schedule, which was revised to reflect ACIP's SCDM recommendation for the COVID-19 vaccine across for all individuals older than 6 months, including pregnant women, even though COVID-19 vaccination during pregnancy was not discussed in the meeting.

10. I disagree with the decisions announced in the May 27 video, the Directive to remove recommendations from the CDC's immunization schedules that pregnant women and children receive the COVID-19 vaccine, the ACIP's SCDM recommendation for all individuals older than 6 months, and the current CDC immunization schedule. These decisions have personally affected my job and caused me to divert a significant amount of my time and attention on attempting to mitigate the damage that the Directive and newly reconstituted ACIP has had on

public health in my county. This diversion of resources has adversely impacted the ability of the Snohomish County Health Department to carry out its other public health responsibilities and initiatives.

11. One initiative that I worked on because of the Directive and other actions by the Secretary that undermine trust in vaccines is an initiative to change local and state laws that have tied vaccine recommendations to the ACIP and CDC guidance. I, along with colleagues with whom I am working on this initiative, no longer trust the new ACIP, its recommendations, or CDC guidance and immunization schedules. Accordingly, we are now forced to change state and local laws to no longer defer to CDC guidance or ACIP recommendations.

12. Every county in Washington State participates in a health officer group known as the Health Officer Committee for the State of Washington. As a result of the Directive and ACIP's actions, this Committee drafted educational materials recommending that the State Legislature enact a law ensuring that any statute that defers to ACIP also defers to other evidence-based bodies, including professional societies such as the American Academy of Pediatrics ("AAP"). The development of these materials required multiple rounds of drafting and review. The materials also had to be presented to the State Medical Association. This has required a significant investment of time and effort without any changes to our budget or staff.

13. I am also preparing for extensive advocacy work that will take place during the upcoming legislative session in the Spring, with the goal of securing passage of the bill. My work for this initiative includes reviewing data, assisting with the development of bill language, speaking with health care providers, gathering their feedback, and confirming that the proposed language meets their needs and reflects what they believe is in the best interest of patients. I have

had internal discussions regarding this effort, as well as external discussions with organizations involved in patient care.

14. The net impact is that I, along with colleagues, am performing work that ACIP typically carries out through the Evidence to Recommendations ("EtR") framework. I would not need to take on this workload if ACIP were functioning as it had for many years and had not issued an unsupported SCDM recommendation for the COVID-19 vaccine. This, in turn, has diverted my ability to work on other tasks and initiatives that serve the residents of Snohomish County.

15. Neither the Snohomish County Health Department nor the Health Officer Committee for the State of Washington receives additional funding for these initiatives. Instead, to meet these new demands, we have been required to shift resources away from other public health efforts. These other public health efforts have slowed significantly, and in some cases have been paused, because the department has had to redirect resources to respond to the SCDM recommendation for COVID-19 issued by ACIP.

16. As part of my duties as Health Officer, I have spoken directly with providers and patients who are trying to navigate the confusion created by ACIP's SCDM recommendation for the COVID-19 vaccine. Patients have reported to me that some providers have refused to administer the COVID-19 vaccine to them because they are concerned about lack of reimbursement or potential liability. Providers have told me that they are considering not stocking the vaccine for the same reason, as they do not want to take on the financial risk of administering a vaccine when they may not be reimbursed through health plans. This work represents new unfunded demands on the time and resources of the Snohomish County Health Department.

17. Providers have also expressed their concerns to me about their personal liability. That are concerned about and do not want to take on the risk that if a patient experiences an adverse

event after receiving a COVID-19 vaccine, the patient could assert that the provider did not follow the proper SCDM process. ACIP has not provided any supporting materials for its SCDM recommendation for the COVID-19 vaccine, and it has offered neither guidelines published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") nor any guidance describing a standard SCDM process for COVID-19 vaccination. As a result, providers across Washington State lack a baseline for how SCDM should be conducted or documented. Although Washington State has issued a standing order to help mitigate liability risks, providers are expending significant resources to meticulously document their SCDM conversations. These efforts include changing patient note templates, revising intake forms, and modifying electronic medical record systems to include prompts related to SCDM. Again, this work represents new unfunded demands on the time and resources of the Snohomish County Health Department.

18. Another initiative that I am working on because of the Directive and the Secretary's other actions is to revise internal Snohomish County policies so that they no longer defer to ACIP recommendations and CDC guidance.

19. On January 5, 2026, Jim O'Neill, Acting Director of CDC, announced the immediate adoption of a completely revised CDC Childhood Immunization Schedule (the "January 5 Childhood Schedule Change"). The January 5 Childhood Schedule Change impacts several routinely administered vaccines, changing them from recommended to SCDM or recommended only for high-risk or certain populations only. These changes were enacted by political appointees without any review or recommendation by the ACIP.

20. In just a handful of the days following the January 5 Childhood Schedule Change announcement, teh January 5 changes to the vaccine schedule had concrete, immediate impacts on my work. As Health Officer for Snohomish County, I had to dedicate several hours of my day

responding to emails and requests for assistance from other local health officers across the state of Washington. These colleagues contacted me for guidance and to enlist my assistance in developing some kind of response effort to communicate our concerns to State and federal leaders. I would not have had to dedicate my time and energy to these efforts were it not for the Mr. O'Neill's announcement, and the time spent addressing these issues required me to neglect or minimize attention to other important duties. As a result, I was forced to redirect time and efforts to projects and tasks that I will never be able to recoup or get back; time that could have been spent on more pressing tasks for our local public health efforts.

21. Based on my review of the January 5 Childhood Schedule Change and supporting material from the federal government, as well as my background, training, and experience, I believe the January 5 Childhood Schedule Change will have serious negative impacts on public health both at the local level and nationwide. The changes enacted by the January 5 Schedule Change have already caused confusion among the public—especially our patients—and will in all likelihood lead to lower rates of vaccination for conditions like RSV, influenza, hepatitis B, and rotavirus. This is especially perplexing and concerning for vaccines that have been particularly effective, like the RSV vaccine. Decreased vaccine uptake for these conditions will ultimately lead to higher rates of infection and greater community spread of infectious diseases. This will in all likelihood lead to higher rates of emergency room utilization and hospitalization, which would substantially burden the public health and healthcare infrastructure on both the micro and macro levels and lead to avoidable illness. Altogether, the January 5 Childhood Schedule Change will cause severe negative effects on public health and will in all likelihood cause more individuals to fall ill with conditions that could otherwise be prevented through vaccination. This will take shape

in the form of more community spread of rotavirus, higher rates of hepatitis A and B infection, and increases in the number of cases of meningitis.

22. I am also troubled by the justification that the January 5 Childhood Schedule Change brings the United States into alignment with supposed peer nations, like Denmark. Based on my training and experience, the United States and Denmark are not comparable in terms of public health and healthcare delivery. To the contrary, there are many disparities that illustrate how the United States are *not* like Denmark. Most notable is the fact that Denmark has a system of socialized medicine paid for by the government. This method has relatively few barriers to access and near universal screening for pregnant women. The United States' public health and healthcare systems, by contrast, have significantly more barriers to access on account of the lack of a national health service or system. We also do not have the same level of health screening for pregnant women. In other words, the United States and Denmark should not be compared in terms of vaccine policy because each nation takes a markedly different approach to public health and healthcare delivery. To suggest otherwise would be to perpetuate a false equivalency that relies on cherry-picked or misconstrued data.

23. Since the changes to the CDC immunization schedule recommendations for Covid-19 vaccination, I continue to have to respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance. I must repeatedly spend time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption directly interferes with my routine work and undermines confidence in vaccination recommendations that I rely on and promote daily as a public health officer. The harms set forth above are ongoing and will worsen unless the Directive and the ACIP's and CDC's changes to the CDC immunization

schedule for Covid-19 vaccination are immediately enjoined and the ACIP and CDC return to the evidence-based, transparent process for making vaccine recommendations for children.

24. . The harms identified above associated with the Directive, CDC's changes to the CDC immunization schedule for Covid-19 vaccination for children, the January 5, 2026 changes to the childhood immunization schedule, as well as the anticipated harms that will result from any additional changes that may result from the upcoming February 26, 2026 ACIP meeting, are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes public health and confidence in the public health systems that keep our communities safe. Each new change increases the burden, amplifies skepticism with my recommendations, increases the time I am spending combatting and counteracting misinformation and disinformation, and diminishes the effectiveness of my public health efforts

25. The harms described above are also compounded by the failure to follow the established GRADE and EtR frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, I must spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does not replace prior work, it is added on top of my existing clinical responsibilities. When this occurs repeatedly, as with the Covid-19 schedule changes, the harm is immediate ,

compounding, and irreversible: vaccine confidence is eroded, routine public health prevention systems have fractured, and public health professionals like me are forced from proactive disease prevention into reactive crisis response. Allowing the February 25–26 ACIP meeting to proceed would further entrench and legitimize these existing harms by extending an already destabilized process, amplifying confusion, and deepening the erosion of trust on which coordinated public health action depends. Once these systems fail and preventable disease spreads, no later remedy can restore the lives lost, the trust broken, or the public health system dismantled. Immediate injunctive relief is therefore necessary to halt further injury and preserve what remains of the evidence-based public health system before the damage becomes permanent.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of the State of Washington, that the foregoing is true and correct.

Executed on January 22, 2026 in Everett, Washington.

/s/ Dr. James Lewis

James Lewis, MD, MPH

EXHIBIT 27

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF SUSAN J. KRESSLY, M.D., FAAP

I, Susan J. Kressly, M.D., FAAP, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' Fourth Amended Complaint filed in the above-captioned action.

2. I am board certified in Pediatrics and Clinical Informatics and a Fellow of the American Academy of Pediatrics.

3. I have over 30 years of clinical experience in general pediatrics, during which I founded Kressly Pediatrics, an independent general pediatrics practice located in Bucks County, Pennsylvania and served as the school physician for Central Bucks School District for over a decade. I also served as the Medical Director of Office Practicum (OP), a pediatric-specific Certified Electronic Health Record Technology (CEHRT) for over a decade.

4. I received my medical degree from Temple University School of Medicine and served my residency at St. Christopher's Hospital for Children, located in Philadelphia, Pennsylvania, where I stayed on for an additional year as Chief Pediatric Resident.

5. I am the immediate past President of the American Academy of Pediatrics (AAP). During my term as President, I led and managed all of the AAP's relationships with our members, operations of AAP, and the standards that our members follow to provide the highest level of care to their patients. I also play a crucial role in developing the AAP's public policies. As such, I have in-depth knowledge of the operations of AAP, its members, the standard of care for our physician members, and the facts and circumstances set forth herein.

6. The AAP was founded in 1930 to serve as an independent forum for addressing children's health and continues to operate with the mission to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents and young adults.

7. The AAP's membership includes over 67,000 pediatricians nationwide, many of whom are currently providing direct care to infants, children, adolescents, and young adults in both hospital and outpatient settings.

8. The AAP's mission is to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults. To accomplish this, the AAP operates to support the professional needs of its members through the publication of evidence-driven, nonpartisan, rigorously reviewed policies on a broad range of topics that impact the health and wellbeing of infants, children, adolescents, and young adults. This includes the maintenance and publication of the AAP Red Book, which contains current guidance on the diagnosis, treatment, and prevention of over 200 childhood infectious diseases; it is used across pediatric practices nationwide. Central to the AAP Red Book is the AAP's immunization recommendations.

9. The AAP has members throughout the United States who are directly affected by the May 19, 2025 directive (the "Directive") issued by United States Secretary of Health and Human Services Robert F. Kennedy Jr. (the "Secretary") rescinding prior recommendations that healthy children ages six months to 17 years old be routinely immunized against COVID-19 and directing the Centers for Disease Control and Prevention (CDC) to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age.[1] If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath.

10. The AAP's members have suffered and will continue to suffer greatly at the hands of the Secretary's changes to COVID-19 vaccine recommendations.

11. Peer-reviewed studies and clinical literature show that administration of the COVID-19 vaccine lowers hospitalization rates and deaths due to COVID-19 infections in child and adult populations.[2] Further, children who receive the COVID-19 vaccine and stay up to date on their boosters are less likely to develop long COVID, which can cause brain fog, shortness of breath, gastrointestinal issues, generalized pain or fatigue, and other long-term, debilitating symptoms.[3]

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[1] A true and correct copy of the directive issued by United States Secretary of Health and Human Services Robert F. Kennedy Jr., dated May 19, 2025, is attached to this declaration as **Exhibit A**.

[2] *See, e.g.*, Sarah K. Wood, et al., *Vaccination of Children in the United States against COVID-19: An Ounce of Prevention*, 115 Southern Medical Journal 347, 347–48 (2022) ("Although the absolute risks of hospitalizations and deaths in children are low, the relative risks are highest in those US states with rates of vaccinations that are lower than the national average and mainly among people who are not vaccinated."). A true and correct copy of this study is attached to this declaration as **Exhibit B**.

[3] *See* AAP, *Study: Vaccines help prevent long COVID in children, adolescents*, AAP News (Jan. 16, 2024). A true and correct copy of this study is attached to this declaration as **Exhibit C**.

12. Members of the AAP have reported that the Secretary's Directive has completely frustrated their ability to effectively counsel patients and their families regarding the effectiveness of the COVID-19 vaccine at preventing serious illness and death, and that the Directive is compromising the standard of care by inciting patient delays or refusals to receive the COVID-19 vaccination.

13. AAP members have also reported that the Secretary's sudden and unilateral Directive removing the COVID-19 vaccine from the routine vaccination recommendations for healthy children ages six months to 17 years old has eroded some patients' faith and trust in all vaccines, causing them to refuse a myriad of routine vaccinations and creating an even more imminent and severe risk of serious illness, hospitalization, and death.

14. As COVID-19 infections typically rise during the respiratory illness season, which begins in October, physician members of the AAP aim to administer the COVID-19 vaccine in late August and throughout September to combat the inevitable surge of COVID-19 infections. The Secretary's dangerous and unsupported decisions regarding the COVID-19 vaccines are causing preventable suffering and death to Americans, which are likely to escalate during the respiratory illness season.

15. The lack of clarity regarding the reach of the Secretary's Directive has also created confusion and uncertainty regarding what the CDC's COVID-19 recommendations are for children ages six months to 17 years old. Although the Secretary's Directive ordered the CDC "to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age," on May 29, 2025, the CDC updated the Child and Adolescent Immunization Schedule to reflect a "shared clinical decision-making" recommendation for the COVID-19 vaccination.

16. The COVID-19 vaccine hesitancy that the Directive has unnecessarily created also requires physician members to spend more time counseling patients regarding the effectiveness of the COVID-19 vaccines, which adds up to time and resources diverted from other patients. If there is another severe COVID-19 outbreak, it would overwhelm AAP members' practices.

17. The Directive has also directly impacted physician members' ability to provide the optimal standard of care that they have been following since the COVID-19 vaccines were approved and placed them in an untenable situation. Although the Secretary has disavowed the efficacy and safety of the COVID-19 vaccine, under the current CDC recommendations, a parent's refusal to allow the administration of a COVID-19 vaccine to their child does not absolve a physician member of potential malpractice liability arising from a failure to administer the vaccine; the blame remains with the physician for failing to persuade parents to get the vaccine.

18. The AAP has adopted clinical practice guidelines that are considered the standard of care for our physician members and are in place to optimize and protect the care provided to our members' patients. Clinical practice guidelines are informed by a systematic review of peer-reviewed research and evidence, and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines follow a sound, transparent methodology to translate best evidence into clinical practice for improved patient outcomes. They are a key component of patient-centered care.

19. As part of its evidence-based clinical practice guidelines, the AAP reviews and has historically endorsed the Child and Adolescent Immunization Schedule, as set forth by the CDC.

20. Until the recent issuance of the Directive, the AAP has consistently recommended the COVID-19 vaccine for infants and children in alignment with the recommendations of the U.S. Food and Drug Administration (FDA), Advisory Committee on Immunization Practices (ACIP),

and the Centers for Disease Control and Prevention (CDC) for the COVID-19 vaccine as these recommendations were made based on the engagement in rigorous analyses and extensive reviews of safety and efficacy data for specific age groups to determine whether to recommend administration of the COVID-19 vaccine to children.

21. On June 18, 2022, after years of carefully analyzing the safety and effectiveness data and evaluating the balance of the risks of the COVID-19 vaccine compared to the severity of the disease across all age brackets, the FDA, the ACIP, and the CDC unwaveringly recommended that the COVID-19 vaccine be administered to children ages six months to 17 years old.[4] That same day, the AAP released an updated policy statement recommending that all eligible infants, children and adolescents without contraindications get vaccinated.[5]

22. However, due to the confusion and lack of evidence-based data supporting the Secretary's Directive modifying the recommendation for COVID-19 vaccinations for children ages six months to 17 years old, the AAP ceased its endorsement of the CDC's current Child and Adolescent Schedule, and instead published and endorsed the CDC Child and Adolescent Immunization Schedule in effect prior to the issuance of the Directive.[6]

23. The Directive's rescission of COVID-19 vaccine recommendations for children ages six months to 17 years old contradicts the years of data and evidence regarding the

[4] A true and correct copy of the 71 Morbidity & Mortality Weekly Rep. 26 (July 1, 2022) is attached hereto as **Exhibit D**.

[5] *See* AAP, *CDC approves COVID-19 vaccines for children under 5; vaccinations could begin this week*, AAP News (June 18, 2022). A true and correct copy of this news report is attached to this declaration as **Exhibit E**.

[6] A true and correct copy of the AAP's Recommended Child and Adolescent Immunization Schedule and accompanying notice published on June 24, 2025 are attached collectively hereto as **Exhibit F**.

effectiveness of the COVID-19 vaccine that has been collected, analyzed, and used to inform the vaccine recommendations in place before the Directive was issued. Without prompt and immediate intervention, the Directive will continue to cause needless negative health outcomes, illnesses, and deaths for the AAP members' patients.

24. In addition to the changes made in the Directive, on January 5, 2026, Jim O'Neill, Acting Director of CDC, adopted a completely revised CDC Childhood Immunization Schedule (the "Schedule Change"). Several routinely recommended vaccines were changed to recommended via SCDM or for high-risk or certain populations only. The changes were not reviewed or recommended by the ACIP. Instead, they were implemented unilaterally by agency leadership.

25. These changes were not triggered by any new professional medical consensus or changes to any practice guidelines published by AAP. There have been no new peer-reviewed studies that call into question the safety and efficacy of vaccines as administered currently. There was no opportunity for public notice and input from professional organizations such as AAP. I am not aware of any alerts from the Food and Drug Administration that have changed the safety and efficacy profiles of vaccines administered currently.

26. The Schedule Change has already forced AAP to divert substantial organizational time, staff attention, and financial resources away from core child-health initiatives consistent with AAP's mission and toward emergency mitigation work responding to the Schedule Change. The diversion is not limited to routine education or ordinary public communications. AAP must urgently develop, revise, and distribute materials to address the confusion created by the Schedule Change, respond to widespread member inquiries, and counteract the rapid spread of misinformation and distrust that the Schedule Change has triggered.

27. One of the most immediate impacts is the need to completely revamp the range of AAP's educational materials that are distributed to our members. For many of the diseases affected by this schedule change, pediatricians and their clinical teams have not seen these illnesses routinely in practice for years. For example, many pediatric clinicians today have never treated a six-week-old child with rotavirus.

28. Because of longstanding vaccination rates, these illnesses became uncommon. As a result, we now have to educate clinicians not just about vaccination policy, but about how to recognize, manage, and safely care for children with diseases that had largely disappeared from routine practice.[7] This is not work we were prepared to do on an emergency basis. The changes made by CDC require the rapid development of new guidance, review of existing materials, and urgent dissemination to clinicians who are already stretched thin.

29. With increased disease burdens and increased parental counseling needs, pediatric practices will face demands for which they were not staffed or structured to handle. We are being asked, in real time, to advise our members on how to meet the needs of children in their communities when the system was not prepared for these changes and was given no meaningful time to plan. Instead of advancing child health, we are now spending time trying to mitigate damage caused by a schedule change that, in my professional judgment, was made irresponsibly and without adequate consideration of downstream consequences.

30. One of the most troubling aspects of the Schedule Change is that it does not appear to have been preceded by basic due diligence. There was no transparent effort to ask fundamental questions such as whether the pediatric healthcare infrastructure in this country can safely absorb the predictable changes that will follow from reduced vaccination. There was no publicly shared

[7] *See* Katherine Wu, Rotavirus Could Come Roaring Back- Very Soon, THE ATLANTIC, Jan. 5, 2026, available at: https://www.theatlantic.com/health/2026/01/childhood-vaccine-schedule-rotavirus-paul-offit/685513/

modeling evaluating how many additional cases of diseases like rotavirus or measles we should expect if vaccination rates drop, over what time period, and in which communities. There was no analysis of whether pediatric hospitals have the beds, staffing, and resources to handle the increases in the incidence of these diseases. In many communities, the answer to that question is plainly no. Pediatric units have closed or downsized because the success of widespread vaccination has reduced hospitalizations. That capacity does not magically reappear overnight. When pediatric beds are unavailable locally, children are transported hours away from their families to receive care. That separates children from parents and places families in impossible positions, especially families with multiple children or limited resources. For those children of school age, this also means missing vital educational opportunities. These are not hypothetical concerns. We have already seen how fragile pediatric capacity can be during seasonal surges, such as the ongoing severe influenza season. Nor has CDC presented any proof that a reduced vaccine schedule will increase the overall pediatric vaccination rate.

31. The Schedule Change also forces AAP to re-examine clinical practice guidelines that were developed with the assumption that children are routinely vaccinated. Many clinical decision pathways implicitly rely on vaccination status, even when not stated explicitly. For example, in acute otitis media, also known as an ear infection, which affects almost all children, widespread vaccination shifted the epidemiology toward viral causes, supporting guidance that it is often safe to have an observation period before starting antibiotics. If vaccination rates drop and bacterial disease becomes more common again, those assumptions may no longer be valid. That means guidelines may need to change. We have not even had time to inventory our full catalog of clinical practice guidelines to determine where vaccination assumptions are embedded or where

decision points need to be added. This is extensive work that was not anticipated and cannot be done responsibly on an emergency timeline.

32. A related concern is that if vaccination rates drop, the entire population may lose the protection known as herd immunity for individual diseases, which occurs when enough people in a group or area have immunity to a germ such as a virus that it no longer spreads easily. Herd immunity benefits people who have not caught a disease, people who had the illness and recovered, and people who got a vaccine. It also protects people who cannot get a vaccine, for example because they are too young to receive the vaccine.

33. Some justifications for the Schedule Change rely on comparisons to other allegedly peer countries. Those comparisons ignore critical differences in healthcare delivery and social support systems. In the comparison countries, the incidence and prevalence of infectious diseases may differ from the United States. There is often a widespread program for screening for infectious diseases. Parents often have paid maternal and family leave for up to one year and can stay home with infants for extended periods. Childcare in these countries is also more accessible and affordable than in the United States. In the United States, many infants enter daycare as early as four weeks of life. That difference matters. Daycare settings increase the exposure risk at precisely the ages when infants are most vulnerable. The U.S. does not have the same safety net or universal access to care that those other systems provide.

34. Rotavirus is a clear example. In the United States, the vaccine is given at two, four, and six months of age because the most severe morbidity and mortality occur in very young infants. Community hospitals in the United States closed pediatric hydration units and reduced pediatric capacity precisely because rotavirus hospitalizations largely disappeared after vaccination. We are not prepared to absorb their return.

35. Increased incidence of diseases like rotavirus also creates practical infection-control problems in pediatric offices. Rotavirus spreads through body fluids. Infants with diarrhea frequently have diaper blowouts that contaminate exam rooms, carpeted floors, furniture, and equipment. When this occurs, rooms must be taken out of service and thoroughly cleaned and disinfected before another patient can be seen. That reduces access and increases wait times. These risks were dramatically reduced by vaccination. They will return if vaccination rates drop.

36. The Schedule Change also creates a serious and immediate supply problem. Pediatricians rely heavily on combination vaccines to reduce the number of injections and to deliver multiple recommended antigens efficiently. Most pediatric practices stock combination vaccines as their primary products. Manufacturers produce vaccines based on forecasted demand tied to the routine schedule. Now that a component vaccine, like Hepatitis B, has been removed from the routine schedule and changed to SCDM, but the remaining antigens are still recommended, there is not sufficient supply of single-antigen vaccine alternatives to replace the combination products. Based on my understanding, it could take 18 months or longer to meaningfully adjust manufacturing and distribution to single-antigen alternatives. In the meantime, pediatricians may simply be unable to obtain enough vaccine to follow the government's own stated recommendations for the remaining antigens. That means children will miss vaccines and will be at an increased risk of contracting illnesses not because clinicians refuse to vaccinate, but because the Schedule Changes makes compliance practically impossible.

37. The Schedule Change no longer treats influenza as a routine recommendation but instead recommends it on the basis of SCDM. In pediatric practice, influenza vaccines have historically been delivered through highly organized clinics operating under standing orders. Standing orders for immunizations allow qualified clinical staff to administer vaccines according

to an approved protocol without requiring an individual physician order for each patient. In influenza clinics, standing orders make it possible to vaccinate large numbers of patients safely and efficiently. These clinics routinely vaccinate hundreds of children per hour and are essential to achieving population-level protection before the end of October, when influenza transmission typically accelerates. The SCDM recommendation may lead to the removal of standing orders for influenza vaccination in some states, making these clinics functionally impossible.

38. Further, pediatric practices and health systems do not have the capacity to conduct individualized decision-making conversations with every family seeking influenza vaccination. Even conservative estimates place each discussion at three to five minutes. Requiring these conversations would dramatically reduce vaccination rates, converting a process that currently allows a single nurse to vaccinate up to twenty-five children per hour into one that reaches only a small fraction of that number. The predictable result is delayed vaccination, missed vaccination opportunities, and increased rates of influenza disease.

39. These changes also impose substantial organizational burden. Existing AAP guidance and operational resources designed to support influenza clinics were built around these types of delivery models. Those materials now require complete revision, diverting time and expertise away from patient care and preparedness.

40. I am already hearing from colleagues that families are questioning not only the vaccines affected by the schedule change, but all vaccines. Parents are asking how they can trust any medical recommendations when federal officials have changed the schedule in a way that deviates from established scientific processes. This distrust is spilling over beyond vaccines. Pediatricians are seeing increased refusal of standard newborn care, including vitamin K (which prevents internal bleeding and strokes in infants), hearing screening, and newborn screening tests

for genetic disorders. Families are expressing the view that "this is too much medicine" and are rejecting interventions that have long been the standard of care. Addressing these refusals requires extensive counseling time and increases the risk of preventable harm to infants. Claims that recommending fewer vaccines will build trust are not supported by evidence. Based on what we are seeing, the opposite is happening—trust is eroding.

41. If the February ACIP meeting is allowed to proceed, this will lead to significant disruption in pediatric practices. Pediatric practices are already facing uncertainty in vaccine ordering and inventory management as a result of ACIP meetings held from June 2025 onwards. These meetings unpredictably targeted and changed recommendations for long-standing routine vaccine recommendations, with little to no supporting scientific evidence. Prior to June 2025, ACIP meetings included public presentations from Work Groups presenting comprehensive evidence, multiple iterations of voting language, and the EtR for each vaccine recommendation, which culminated in a predictable vote at a future meeting. In contrast, this ACIP has not allowed Work Groups to present before changing a vaccine recommendation and has not been transparent about which vaccines will be deliberated on at the next meeting. As a direct result, clinicians do not know which vaccines will continue to be recommended, how schedules may change, or how patient acceptance will shift.

42. Confidence in the ACIP process itself has eroded. There is widespread uncertainty about whether future recommendations will be meaningful, whether public comment will be respected, and whether decisions are being made through a credible, science-based process. That loss of confidence will be compounded if the February ACIP meeting is allowed to occur. It will deepen uncertainty at every level of care delivery and makes it harder for clinicians to counsel families with clarity and authority.

43. Vaccines require substantial upfront financial investment, specialized storage, and careful planning. Faced with unpredictability, practices are attempting just-in-time ordering, a model that does not work for routine pediatric care. As a result, practices are running out of vaccines, and children are arriving at visits unable to receive immunizations because inventory cannot reliably match community needs. Allowing the February ACIP meeting to continue will add to this supply issue.

44. The unpredictability of ACIP has destabilized the technical infrastructure that supports vaccine delivery nationwide. Electronic health records, immunization registries, clinical decision support tools, and vaccine forecasting systems all depend on stable schedules and advance planning. These systems cannot be rapidly reconfigured in response to abrupt or unclear changes. Allowing the February ACIP meeting to continue will make reporting requirements, ordering mechanisms, and registry-based forecasting increasingly unreliable, increasing burdens on physicians and risks to patients.

45. This instability also increases the risk of clinical error. Safe vaccination depends on standardized, streamlined schedules with minimal variability. Rapidly changing guidance, which is likely to continue with the February ACIP meeting, undermines that standardization. Most pediatric offices do not have advanced technological safeguards like hospitals such as full barcode medication administration systems. When schedules and recommendations are in constant flux, the likelihood of human error by nursing and clinical staff rises, placing children at risk.

46. Given the significant misinformation and anti-vaccine rhetoric spread during the June, September, and December 2025 ACIP meetings, there is also serious concern that the February ACIP meeting will also continue to elevate individuals who promote misinformation about vaccines. When misleading or false claims are aired under the authority of ACIP,

pediatricians face more questions, more confusion, and greater doubt from families. Addressing misinformation consumes time and resources and causes moral injury to clinicians who know the science but must constantly defend it. This burden extends to nursing staff and trainees, who are increasingly questioning whether they can practice medicine consistent with their training and ethical obligations. Early-career pediatricians are expressing distress and reconsidering their commitment to pediatrics as a result. The February ACIP meeting will only serve to exacerbate these issues.

47. Recent new addition of two OB/GYNs to the ACIP heightens my fears that vaccination during pregnancy will be targeted next, potentially during the February ACIP meeting. One of these doctors has publicly stated that she is "anti-vax." Any remaining doubt that this ACIP is dominated by individuals opposed to routine vaccination is dispelled by the appointment of these new members, which decisively biases the committee further in that direction.

48. Undermining established prenatal immunization practices would have immediate and severe consequences on pediatricians. Vaccines given during pregnancy reduce serious illness, premature birth, and infant death, and they protect newborns who are too young to be immunized themselves. For example, vaccination with Tdap during pregnancy is a critical and well-established standard of care to protect infants from pertussis during the first months of life, when they are too young to be fully immunized. Maternal Tdap vaccination allows protective antibodies to pass to the fetus, significantly reducing the risk of severe pertussis infection, hospitalization, and death in newborns. Any action or messaging that undermines confidence in Tdap vaccination during pregnancy is expected to result in decreased uptake among pregnant patients. That decrease would directly increase infant vulnerability to pertussis at a time when cases, hospitalizations, and deaths are already rising. The anticipated consequences include more severely ill infants, increased

strain on pediatric and neonatal care, and preventable morbidity and mortality. In addition, erosion of trust around Tdap in pregnancy is likely to spill over into broader vaccine decision making, weakening parental confidence in infant immunization schedules from the very beginning of a child's care.

49. If the February ACIP meeting is allowed to continue with these new OB/GYN members, there is a very real possibility that the committee will vote on downgrading or removing routine recommendations for pregnant women. Trust between obstetric providers, pediatricians, and families would be further eroded, particularly for first-time parents who lack an established relationship with a pediatrician. More concerningly, pregnant women would forgo vaccination as a result, leading to increased illness in children. This harm is imminent because, for some vaccines, there is only a short window during which pregnant women may get vaccinated in order to pass immunity down to their newborns.

50. Equally damaging is what is not being addressed at ACIP meetings. Work on improving existing vaccines, expanding strain coverage, and evaluating long-term cancer prevention benefits of the HPV vaccine has stalled. Advancing protection for children requires ongoing scientific evaluation and forward-looking discussion. The absence of that work delays progress and leaves patients without the benefits of improved prevention strategies.

51. Pediatricians are being placed in an ethically untenable position. We are expected to follow a schedule that we believe is not based on science and will harm children. That causes moral distress, emotional strain, and burnout. It also increases malpractice risk. Pediatricians remain liable when children get sick, including potential exposure in clinic settings, even when those risks are increased by policy decisions outside their control.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 19, 2026 in Palm Coast, Florida.

Susan J. Kressly

Susan J. Kressly, M.D., FAAP
On behalf of the American Academy of Pediatrics

EXHIBIT A

SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN

May 19, 2025

The Department of Health and Human Services (HHS) continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available Food and Drug Administration (FDA) approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

By Secretarial Directive on June 18, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of Pfizer- BioNTech and the Moderna COVID-19 vaccines in the U.S. population for children ages six months through five years, consistent with the parameters of the Emergency Use Authorizations (EUAs) issued by FDA, for the Pfizer- BioNTech and the Moderna COVID-19 vaccines.[1]

By Secretarial Directive on June 24, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of COVID-19 vaccines in the U.S. population for children ages six through 17 years, consistent with the parameters of EUAs issued by FDA.

The CDC also currently recommends the COVID-19 vaccine during pregnancy.[2]

Based on a review of the recommendation of the FDA and National Institutes of Health (NIH), I have determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine. Accordingly, the HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years and are rescinded.

Based on a review of the recommendation of the FDA, I have similarly determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby. Therefore, the CDC recommendation that pregnant women receive the COVID-19 vaccine is rescinded.

Accordingly, the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above.

Robert F. Kennedy, Jr.
Secretary

[1] The Pfizer and Moderna vaccines are currently approved by the FDA for children 12 years of age and older.
[2] https://www.cdc.gov/vaccines-pregnancy/recommended-vaccines/index.html.

EXHIBIT B

Perspective

Vaccination of Children in the United States against COVID-19: An Ounce of Prevention

Sarah K. Wood, MD, Dennis G. Maki, MD, and Charles H. Hennekens, MD

As of October 28, 2021, the United States was the epicenter of the coronavirus disease 2019 (COVID-19) pandemic. The United States accounts for >45.6 million of the >244 million cases of COVID-19 worldwide, or 18.5% in a population of <5% of the world. Accounting for deaths, >940,000 of the >4.95 million deaths worldwide have occurred in the United States since February 2020, a death rate that exceeds that of the "Spanish" flu in 1918 to 1919. As such, deaths in the United States account for approximately 15% of all deaths from COVID-19. At present, >1 in 500 Americans have died from COVID-19.[1] Although cases and hospitalizations are decreasing, on August 15, 2021, Arkansas, Florida, Louisiana, and Mississippi were each recording >500,000 new cases per week.[2,3]

Approximately 54% of the US public are fully vaccinated—the highest rates among older adults at 85% and lowest among children at 32%.[4] Furthermore, 85% trust their healthcare providers, more than 95% of whom are vaccinated.[4] In this perspective, we provide our scientific rationale to support the urgent plea to vaccinate children and young adults who make up 27% of cases, virtually all of them among unvaccinated people, compared with 3% in 2020.[5]

Primary healthcare providers and pediatricians play major roles in the prevention and treatment of illness in US children. These circumstances have increased since January 19, 2020, when the first cases of COVID-19 were introduced into the United States by travelers from Wuhan, China, the initial epicenter of the subsequent pandemic.[6] In the United States, mitigation strategies were not performed promptly and containment strategies varied based on the responses of individual states.[7]

Primary healthcare providers and pediatricians are in a unique position to use their effective, knowledgeable, and trusted voices to educate patients and their families to increase rates of vaccination. Primary healthcare providers and pediatricians routinely administer and patients and their families routinely accept. These include vaccines against polio (92.6%), measles, mumps, and rubella (90.8%), hepatitis B (90.6%), and varicella (90.2%).[8]

Primary care providers and pediatricians should emphasize to the parents and families of children that the COVID-19 vaccines have better safety and efficacy profiles than all of the routinely administered vaccines. With respect to safety, serious adverse effects of the COVID-19 vaccine occur at an extremely low rate. In the largest and most recently published real-world study of COVID-19 vaccine safety, the authors concluded that "in contrast to the relatively small number of adverse effects associated with the vaccine, high rates of multiple serious adverse events were associated with coronavirus infection among unvaccinated patients." For example, with respect to myocarditis, the number of nonvaccinees who developed COVID-19 were 11 excess cases per 100,000 population. In contrast, vaccinees experienced 2.7 excess cases of myocarditis per 100,000, a fourfold difference. Furthermore, the rates of myocarditis were highest among men aged 20 to 34 years. The database was large, but the lower limit of age was 16. In addition, the findings may be restricted in generalizability because the patients were Israeli and the vaccine was manufactured by Pfizer.[9]

In regard to the efficacy of COVID-19 vaccines, the rates exceed 95% compared with approximately 50% of that for influenza. In addition, the mortality rate from COVID-19 is 30-fold higher, and a positive patient will transmit COVID-19 to approximately 5 to 6 other individuals compared with 1 to 2 for influenza.[10] This situation is exacerbated by the prevalence of the Delta and Omicron variants, which have even greater infectivity and virulence than the conventional strain of COVID-19. Although vaccinated patients may become positive when exposed, it is important to note that the majority of breakthrough infections are asymptomatic positive tests.

Collaborations among academicians, industry, and government previously led to vaccines for COVID-19 in adults to be developed, approved, and distributed in record time throughout the United States under emergency use authorizations by the US Food and Drug Administration (FDA). In addition, both the FDA and the Centers for Disease Control and Prevention granted full and permanent approval of the Pfizer vaccine. Moderna was launched later and was approved by the FDA on January 31, 2022.

At present, primary healthcare providers and pediatricians should emphasize to parents and other family members that among those who develop symptoms, they are less likely to experience severe infection and the virus is less transmissible to others. In addition, parents and family should be made aware that COVID-19 vaccines offer almost complete protection against hospitalization and death. Finally, they should emphasize that in randomized trials among 300 children, there were no reported cases of myocarditis.[9]

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S.K.W. has received compensation from Florida International University, the Texas Higher Education Coordinating Board and Amgen. D.G.M. did not report any financial relationships or conflicts of interest. C.H.H. has received compensation from Amgen, the British Heart Foundation, Cadila, the Canadian Institutes of Health Research, the Collaborative Institutional Training Initiative DalCor, the Food and Drug Administration, Pfizer, Regeneron, and UpToDate. He receives royalties for authorship or editorship of 3 textbooks and as co-inventor on patents for inflammatory markers and cardiovascular disease that are held by Brigham and Women's Hospital. He has an investment management relationship with the West-Bacon Group within Truist Investment Services.

Accepted November 15, 2021.

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0038-4348/0–2000/115-347

DOI: 10.14423/SMJ.0000000000001388

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On October 26, 2021, the FDA Vaccine Advisory Committee[11] and on November 2, 2021, the Centers for Disease Control and Prevention[10] recommended approval of the Pfizer vaccine for use in children 5 to 11 years of age. Although children are less likely to develop serious illnesses, among those 5 to 11 years of age, there have been >1.9 million infections, >8300 hospitalizations, and > 1500 inflammatory disorders.[10]

In the United States, the epidemic in 2021 was occurring mainly among unvaccinated individuals and in 2020 mainly among those who did not practice masking, social distancing, crowd avoidance, and frequent handwashing.[12] Primary care providers and pediatricians may wish to explain efficacy and safety to parents and families and to reinforce the possibilities for school-based efforts. For children younger than 5 years of age, randomized data on efficacy and safety are beginning to emerge suggesting that the benefit to risk ratio may not be favorable.[11] In the meantime, it is our perspective that there is a need for primary health education of parents of unvaccinated children to attempt to restrict their surroundings to vaccinated individuals who are masked.

For US children aged 5 to 18 years old, we believe that primary care providers and pediatricians face clear and achievable clinical challenges. Specifically, there is an urgent need to achieve higher vaccination rates against COVID-19 in United States children as soon as possible. The urgency derives, in part, because during the summer of 2021 pediatric hospitalizations in the United States were at their highest level at the time that generally corresponds to the nadir of the respiratory virus season. The omicron surge that occurred in the late fall of 2021 implies that herd immunity has been achieved through vaccinations and the high infection rates. Thus, continued replication of the virus will sooner or later lead to the emergence of a vaccine-resistant strain. Primary care providers and pediatricians also can educate and influence entire families at a critical moment that will decrease morbidity and mortality.

The large racial inequalities in deaths from COVID-19 have been decreasing, not because deaths in Blacks are decreasing, but because deaths in largely unvaccinated Whites are increasing, especially in children and younger adults.[13] Although the absolute risks of hospitalizations and deaths in children are low, the relative risks are highest in those US states with rates of vaccinations that are lower than the national average and mainly among people who are not vaccinated.[11]

Approximately 30% of vaccine-hesitant parents reported that they were awaiting full FDA approval before accepting vaccinations.[8] As such, it is our belief that this is an important moment for primary health providers and pediatricians to discuss with all of their patients and families the efficacy and safety of the COVID-19 vaccines. They may also wish to emphasize that in the United States >550 million doses have been administered and globally >10 billion.[13,14]

It is also our perspective to do the most good for the most patients rather than following a strategy of risk avoidance. Based on the available evidence, the benefits of COVID-19 vaccination of children aged 5 to 18 years of age outweigh the risks. Furthermore, we believe that increasing vaccination rates among children eligible to receive the COVID-19 vaccine would have major clinical and public health benefits by reducing hospitalizations and deaths. We are fortunate to live in a country where COVID-19 vaccines are so readily available and accessible and applaud the recent actions by the US government to protect our children. We hope that US primary healthcare providers and pediatricians will agree and act on this perspective, as there is a real and impending threat of increasing cases and deaths unless more children and young adults are vaccinated. Last but not least, our perspective to primary health care providers and pediatricians is to apply to parents and families of children the Benjamin Franklin axiom that "an ounce of prevention is worth a pound of cure" by increasing the vaccination rates of US children against COVID-19.

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EXHIBIT C

AAP News™



Study: Vaccines help prevent long COVID in children, adolescents

January 16, 2024

Melissa Jenco, News Content Editor

Article type: News

Topics: COVID-19, Infectious Diseases, Vaccine/Immunization

Editor's note: *For the latest news on COVID-19, visit http://bit.ly/AAPNewsCOVID19.*

COVID-19 vaccines are about 35% effective in preventing long COVID in children for a year, according to a new study.

"This study provides us with important data showing the protective effects of the vaccine against long-haul COVID and suggests that this protection is mostly from preventing visible infections," senior study author Charles Bailey, M.D., Ph.D, an academic investigator in clinical informatics at Children's Hospital Philadelphia, said in a press release. "We hope this means that as vaccines are improved to be more effective against current strains of SARS-CoV-2, their protection against long COVID will get better, too."

Experts are still trying to understand post-COVID conditions, also known as long COVID. People with long COVID may experience brain fog, shortness of breath, gastrointestinal issues, generalized pain or fatigue. The study, "Vaccine Effectiveness Against Long COVID in Children" (Razzaghi H, et al. *Pediatrics*. Jan. 16, 2024), was part of the National Institutes of Health's Researching COVID to Enhance Recovery initiative.

Researchers analyzed electronic health record data on more than 1 million children ages 5-17 years to determine how effective COVID vaccines are preventing long COVID. Just over half had received at least one vaccine dose.

Long COVID was classified as "diagnosed" if the child had two or more health care visits with diagnosis codes for long COVID. Cases were "probable" if they only had one diagnosis code, or they had two

diagnoses similar to long COVID within 6 months after a COVID infection.

About 4.5% of the cohort had probable long COVID while just under 1% had a long COVID diagnosis.

The team calculated adjusted vaccine effectiveness (VE) of 35.4% against probable or diagnosed long COVID within 12 months. Vaccine effectiveness against diagnosed long COVID was 41.7%.

Adolescents had a higher vaccine effectiveness against probable or diagnosed long COVID (50.3%) compared to children ages 5-11 years (23.8%). The adolescents were studied during both the delta and omicron era while data on younger child is only from omicron period.

Data also showed effectiveness to be higher at 6 months (61.4%) than at 12 months (35.4%) or 18 months (10.6%) post vaccine.

“Evaluations of VE over time are needed to address whether these waning effects can be overcome through booster or annual vaccine doses,” authors wrote.

A mediation analysis found the protection vaccines provide against long COVID is largely tied to preventing children from getting a COVID infection.

“These retrospective data provide guidance for additional research into the ways long COVID develops, and how we can better protect children and adolescents,” Dr. Bailey said.

The AAP and Centers for Disease Control and Prevention (CDC) recommend everyone 6 months and older get vaccinated. However, just 8% of children and 21.4% of adults have received the updated 2023-’24 vaccine, according to the CDC.

COVID hospitalizations rose 3.2% and deaths rose 14.3% during the week ending Jan. 6, 2024, compared to the previous week, according to CDC data. Wastewater testing also has found increasing viral activity.

The current vaccines, tests and treatments work against JN.1, which has become the most widely circulating COVID variant, according to the CDC. There is no evidence it causes more severe disease than other circulating variants.

Resources

- CDC webinar “Evaluating and Supporting Children and Adolescents Presenting with Post-COVID Conditions”
- American Academy of Physical Medicine and Rehabilitation guidance on diagnosis and treatment of long COVID in children and adolescents
- Information from the AAP on COVID-19 vaccines, including a dosing guide and information on payment
- *AAP News* story “Battling long COVID: Pediatricians talk strategies, prevention measures for children with lingering symptoms”
- CDC interim clinical guidance on COVID-19 vaccines
- COVID-19 vaccine checklist for children from HealthyChildren.org

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EXHIBIT D

Morbidity and Mortality Weekly Report

Interim Recommendations of the Advisory Committee on Immunization Practices for Use of Moderna and Pfizer-BioNTech COVID-19 Vaccines in Children Aged 6 Months–5 Years — United States, June 2022

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On June 28, 2022, this report was posted as an MMWR *Early Release on the* MMWR *website (https://www.cdc.gov/mmwr).*

On June 17, 2022, the Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) amendments for the mRNA-1273 (Moderna) COVID-19 vaccine for use in children aged 6 months–5 years, administered as 2 doses (25 μg [0.25 mL] each), 4 weeks apart, and BNT162b2 (Pfizer-BioNTech) COVID-19 vaccine for use in children aged 6 months–4 years, administered as 3 doses (3 μg [0.2 mL] each), at intervals of 3 weeks between doses 1 and 2 and ≥8 weeks between doses 2 and 3. On June 18, 2022, the Advisory Committee on Immunization Practices (ACIP) issued separate interim recommendations for use of the Moderna COVID-19 vaccine in children aged 6 months–5 years and the Pfizer-BioNTech COVID-19 vaccine in children aged 6 months–4 years for the prevention of COVID-19.* Both the Moderna and Pfizer-BioNTech COVID-19 vaccines met the criteria for immunobridging, which is the comparison of neutralizing antibody levels postvaccination in young children with those in young adults in whom efficacy had been demonstrated. Descriptive efficacy analyses were also conducted for both Moderna and Pfizer-BioNTech COVID-19 vaccines during the period when the Omicron variant of SARS-CoV-2 (the virus that causes COVID-19) predominated. No specific safety concerns were identified among recipients of either vaccine. ACIP recommendations for the use of the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine in children aged 6 months–5 years and 6 months–4 years, respectively, are interim and will be updated as additional information becomes available. Vaccination is important for protecting children aged 6 months–5 years against COVID-19.

The Moderna and Pfizer-BioNTech COVID-19 vaccines are lipid nanoparticle–formulated, nucleoside-modified mRNA vaccines encoding the prefusion spike glycoprotein of SARS-CoV-2. On January 31, 2022, FDA approved a Biologics License Application (BLA) for use of the Moderna COVID-19 vaccine (Spikevax, ModernaTX, Inc.) in persons aged ≥18 years, and the Moderna COVID-19 vaccine is also recommended under EUA for children and adolescents aged 6–17 years (*1*). On August 23, 2021, FDA approved a BLA for use of the Pfizer-BioNTech COVID-19 vaccine (Comirnaty, Pfizer, Inc.) in persons aged ≥16 years, and the Pfizer-BioNTech COVID-19 vaccine is also recommended under EUA for children and adolescents aged 5–15 years (*2*). Recommendations regarding products, dosing intervals, and booster doses and for persons who are moderately to severely immunocompromised, which differ from recommendations for persons without immunocompromising conditions, are available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html. As of June 17, 2022, among persons aged ≥18 years, 223 million doses of the Moderna COVID-19 vaccine have been administered in the United States, and among persons aged ≥5 years, 349 million doses of the Pfizer-BioNTech COVID-19 vaccine have been administered (*3*).

Since June 2020, ACIP has convened 28 public meetings to review data relevant to the epidemiology of COVID-19 and considerations for the use of COVID-19 vaccines, including the Moderna and Pfizer-BioNTech COVID-19 vaccines.† The ACIP COVID-19 Vaccines Work Group (Work Group), comprising experts in pediatrics, infectious diseases, vaccinology, vaccine safety, public health, and ethics, has held weekly meetings to review COVID-19 surveillance data; evidence for vaccine efficacy, postauthorization effectiveness, and safety; and implementation considerations for COVID-19 vaccines. To guide its deliberations regarding recommendations for use of these vaccines, ACIP used the Evidence to Recommendation (EtR) Framework§ and incorporated a Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.¶ Within the EtR Framework, ACIP considered the importance of COVID-19 as a public health problem, as well as parents' values and preferences, acceptability, feasibility, resource use, and equity regarding use of mRNA COVID-19 vaccines among children aged 6 months–5 years. Consistent with the age groups for each

* On June 18, 2022, ACIP voted 12 to 0 (three members absent) in favor of the interim recommendation for the use of the Moderna COVID-19 vaccine for children aged 6 months–5 years. ACIP voted 12 to 0 (three members absent) in favor of the interim recommendation for the use of the Pfizer-BioNTech COVID-19 vaccine for children aged 6 months–4 years.

† https://www.cdc.gov/vaccines/acip/meetings/index.html

§ https://www.cdc.gov/vaccines/acip/recs/grade/downloads/acip-evidence-recs-framework.pdf

¶ https://www.cdc.gov/vaccines/acip/recs/grade/about-grade.html

vaccine included under EUA, ACIP also considered, within the EtR Framework, the benefits and harms of using each vaccine (i.e., the Moderna COVID-19 vaccine among children aged 6 months–5 years and the Pfizer-BioNTech COVID-19 vaccine among children aged 6 months–4 years), independently compared with no vaccine. After conducting systematic reviews of published and unpublished evidence for benefits and harms, the Work Group used the GRADE approach to independently assess the certainty of evidence for outcomes related to the Moderna and Pfizer-BioNTech COVID-19 vaccines, rated on a scale of type 1 (high certainty) to type 4 (very low certainty).** Work Group conclusions regarding evidence for the use of Moderna COVID-19 vaccine among children aged 6 months–5 years and Pfizer-BioNTech COVID-19 vaccine among children aged 6 months–4 years were presented to ACIP at a public meeting during June 17–18, 2022.

Summary of Evidence for Use of the Moderna COVID-19 Vaccine in Children Aged 6 Months–5 Years

The body of evidence regarding immunogenicity, efficacy, and safety of the Moderna COVID-19 vaccine among children aged 6 months–5 years was guided by one randomized, double-blind, placebo-controlled phase II/III clinical trial in which 6,388 participants aged 6 months–5 years were enrolled and randomized 3:1 to receive either 2 doses of vaccine (25 μg) or saline placebo, separated by an interval of 28 days (*4*). Interim findings from this clinical trial were based on data from participants with a median blinded follow-up after dose 2 of 68 days for children aged 6–23 months and 71 days for children aged 2–5 years. Vaccine efficacy against symptomatic, laboratory-confirmed COVID-19 was supported by two types of evidence: 1) direct efficacy of 2 doses against symptomatic COVID-19, and 2) immunobridging (i.e., comparing neutralizing antibody levels in one population [e.g., young children] with antibody levels in another population [e.g., young adults] with demonstrated efficacy). Vaccine efficacy ≥14 days after dose 2 was 37.8% (95% CI = 20.9%–51.1%) in preventing symptomatic, laboratory-confirmed COVID-19†† in children aged 6 months–5 years with or without evidence of previous SARS-CoV-2 infection.§§ This estimate was based on symptomatic illness in 181 vaccine recipients and 97 placebo recipients, none of whom were hospitalized. Vaccine efficacy against symptomatic COVID-19 was also inferred based on immunobridging criteria. The measure of immune response to 2 doses (25 μg each) of the Moderna COVID-19 vaccine in children aged 6–23 months and 2–5 years without evidence of previous SARS-CoV-2 infection was at least as high as the response observed in young adults aged 18–25 years after 2 doses (100 μg each) of the Moderna COVID-19 vaccine, with a geometric mean ratio (GMR) for 50% neutralizing antibody titer of 1.28 (95% CI = 1.12–1.47) for children aged 6–23 months and 1.01 (95% CI = 0.88–1.17) for children aged 2–5 years, satisfying the noninferiority criteria¶¶ for both age groups. In addition, vaccine efficacy against asymptomatic, laboratory-confirmed SARS-CoV-2 infection*** was 16.0% (95% CI = –18.5%–40.5%) among children aged 6 months–5 years with or without evidence of previous SARS-CoV-2 infection, based on asymptomatic infection in 111 vaccine recipients and 44 placebo recipients.

Among vaccine recipients aged 6 months–5 years, reactogenicity, defined as solicited local and systemic adverse reactions during the 7 days after vaccination, were reported frequently. After dose 2, 66.1% of caregivers reported any local reaction among the child vaccine recipients after vaccination, and 65.9% reported any systemic reaction; most reactions were mild to moderate with symptom onset 1–2 days after vaccination and resolving after 2–3 days. Reactogenicity was usually less frequent in children aged 6 months–5 years than in those aged 6–11 years. Among children aged 6 months–5 years, severe local and systemic adverse reactions (grade 3 or higher, defined as interfering with daily activity) occurred in 7.7% of vaccine recipients, more commonly after dose 2, and in 4.1% of placebo recipients. The most common grade 3 or higher local symptom reported by vaccine recipients after dose 2 was pain at the injection site (0.4%). The most commonly reported reactions of grade 3 or higher after dose 2 were fever (2.6%) and irritability or crying (1.2%) among vaccine recipients aged 6–36 months and fever (3.1%) and fatigue (2.3%) among those aged 37 months–5 years. Serious adverse events††† were

** https://www.cdc.gov/vaccines/acip/recs/grade

†† In the Moderna COVID-19 vaccine clinical trial, symptomatic, laboratory-confirmed COVID-19 was defined based on the CDC case definition, which required at least one clinical symptom (fever ≥100.4°F [≥38°C], chills, fatigue, headache, myalgia, nasal congestion or rhinorrhea, new loss of taste or smell, sore throat, abdominal pain, diarrhea, nausea or vomiting, poor appetite or poor feeding, cough, or shortness of breath or difficulty breathing), and a positive COVID-19 test result using reverse transcription–PCR (RT-PCR).

§§ In the Moderna COVID-19 vaccine clinical trial, approximately 10% of children aged 6 months–5 years were seropositive, indicating previous SARS-CoV-2 infection, at baseline.

¶¶ Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR is >0.67 and the point estimate of GMR is ≥0.8.

*** In the Moderna COVID-19 vaccine clinical trial, asymptomatic SARS-CoV-2 infection was identified by absence of symptoms and at least one of the following conditions: 1) binding antibody level against SARS-CoV-2 nucleocapsid protein negative at baseline (or day 1) that became positive post-baseline (testing performed only on the immunogenicity subset [494]), or 2) a positive COVID-19 test result using RT-PCR post-baseline at a scheduled (29 days after dose 2) or unscheduled visit.

††† Serious adverse event is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability or incapacity, or is a congenital anomaly or birth defect. Serious adverse events occurring after dose 1 or dose 2 were reported.

uncommon and occurred with similar frequency among vaccine (0.5%) and placebo (0.2%) recipients, with no statistically significant difference in frequency. Two serious adverse events in one participant were determined to be potentially related to vaccination.[§§§] No specific safety concerns were identified among vaccine recipients aged 6 months–5 years. A detailed summary of safety data, including information on reactogenicity, is available at https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/reactogenicity.html.

From the GRADE evidence assessment, the level of certainty for the benefits of Moderna COVID-19 vaccination among children aged 6 months–5 years was type 1 (high certainty) for the prevention of symptomatic laboratory-confirmed COVID-19 assessed using direct efficacy and type 2 (moderate certainty) assessed using immunobridging, because of serious concerns for indirectness, because immunogenicity is a surrogate measure of efficacy. The level of certainty for prevention of asymptomatic SARS-CoV-2 infection was type 3 (low certainty) because of serious concerns of indirectness, because serial SARS-CoV-2 polymerase chain reaction (PCR) testing was not performed, and serology was only performed for a subset of participants[¶¶¶]; serious concerns of imprecision were also noted because of the width of the 95% CI. Regarding potential harms after vaccination, evidence was type 4 (very low certainty) for serious adverse events because of short follow-up time (median = 68 and 71 days after dose 2 for children aged 6–23 months and 2–5 years, respectively), study size, and the width of the 95% CI. Evidence was type 1 (high certainty) for reactogenicity. No data were available to assess the other GRADE benefits, including prevention of COVID-19–associated hospitalization or multisystem inflammatory syndrome in children (MIS-C).

Summary of Evidence for Use of the Pfizer-BioNTech COVID-19 Vaccine in Children Aged 6 Months–4 Years

The body of evidence regarding immunogenicity, efficacy, and safety of the Pfizer-BioNTech COVID-19 vaccine among children aged 6 months–4 years was composed of data from one randomized, double-blind, placebo-controlled phase II/III clinical trial in which 4,526 participants aged 6 months–4 years were enrolled and randomized 2:1 to receive either vaccine or saline placebo (*5*). The protocol initially specified 2 doses of vaccine (3 μg) or saline placebo separated by an interval of 3 weeks. Per protocol, participants were unblinded 6 months after dose 2 or at age 5 years (whichever occurred first). Based on an interim analysis where the predefined criteria for immunobridging and efficacy of the trial were not met after 2 doses, a protocol amendment was implemented on February 1, 2022, to include a third dose of either vaccine (3 μg) or saline placebo, administered ≥56 days after dose 2. Dose 3 was offered to blinded and unblinded participants in the vaccine arm, and blinded participants in the placebo arm were offered a third dose of placebo. Among trial participants, 1,456 (32.2%) received a blinded third dose and were included in a 3-dose efficacy analysis (992 in the vaccine arm and 464 in the placebo arm). The median interval between doses 2 and 3 was 16 weeks among children aged 6–23 months and 11 weeks among children aged 2–4 years. Safety analyses included blinded participants and assessed outcomes starting at dose 1. Interim findings from this clinical trial were based on data from participants with a median blinded follow-up of 35 days after dose 3 for children aged 6–23 months and 40 days for children aged 2–4 years.

Vaccine efficacy was supported by two types of evidence: 1) direct efficacy of 3 doses against symptomatic laboratory-confirmed COVID-19[****] and 2) immunobridging data. Vaccine efficacy ≥7 days after dose 3 was 80.0% (95% CI = 22.8%–94.8%)[††††] in preventing symptomatic, laboratory-confirmed COVID-19 in children aged 6 months–4 years with and without evidence of previous SARS-CoV-2 infection,[§§§§] based on infection in three vaccine recipients and seven placebo recipients, none of whom were hospitalized. In the immunobridging analysis, the measure of immune response to 3 doses (3 μg each) of the Pfizer-BioNTech COVID-19 vaccine in children aged 6 months–4 years without evidence of previous SARS-CoV-2 infection was at least as high as the response observed in persons aged 16–25 years who had received 2 doses (30 μg each) of the Pfizer-BioNTech COVID-19 vaccine, with a GMR for 50% neutralizing

[§§§] One recipient in the Moderna COVID-19 vaccine clinical trial experienced two serious adverse events (i.e., fever and febrile seizure) that the investigator and FDA determined to be potentially related to the vaccine.

[¶¶¶] The definition of asymptomatic SARS-CoV-2 infection specified for GRADE: SARS-CoV-2 infection with no reported symptoms identified through 1) serial RT-PCR testing, or 2) testing of binding antibody level against SARS-CoV-2 nucleocapsid protein, on the entire cohort or a representative sample.

[****] In the Pfizer-BioNTech COVID-19 vaccine clinical trial, symptomatic laboratory-confirmed COVID-19 was defined based on the CDC case definition, which required at least one clinical symptom (fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, vomiting, and inability to eat or poor feeding), and a positive SARS-CoV-2 nucleic acid amplification test result within 4 days of the symptomatic period.

[††††] For GRADE, relative risks (RR) were calculated from numerators and denominators available in the body of evidence. Vaccine efficacy estimates were defined as 100% x (1–RR). Manufacturer vaccine efficacy estimates were calculated using incident rate ratios. Based on the Pfizer-BioNTech COVID-19 vaccine clinical trial analysis, the vaccine efficacy against symptomatic SARS-CoV-2 infection was 80.3% (95% CI = 13.9%–96.7%).

[§§§§] In the Pfizer-BioNTech COVID-19 vaccine clinical trial, approximately 30% of children aged 6 months–4 years were seropositive, indicating a previous SARS-CoV-2 infection, before dose 3.

antibody titer of 1.19 (95% CI = 1.00–1.43) for children aged 6–23 months and 1.30 (95% CI = 1.13–1.50) for children aged 2–4 years, satisfying the noninferiority criteria[¶¶¶¶] for both age groups.

Among vaccine recipients aged 6 months–4 years, reactogenicity, defined as solicited local injection site or systemic signs or symptoms during the 7 days after vaccination, were common (47.8% reported any local reaction, and 63.8% reported any systemic reaction); most reactions were mild to moderate. Local and systemic reactogenicity symptoms were usually less frequent in children aged 6 months–4 years (63.8%) than in children aged 5–11 years (86.2%) (*6*). Severe local and systemic adverse reactions (grade 3 or higher, defined as interfering with daily activity) occurred in 4.3% and 3.6% of vaccine recipients and placebo recipients, respectively. The most commonly reported reactions of grade 3 or higher among vaccine recipients aged 6–23 months were fever (4.0%) and irritability (1.3%), and among recipients aged 2–4 years, were fatigue (0.8%) and fever (2.2%). Overall, reactions of grade 3 or higher were also more commonly reported after the second dose than after the first or third dose. Serious adverse events[*****] were uncommon and occurred with similar frequency among recipients of vaccine (1.0%) and placebo (1.5%), with no statistically significant difference in frequency. Two serious adverse events in one participant in the vaccinated group were determined to be potentially related to vaccination.[†††††] No specific safety concerns were identified among vaccine recipients aged 6 months–4 years. A detailed summary of safety data, including information on reactogenicity, is available at https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/reactogenicity.html.

From the GRADE evidence assessment, the level of certainty for the benefits of Pfizer-BioNTech COVID-19 vaccination among children aged 6 months–4 years was type 4 (very low certainty) for the prevention of symptomatic laboratory-confirmed COVID-19 assessed using direct efficacy because of serious concern about the short duration of follow-up (median = 35 and 40 days for children aged 6–23 months and 2–4 years, respectively) and very serious concerns about imprecision because of case accrual and study size. For the prevention of symptomatic, laboratory-confirmed COVID-19 assessed using immunobridging, the evidence was type 2 (moderate certainty) because of serious concerns for indirectness, because immunogenicity is a surrogate measure of efficacy. Regarding potential harms after vaccination, the evidence was type 4 (very low certainty) for serious adverse events because of very serious concerns for indirectness because of the short duration of follow-up of 1 month after dose 3 and because only 31% of trial participants received dose 3, limiting the ability to detect serious adverse events that might occur at a higher rate after dose 3, and serious concern of imprecision because of the study size. For reactogenicity, the evidence was type 2 (moderate certainty) because of serious concern for indirectness, as only 31% of trial participants received dose 3, limiting the ability to detect severe reactogenicity that might occur specifically after dose 3. No data were available to assess the other GRADE benefits, specifically prevention of COVID-19–associated hospitalization, MIS-C, or asymptomatic SARS-CoV-2 infection.

[¶¶¶¶] Noninferiority is declared if the lower bound of the 2-sided 95% CI for the GMR >0.67 and the point estimate of GMR is ≥0.8.

[*****] Serious adverse event is defined as any untoward medical occurrence that results in death, is life threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent disability or incapacity, or is a congenital anomaly or birth defect. Serious adverse events occurring after dose 1, dose 2, or dose 3 were reported.

[†††††] One recipient in the Pfizer-BioNTech COVID-19 vaccine clinical trial had two serious adverse events (i.e., fever and pain in extremity requiring hospitalization) that the investigator and FDA determined to be potentially related to the vaccine. FDA noted that the events were also consistent with viral myositis.

Recommendations for the Use of the Moderna COVID-19 Vaccine in Children Aged 6 Months–5 Years and the Pfizer-BioNTech COVID-19 Vaccine in Children Aged 6 Months–4 Years

Data reviewed with the EtR Framework supported the use of COVID-19 vaccine in children aged 6 months–5 years. COVID-19 is a major public health problem among young children. As of June 12, 2022, approximately 2 million COVID-19 cases, 20,000 hospitalizations, and 200 deaths from COVID-19 have been reported among U.S. children aged 6 months–4 years (*7*,*8*). The SARS-CoV-2 Omicron variant emerged in the United States in December 2021 and led to the highest COVID-19 incidence, rates of COVID-19–associated emergency department visits and COVID-19–associated hospitalization among children aged 6 months–4 years yet seen during the pandemic (*9*). Approximately one half (51%–54%) of children aged 6 months–4 years with a COVID-19–associated hospitalization had no underlying health conditions, highlighting the risk for severe COVID-19 even among young children without underlying health conditions (*9*). During the period of Omicron predominance, illness among children aged 6 months–4 years with COVID-19–associated hospitalizations was as severe or more severe than that among children and adolescents aged 5–17 years, who were eligible for COVID-19 vaccination during that period (*9*). Furthermore, COVID-19 hospitalization rates among children aged 6 months–4 years during October 2021–April 2022 were as high or higher than were influenza-associated hospitalization rates during the 2017–18, 2018–19, and 2019–20 influenza seasons (*10*).

SARS-CoV-2 can also lead to complications after acute infection. MIS-C is a severe illness in persons aged <21 years that occurs 2–6 weeks after SARS-CoV-2 infection and is characterized by fever, multisystem organ involvement, and laboratory evidence of inflammation (*11*). As of May 31, 2022, CDC has received 8,525 reports of cases of MIS-C in the United States, including 69 deaths (*12*); children aged 6 months–4 years account for 1,990 (23%) of these cases and 9 (13%) of the deaths among MIS-C cases (*9*). Post–COVID-19 conditions, which include a range of new, returning, or ongoing, health problems occurring ≥4 weeks after acute SARS-CoV-2 infection, also occur in children, including those aged <5 years (*13*–*15*). However, evidence regarding the prevalence and spectrum of these conditions in children, especially young children, is limited by the inability of younger children to verbalize symptoms, few studies that include children, lack of appropriate control groups, and because symptoms similar to those seen in post–COVID-19 conditions are frequently reported among children without known SARS-CoV-2 infection (*13*,*14*,*16*).

The pandemic has also had additional indirect effects on children and families, including missed routine childhood immunizations and health care visits; worsening of children's social, emotional, and mental well-being; and disruptions in early child care and education programs (*17*–*19*). In a survey conducted during July 15–August 2, 2021, 39% of parents reported that an adult in their household either left a job or changed work schedules to care for children during the past year; parents of a child aged <5 years, Black and African American parents, Hispanic or Latino parents, and parents with an annual household income of <$40,000 were most likely to report household job disruptions (*20*). COVID-19 vaccination in this age group may provide parents with increased confidence to return to prepandemic activities, improving social interactions in young children.

Implementation of these recommendations will require educating vaccine providers about the correct age-appropriate product (Table 1) and vaccination schedule (Table 2) for each vaccine, to avoid vaccine administration errors. ACIP determined that use of the Moderna and Pfizer-BioNTech COVID-19 vaccines among children is a reasonable and efficient allocation of resources. To expand COVID-19 vaccine access, additional considerations should be given to demographic groups that have experienced disproportionate COVID-19 morbidity and mortality, as well as those with barriers to routine health care (e.g., members of certain racial and ethnic groups and those living in a rural area, experiencing homelessness, or lacking health insurance). Children from racial and ethnic minority groups have experienced a disproportionately high incidence of COVID-19, associated hospitalization, and MIS-C (*7*,*12*,*21*). Pediatricians and health care providers remain the most trusted source among parents for information about COVID-19 vaccines for children (*22*). Based on the National Immunization Survey-Child COVID Module interviews conducted in May 2022, 33.5% of parents said they would definitely vaccinate their child aged 6 months–4 years for COVID-19, once eligible, and 19.6% said they would probably vaccinate their child aged 6 months–4 years (*7*). Thus, pediatricians and other primary care providers who care for children will be critical to increasing COVID-19 vaccine confidence among parents and coverage with COVID-19 vaccine among young children.

ACIP reviewed the balance of known and potential benefits and risks regarding the use of the Moderna COVID-19 vaccine in children aged 6 months–5 years and Pfizer-BioNTech COVID-19 vaccine in children aged 6 months–4 years, each compared with no vaccine. Both vaccines demonstrated ability to prevent COVID-19 and met noninferiority criteria based on immunobridging data. Although both the Moderna and Pfizer-BioNTech COVID-19 vaccine trials were conducted when Omicron was the predominant circulating SARS-CoV-2 variant, case accrual after the final dose occurred in different months, resulting in differences in COVID-19 incidence across the trials. Thus, efficacy estimates cannot be directly compared between these two vaccines. Moreover, vaccine efficacy from these trials should be interpreted in the context of what is known about vaccine effectiveness against Omicron infection. Postauthorization observational studies in persons aged ≥5 years have demonstrated that the vaccine effectiveness against Omicron infection is lower than that observed against earlier SARS-CoV-2 variants (*23*,*24*). However, postauthorization observational data also indicate that mRNA vaccine effectiveness is higher, even during Omicron predominance, against hospitalization (68% a median of 37 days after the second dose in children aged 5–11 years) than against infection (40% during the 2 months after the second dose in children aged 5–11 years) (*25*). Importantly, during Omicron predominance, mRNA vaccine effectiveness against MIS-C remained high (78%) among children aged 5–11 years (*25*). The clinical trials were not powered to detect efficacy against severe disease in young children, but similar patterns are expected in this age group to what has been observed in persons aged ≥5 years.

ACIP also considered evidence from known and potential harms from COVID-19 vaccines. Myocarditis and pericarditis are rare adverse events that have been reported after receipt of mRNA COVID-19 vaccines (*26*,*27*). Among vaccine recipients aged ≥5 years, the observed risk for myocarditis is highest among males aged 12–39 years (*26*,*28*,*29*). Cases of myocarditis among children aged 5–11 years after Pfizer-BioNTech COVID-19 vaccination have been rarely reported, primarily in boys and after dose 2 (*28*,*29*). To date, monitoring in CDC's

TABLE 1. COVID-19 vaccines approved or authorized by the Food and Drug Administration for children aged 6 months–17 years — United States, June 2022

Vaccine manufacturer	Age group at vaccination	Vial cap color	Label border color	Concentration of mRNA per primary dose	Injection volume per primary dose	Diluent volume	Primary doses per vial
Moderna	6 mos–5 yrs	Dark blue	Magenta	25 μg	0.25 mL	None	10
	6–11 yrs	Dark blue	Purple*	50 μg	0.5 mL	None	5
	6–11 yrs	Dark blue	Teal*	50 μg	0.5 mL	None	5
	12–17 yrs	Red	Light blue	100 μg	0.5 mL	None	10–11
Pfizer-BioNTech	6 mos–4 yrs	Maroon	Maroon	3 μg	0.2 mL	2.2 mL	10†
	5–11 yrs	Orange	Orange	10 μg	0.2 mL	1.3 mL	10†
	12–17 yrs	Gray	Gray	30 μg	0.3 mL	None	6

Abbreviation: FDA = Food and Drug Administration.

* Moderna COVID-19 vaccine supplied in a vial with a dark blue cap and a label with a teal border stating "Age 6y through 11y" is currently not available. Moderna COVID-19 vaccine supplied in a vial with a dark blue cap and a label with a purple border stating "BOOSTER DOSES ONLY" is FDA-authorized for use in children aged 6–11 years to provide primary series doses.

† After dilution with 0.9% sodium chloride (normal saline, preservative-free).

Vaccine Safety Datalink have not detected an increased risk for myocarditis and pericarditis in children aged 5–11 years (*29*). No cases of myocarditis occurred among 7,804 children aged 6 months–5 years in the Moderna and Pfizer-BioNTech COVID-19 vaccine clinical trials who received an mRNA vaccine and had ≥7 days of follow-up, although the trials were not adequately powered to detect rare adverse events. Postauthorization safety monitoring, including monitoring for myocarditis and pericarditis after mRNA COVID-19 vaccination, is conducted through multiple national safety surveillance systems.

ACIP determined that the benefits of COVID-19 vaccination outweigh the known and potential risks, even in the setting of high seroprevalence among young children; by April 2022, in a national sample of children aged 6 months–4 years, 71% had infection-induced SARS-CoV-2 antibodies (*9*). Past infection with SARS-CoV-2 provides some protection against reinfection, but the immune response to infection can vary, especially by disease severity, and might not provide broad protection against all SARS-CoV-2 variants (*30*). The Omicron-wave surges of pediatric COVID-19 hospitalizations occurred even in the setting of high seroprevalence, suggesting this alone is not sufficient to provide broad population-level protection. Vaccination in previously infected persons enhances protection against reinfection (*30*–*32*) and COVID-19–associated hospitalization, including infections and hospitalizations due to the Omicron variant (*32*,*33*). No concerns have been identified in postauthorization safety surveillance associated with vaccination of seropositive persons aged ≥5 years. After assessing the balance of benefits and risks for COVID-19 vaccination, ACIP made an interim recommendation for vaccination with the Moderna COVID-19 vaccine for children aged 6 months–5 years as a 2-dose primary series as authorized under the EUA and an interim recommendation for vaccination with the Pfizer-BioNTech COVID-19 vaccine for children aged 6 months–4 years as a 3-dose primary series as authorized under the EUA. ACIP does not state a product preference between the two recommended vaccines for children aged 6 months–5 years; children may receive any ACIP-recommended COVID-19 vaccine and are encouraged to receive the earliest vaccine available to them. Once a primary series is started, the same mRNA vaccine product should be used for all doses in the series.

The GRADE evidence profiles, which provide details on the identification and assessment of relevant evidence, are available for the Moderna COVID-19 vaccine at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-vaccine-6-months-5-years.html and for the Pfizer-BioNTech COVID-19 vaccine at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine-6-months-4-years.html. The EtR supporting evidence for both the Moderna COVID-19 vaccine and the Pfizer-BioNTech COVID-19 vaccine is available at https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-moderna-pfizer-children-vaccine-etr.html. Additional clinical considerations, including recommendations for children who are moderately or severely immunocompromised, are available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

These interim recommendations and clinical considerations are based on use of the Moderna COVID-19 vaccine under an EUA and on the Pfizer-BioNTech COVID-19 vaccine under an EUA and might change as more evidence becomes available. COVID-19 vaccines must be administered according to applicable state and territorial vaccination laws. Before vaccination, the EUA Fact Sheet (available at https://www.fda.gov/media/159309/download for the Moderna COVID-19 vaccine and https://www.fda.gov/media/159313/download for the Pfizer-BioNTech COVID-19 vaccine) should be provided to parents or guardians. ACIP will continue to review additional data as they become available; updates to recommendations or clinical considerations will be posted on the ACIP website (https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html).

TABLE 2. Interim COVID-19 immunization schedule for children aged 6 months–17 years — United States, June 2022

Vaccine manufacturer*	Age group at vaccination	Immunocompromise status: Not moderately or severely immunocompromised† — Primary series§	Not moderately or severely immunocompromised† — Booster dose	Moderately or severely immunocompromised† — Primary series	Moderately or severely immunocompromised† — Booster doses
Moderna	6 mos–5 yrs	2 doses 4–8 weeks between doses 1 and 2	Not authorized	3 doses 4 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	Not authorized
	6–11 yrs	2 doses 4–8 weeks between doses 1 and 2	Not authorized	3 doses 4 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	Not authorized
	12–17 yrs	2 doses 4–8 weeks between doses 1 and 2	Not authorized	3 doses 4 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	Not authorized
Pfizer-BioNTech	6 mos–4 yrs	3 doses 3–8 weeks between doses 1 and 2; ≥8 weeks between doses 2 and 3	Not authorized	3 doses 3 weeks between doses 1 and 2; ≥8 weeks between doses 2 and 3	Not authorized
	5–11 yrs	2 doses 3–8 weeks between doses 1 and 2	≥5 mos after primary series	3 doses 3 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	≥3 mos after primary series
	12–17 yrs	2 doses 3–8 weeks between doses 1 and 2	≥5 mos after primary series	3 doses 3 weeks between doses 1 and 2; ≥4 weeks between doses 2 and 3	2 booster doses First: ≥3 mos after primary series Second: ≥4 mos after first booster

Abbreviation: FDA = Food and Drug Administration.

* More information on product and dosage is available at https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html.

† https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

§ mRNA COVID-19 vaccines are FDA-approved or FDA-authorized for a 3-week (Pfizer-BioNTech vaccine) or 4-week (Moderna vaccine) interval between the first and second dose. CDC recommends that an 8-week interval might be optimal for some persons aged 6 months–64 years, especially for males aged 12–39 years because it might reduce the small risk of myocarditis or pericarditis associated with mRNA COVID-19 vaccines. A shorter interval (3 weeks for Pfizer-BioNTech and 4 weeks for Moderna) between the first and second doses remains the recommended interval for persons who are moderately or severely immunocompromised, adults aged ≥65 years, and those in situations in which there is increased concern about COVID-19 community levels or a person's higher risk for severe disease.

Reporting of Vaccine Adverse Events

FDA requires that vaccination providers report vaccination administration errors, serious adverse events, multisystem inflammatory syndrome cases, and COVID-19 cases that result in hospitalization or death after administration of COVID-19 vaccine under an EUA. Adverse events that occur after receipt of any COVID-19 vaccine should be reported to the Vaccine Adverse Events Reporting System (VAERS). Information on how to submit a report to VAERS is available at https://vaers.hhs.gov/index.html or 1-800-822-7967. Any person who administers or receives a COVID-19 vaccine (or their parent or guardian) is encouraged to report any clinically significant adverse event, whether it is clear that a vaccine caused the adverse event. In addition, CDC has developed a voluntary smartphone-based online tool (v-safe) that uses text messaging and online surveys to provide near real-time health check-ins after receipt of a COVID-19 vaccine. Parents or guardians can register their children in v-safe and complete

Summary

What is already known about this topic?

On June 17, 2022, the Food and Drug Administration granted Emergency Use Authorization for the Moderna and Pfizer-BioNTech COVID-19 vaccines for children aged 6 months–5 years and 6 months–4 years, respectively.

What is added by this report?

On June 18, 2022, the Advisory Committee on Immunization Practices (ACIP) issued interim recommendations for the use of the Moderna COVID-19 vaccine for children aged 6 months–5 years and for the Pfizer-BioNTech COVID-19 vaccine for children aged 6 months–4 years in the United States for prevention of COVID-19. ACIP determined that the benefits of vaccination outweigh risks for this population.

What are the implications for public health practice?

Vaccination is important for protecting children aged 6 months–5 years against COVID-19.

the health surveys on their behalf. CDC's v-safe call center follows up on reports to v-safe that include possible medically significant health events to collect additional information for completion of a VAERS report. Information about v-safe is available at https://www.cdc.gov/vsafe.

Acknowledgments

LeAnne M. Fox, Matthew Oster, Naomi Tepper, CDC; Karen Broder, Tom Shimabukuro, John Su, CDC Immunization Safety Office, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Diseases, CDC. Members of the CDC Advisory Committee on Immunization Practices clinical guidelines team: Mary Chamberland, Laura Daniel, Megan Freedman, Susan Goldstein, Joy Hsu, Valerie Morelli, Tamara Pilishvili, Hannah Rosenblum, JoEllen Wolicki. Voting members of the Advisory Committee on Immunization Practices: Kevin A. Ault, University of Kansas Medical Center; Lynn Bahta, Minnesota Department of Health; Beth P. Bell, University of Washington; Oliver Brooks, Watts HealthCare Corporation and past president, National Medical Association; Wilbur Chen, University of Maryland School of Medicine; Sybil Cineas, Warren Alpert Medical School of Brown University; Matthew Daley, Kaiser Permanente Colorado; Camille N. Kotton, Massachusetts General Hospital and Harvard Medical School; Grace M. Lee, Lucile Packard Children's Hospital and Stanford University School of Medicine; James Loehr, Cayuga Family Medicine; Sarah Long, Drexel University College of Medicine; Veronica V. McNally, Franny Strong Foundation; Katherine A. Poehling, Wake Forest University School of Medicine; Pablo J. Sánchez, The Research Institute at Nationwide Children's Hospital; H. Keipp Talbot, Vanderbilt University School of Medicine. Members of the Advisory Committee on Immunization Practices COVID-19 Vaccines Work Group (in addition to listed authors): Edward Belongia, Center for Clinical Epidemiology & Population Health, Marshfield Clinic Research Institute; Henry Bernstein, Cohen Children's Medical Center, Zucker School of Medicine at Hofstra/Northwell; Dayna Bowen Matthew, George Washington University Law School; Uzo Chukwuma, Indian Health Service; Marci Drees, Society for Healthcare Epidemiology of America; Jeffrey Duchin, Infectious Diseases Society of America; Doran Fink, Food and Drug Administration; Sandra Fryhofer, American Medical Association; Jason M. Goldman, American College of Physicians; Michael Hogue, American Pharmacists Association; Denise Jamieson, American College of Obstetricians and Gynecologists; Jeffrey Kelman, Centers for Medicare & Medicaid Services; David Kim, U.S. Department of Health and Human Services; Kathy Kinlaw, Center for Ethics, Emory University; Susan Lett, Council of State and Territorial Epidemiologists; Lauri Markowitz, CDC; Kendra McMillan, American Nurses Association; Kathleen Neuzil, Center for Vaccine Development and Global Health, University of Maryland School of Medicine; Sean O'Leary, American Academy of Pediatrics; Christine Oshansky, Biomedical Advanced Research and Development Authority, U.S. Department of Health and Human Services; Stanley Perlman, Department of Microbiology and Immunology, Carver College of Medicine, University of Iowa; Marcus Plescia, Association of State and Territorial Health Officials; Chris Roberts, National Institutes of Health; William Schaffner, National Foundation for Infectious Diseases; Rob Schechter, Association of Immunization Managers; Kenneth Schmader, American Geriatrics Society; Bryan Schumacher, U.S. Department of Defense; Peter Szilagyi, University of California, Los Angeles; Jonathan Temte, American Academy of Family Physicians; Matthew Tunis, National Advisory Committee on Immunization Secretariat, Public Health Agency of Canada; Melinda Wharton, CDC; Matthew Zahn, National Association of County and City Health Officials; Rachel Zhang, Food and Drug Administration.

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All authors have completed and submitted the International Committee of Medical Journal Editors form for disclosure of potential conflicts of interest. No potential conflicts of interest were disclosed.

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EXHIBIT E

AAP News™



CDC approves COVID-19 vaccines for children under 5; vaccinations could begin this week

June 18, 2022

Steve Schering, Staff Writer

Article type: News

Topics: COVID-19, Infectious Diseases, Vaccine/Immunization

***Editor's note**: For the latest news on COVID-19, visit* http://bit.ly/AAPNewsCOVID19.

About 20 million U.S. children under 5 years old are eligible to receive a COVID-19 vaccine as early as next week following approval from the Centers for Disease Control and Prevention (CDC) Saturday afternoon.

The CDC's Advisory Committee on Immunization Practices (ACIP) voted 12-0 to recommend Moderna COVID-19 vaccine for children ages 6 months through 5 years and Pfizer-BioNTech vaccine for children ages 6 months through 4 years.

Shortly afterward, CDC Director Rochelle P. Walensky, M.D., M.P.H., gave final approval for both vaccines, which were granted emergency use authorization from the Food and Drug Administration Friday.

The AAP released an updated policy statement Saturday recommending that all eligible infants, children and adolescents without contraindications get vaccinated.

"Pediatricians know the power of vaccines to protect infants, children, adolescents and entire communities against deadly and debilitating infectious diseases," Yvonne "Bonnie" A. Maldonado, M.D., FAAP, chair of the AAP Committee on Infectious Diseases, said during the ACIP meeting. "We've successfully immunized millions of children and adolescents to protect them from COVID-19. Families with infants and toddlers need and deserve the same chance to protect their children against the virus."

Vaccine administration

The Moderna vaccine will be available to children ages 6 months through 5 years as a primary series of two 25-microgram (µg) doses administered four to eight weeks apart. Children who are moderately or severely immunocompromised can receive three doses, each given four weeks apart.

The Pfizer-BioNTech vaccine will be available to children ages 6 months through 4 years as a primary series of three 3-µg doses. Dose 1 and dose 2 should be administered three to eight weeks apart, while the third dose should be given at least eight weeks after the second dose. Immunocompromised children should receive a second dose four weeks after the first dose, and dose 3 should be given at least four weeks after dose 2.

Among children, COVID-19 vaccine induces a broader neutralizing antibody response when compared with infection-induced immunity. In contrast with SARS-CoV-2 infection, children vaccinated with two doses demonstrated higher titers against alpha, beta, gamma, delta and omicron variants. Officials say the data show the importance of vaccinating children with prior infection to prevent both severe disease and future infections.

Vaccine rollout

Children should receive the age-appropriate vaccine formulation and follow the schedule based on their age on the day of vaccination, regardless of their size or weight. Children who move from the younger age group to an older age group during the primary series or between the primary series and receipt of the booster dose(s) should receive the vaccine dosage for the older age group for all subsequent doses.

The same mRNA vaccine product should be used for all primary series doses. In accordance with general best practices from ACIP, routine administration of all age-appropriate vaccines simultaneously is recommended for children for whom no specific contraindications exist at the time of the health care visit.

While some children over 5 years old were vaccinated at school and community clinics, experts said physicians are likely to be the leaders in vaccinating children under 5.

The Moderna vaccine for children ages 6 months through 5 years will ship with a magenta label, contains a new National Drug Code and does not require diluent.

The Pfizer-BioNTech vaccine will ship with a maroon cap, with a new National Drug Code and a different amount of diluent added (2.2 milliliters vs. 1.3 milliliters for doses given to children ages 5-11 years). While the vaccine label says “Age 2y to < 5y,” officials said the vaccine can be used in children as young as 6 months. The label also states the vaccine must be discarded six hours after dilution, but officials said the vaccine may be discarded 12 hours after dilution.

Both products come in cartons containing 10 vials that each have 10 doses (100 doses total) with a minimum order quantity of 100 doses per product. While providers may be hesitant to open new vials, officials said getting as many children vaccinated as possible is the priority, noting no opportunity should be missed.

“It’s extremely important that we get this vaccine now and there will be waste, we understand that, but it’s important to get shots in the arms and take advantage of every opportunity. Don’t feel guilty about having to open a vial to administer two doses or one dose,” said José R. Romero, M.D., FAAP, director of the CDC’s National Center for Immunization and Respiratory Diseases.

Clinical trials

Moderna's clinical trial was conducted from December 2021 through February 2022 and involved 6,400 children. No deaths occurred among trial participants, and no cases of myocarditis/pericarditis or vaccine-associated anaphylaxis were reported.

Pfizer-BioNTech's vaccine clinical trial included 3,000 children and was conducted from June 2021 through April 2022. Initially, it involved review of a two-dose series, but the company soon began studying a three-dose primary series.

No deaths were reported in any trial participants, and serious adverse events (SAEs) were rare overall. SAEs occurred in 1% of vaccine recipients and 1.5% of placebo receipts. No cases of myocarditis/pericarditis or vaccine-associated anaphylaxis were reported.

COVID-19 in children

Between March 1, 2020, and April 30, 2022, 269 children younger than 1 year and 134 children ages 1-4 years died as a result of COVID-19.

More than 2 million cases of COVID-19 have been reported among children ages 6 months through 4 years. Children in this age group are at risk of severe illness from COVID-19, and more than half of all hospitalized children ages 6 months through 4 years had no underlying conditions.

Resources

- CDC's Pediatric COVID-19 Vaccination Operational Planning Guide
- AAP COVID vaccination resources
- CDC clinical considerations for administering COVID-19 vaccines
- Information from HealthyChildren.org: What Should Parents Know About the COVID Vaccine for Kids Under 5?
- CDC information on U.S. COVID-19 products

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EXHIBIT F



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Immunization Schedules

June 24, 2025

The evidence-based Child and Adolescent Immunization Schedule endorsed by the American Academy of Pediatrics in November 2024 can be found here.

The Child and Adolescent Immunization Schedule, published by the CDC, which is not currently endorsed by the AAP, can be found at https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

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Article type: Resources

Topics: Vaccine/Immunization

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger

UNITED STATES 2025

Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody (Nirsevimab)	RSV-mAb	Beyfortus
Vaccine	**Abbreviation(s)**	**Trade name(s)**
COVID-19 vaccine	1vCOV-mRNA	Comirnaty/Pfizer-BioNTech COVID-19 Vaccine
		Spikevax/Moderna COVID-19 Vaccine
	1vCOV-aPS	Novavax COVID-19 Vaccine
Dengue vaccine	DEN4CYD	Dengvaxia
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel Infanrix
Haemophilus influenzae type b vaccine	Hib (PRP-T)	ActHIB Hiberix
	Hib (PRP-OMP)	PedvaxHIB
Hepatitis A vaccine	HepA	Havrix Vaqta
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
Human papillomavirus vaccine	HPV	Gardasil 9
Influenza vaccine (inactivated: egg-based)	IIV3	Multiple
Influenza vaccine (inactivated: cell-culture)	ccIIV3	Flucelvax
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M-M-R II Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB-4C	Bexsero
	MenB-FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/ MenB-FHbp	Penbraya
Mpox vaccine	Mpox	Jynneos
Pneumococcal conjugate vaccine	PCV15 PCV20	Vaxneuvance Prevnar 20
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo
Rotavirus vaccine	RV1 RV5	Rotarix RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac Tdvax
Varicella vaccine	VAR	Varivax
Combination vaccines *(use combination vaccines instead of separate injections when appropriate)*		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	DTaP-IPV/Hib	Pentacel
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix Quadracel
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

11/21/2024

How to use the child and adolescent immunization schedule

1. Determine recommended vaccine by age **(Table 1)**
2. Determine recommended interval for catch-up vaccination **(Table 2)**
3. Assess need for additional recommended vaccines by medical condition or other indication **(Table 3)**
4. Review vaccine types, frequencies, intervals, and considerations for special situations **(Notes)**
5. Review contraindications and precautions for vaccine types **(Appendix)**
6. Review new or updated ACIP guidance **(Addendum)**

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/acip/index.html) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American Academy of Pediatrics (www.aap.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), American Academy of Physician Associates (www.aapa.org), and National Association of Pediatric Nurse Practitioners (www.napnap.org).

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays.

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/hcp/imz-schedules/app.html

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/acip-recs/hcp/vaccine-specific/index.html
- ACIP Shared Clinical Decision-Making Recommendations: www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/surv-manual/php/

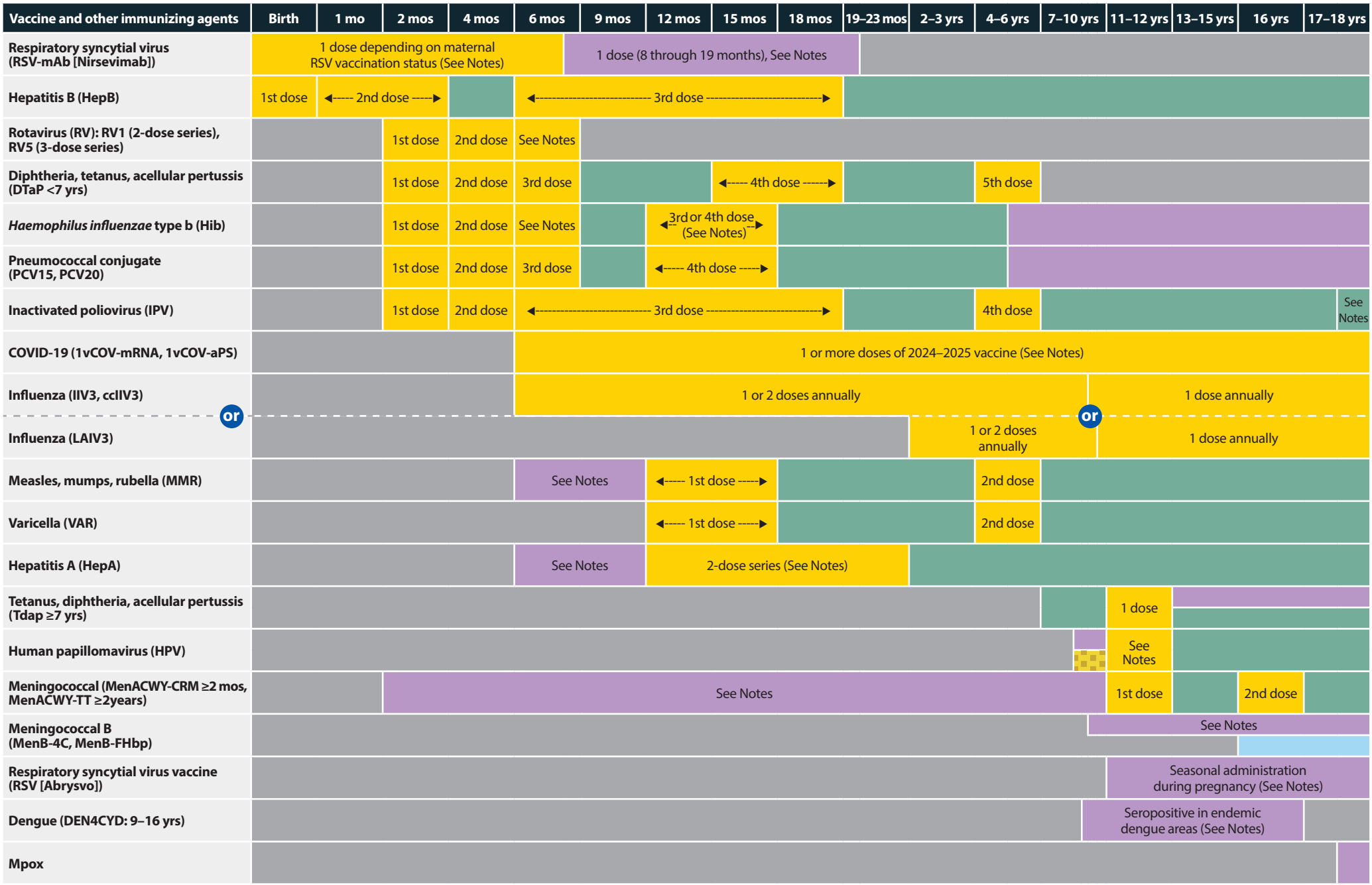
U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Scan QR code for access to online schedule

CS310020-E

Table 1 Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).



Range of recommended ages for all children
Range of recommended ages for catch-up vaccination
Range of recommended ages for certain high-risk groups or populations
Recommended vaccination can begin in this age group
Recommended vaccination based on shared clinical decision-making
No Guidance/ Not Applicable

Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2025

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the Notes that follow.**

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Children age 4 months through 6 years					
Hepatitis B	Birth	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose** minimum age for the final dose is 24 weeks		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days.	**4 weeks**	**4 weeks** maximum age for final dose is 8 months, 0 days		
Diphtheria, tetanus, and acellular pertussis	6 weeks	**4 weeks**	**4 weeks**	**6 months**	**6 months** A fifth dose is not necessary if the fourth dose was administered at age 4 years or older ***and*** at least 6 months after dose 3
Haemophilus influenzae type b	6 weeks	**No further doses needed** if first dose was administered at age 15 months or older. **4 weeks** if first dose was administered before the 1st birthday. **8 weeks (as final dose)** if first dose was administered at age 12 through 14 months.	**No further doses needed** if previous dose was administered at age 15 months or older **4 weeks** if current age is younger than 12 months ***and*** first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib, Pentacel, Hiberix), Vaxelis or unknown **8 weeks *and* age 12 through 59 months (as final dose)** if current age is younger than 12 months ***and*** first dose was administered at age 7 through 11 months; **OR** if current age is 12 through 59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose was administered at younger than 15 months; **OR** if both doses were PedvaxHIB and were administered before the 1st birthday	**8 weeks (as final dose)** This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	**No further doses needed** for healthy children if first dose was administered at age 24 months or older **4 weeks** if first dose was administered before the 1st birthday **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after	**No further doses needed** for healthy children if previous dose was administered at age 24 months or older **4 weeks** if current age is younger than 12 months ***and*** previous dose was administered at <7 months old **8 weeks (as final dose for healthy children)** if previous dose was administered between 7–11 months (wait until at least 12 months old); **OR** if current age is 12 months or older ***and*** at least 1 dose was administered before age 12 months	**8 weeks (as final dose)** This dose is only necessary for children age 12 through 59 months regardless of risk, or age 60 through 71 months with any risk, who received 3 doses before age 12 months.	
Inactivated poliovirus	6 weeks	**4 weeks**	**4 weeks** if current age is <4 years **6 months (as final dose)** if current age is 4 years or older	**6 months (minimum age 4 years for final dose)**	
Measles, mumps, rubella	12 months	**4 weeks**			
Varicella	12 months	**3 months**			
Hepatitis A	12 months	**6 months**			
Meningococcal ACWY	2 months MenACWY-CRM 2 years MenACWY-TT	**8 weeks**	See Notes	See Notes	
Children and adolescents age 7 through 18 years					
Meningococcal ACWY	Not applicable (N/A)	**8 weeks**			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	**4 weeks**	**4 weeks** if first dose of DTaP/DT was administered before the 1st birthday **6 months (as final dose)** if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday	**6 months** if first dose of DTaP/DT was administered before the 1st birthday	
Human papillomavirus	9 years	**Routine dosing intervals are recommended.**			
Hepatitis A	N/A	**6 months**			
Hepatitis B	N/A	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose**		
Inactivated poliovirus	N/A	**4 weeks**	**6 months** A fourth dose is not necessary if the third dose was administered at age 4 years or older ***and*** at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years **OR** if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	**4 weeks**			
Varicella	N/A	**3 months** if younger than age 13 years. **4 weeks** if age 13 years or older			
Dengue	9 years	**6 months**	6 months		

Table 3 Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2025

Always use this table in conjunction with Table 1 and the Notes that follow. Medical conditions are often not mutually exclusive. If multiple conditions are present, refer to guidance in all relevant columns. See Notes for medical conditions not listed.

Vaccine and other immunizing agents	Pregnancy	Immunocompromised (excluding HIV infection)	HIV infection CD4 percentage and count[a]		CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Heart disease or chronic lung disease	Kidney failure, End-stage renal disease or on dialysis	Chronic liver disease	Diabetes
			<15% or <200/mm³	≥15% and ≥200/mm³						
RSV-mAb (nirsevimab)		2nd RSV season		1 dose depending on maternal RSV vaccination status (See Notes)			2nd RSV season for chronic lung disease (See Notes)	1 dose depending on maternal RSV vaccination status (See Notes)		
Hepatitis B										
Rotavirus		SCID[b]								
DTaP/Tdap	DTaP Tdap: 1 dose each pregnancy									
Hib		HSCT: 3 doses	See Notes			See Notes				
Pneumococcal										
IPV										
COVID-19		See Notes								
Influenza inactivated		Solid organ transplant: 18yrs (See Notes)								
LAIV3							Asthma, wheezing: 2–4 years[c]			
MMR	*									
VAR	*									
Hepatitis A										
HPV	*	3-dose series (See Notes)								
MenACWY										
MenB										
RSV (Abrysvo)	Seasonal administration (See Notes)									
Dengue										
Mpox	See Notes									

- Recommended for all age-eligible children who lack documentation of a complete vaccination series
- Not recommended for all children, but recommended for some children based on increased risk for or severe outcomes from disease
- Recommended for all age-eligible children, and additional doses may be necessary based on medical condition or other indications. See Notes.
- Precaution: Might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended *Vaccinate after pregnancy, if indicated
- No Guidance/ Not Applicable

a. For additional information regarding HIV laboratory parameters and use of live vaccines, see the General Best Practice Guidelines for Immunization, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

b. Severe Combined Immunodeficiency

c. LAIV3 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

Notes

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule, 2025.

Additional information

- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3-2, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Barnett ED, Lynfield Ruth, Sawyer MH, eds. *Red Book: 2021–2024 Report of the Committee on Infectious Diseases*. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021:72–86).
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the child and adolescent vaccine schedule are covered by VICP except dengue, PPSV23, RSV, Mpox and COVID-19 vaccines. Mpox and COVID-19 vaccines are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID-19 vaccination

(minimum age: 6 months [Moderna and Pfizer-BioNTech COVID-19 vaccines], 12 years [Novavax COVID-19 Vaccine])

Routine vaccination

Age 6 months–4 years

All vaccine doses should be from the same manufacturer.

- **Unvaccinated:**
  - 2 doses 2024–25 Moderna at 0, 4–8 weeks
  - 3 doses 2024–25 Pfizer-BioNTech at 0, 3–8, and at least 8 weeks after dose 2
- **Incomplete initial vaccination series before 2024–25 vaccine with:**
  - **1 dose Moderna:** complete initial series with 1 dose 2024–25 Moderna 4–8 weeks after most recent dose
  - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech 8 weeks apart (administer dose 1 3–8 weeks after most recent dose).
  - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 8 weeks after the most recent dose.
- **Completed initial vaccination series before 2024–25 vaccine with:**
  - **2 or more doses Moderna:** 1 dose 2024–25 Moderna at least 8 weeks after the most recent dose.
  - **3 or more doses Pfizer-BioNTech:** 1 dose 2024–25 Pfizer-BioNTech at least 8 weeks after the most recent dose.

Age 5–11 years

- **Unvaccinated:** 1 dose 2024–25 Moderna or Pfizer-BioNTech
- **Previously vaccinated before 2024–25 vaccine with 1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Pfizer-BioNTech at least 8 weeks after the most recent dose.

Age 12–18 years

- **Unvaccinated:**
  - 1 dose 2024–25 Moderna or Pfizer-BioNTech
  - 2 doses 2024–25 Novavax at 0, 3–8 weeks
- **Previously vaccinated before 2024–25 vaccine with:**
  - **1 or more doses Moderna or Pfizer-BioNTech:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.
  - **1 dose Novavax:** 1 dose 2024–25 Novavax 3–8 weeks after most recent dose. If more than 8 weeks after most recent dose, administer 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech.
  - **2 or more doses Novavax:** 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech at least 8 weeks after the most recent dose.

Special situation

Persons who are moderately or severely immunocompromised.

Age 6 months–4 years

*Use vaccine from the same manufacturer for all doses **(initial vaccination series and additional doses*)**.*

- **Unvaccinated:**
  - 4 doses (**3-dose initial series 2024–25 Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna 6 months later [minimum interval 2 months]).May administer additional doses.*
  - 4 doses (**3-dose initial series 2024–25 Pfizer-BioNTech** at 0, 3 weeks, and at least 8 weeks after dose 2, followed by 1 dose 2024–25 Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
- **Incomplete initial 3-dose vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna 6 months later (minimum interval 2 months). May administer additional doses of Moderna.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna 6 months later (minimum interval 2 months). May administer additional doses of Moderna.*
  - **Previous vaccination with Pfizer-BioNTech**
    - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 8 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Pfizer-BioNTech.*
    - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 8 weeks after most recent dose, followed by 1 dose 2024–25 Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Pfizer-BioNTech.*

Notes

COVID-19 vaccination - *continued*

- **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**
  - **3 or more doses Moderna:** 2 doses 2024–25 Moderna 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna.*
  - **3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Pfizer-BioNTech.*

Age 5–11 years

Use vaccine from the same manufacturer for all doses in the initial vaccination series.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series 2024–25 Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
  - 4 doses (**3-dose initial series 2024–25 Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses.*
- **Incomplete initial 3-dose vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
  - **Previous vaccination with Pfizer-BioNTech**
    - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
    - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Pfizer-BioNTech.*
- **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**
  - **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Pfizer-BioNTech.*

Age 12–18 years

Use vaccine from the same manufacturer for all doses in the initial vaccination series.

- **Unvaccinated:**
  - 4 doses (**3-dose initial series Moderna** at 0, 4 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - 4 doses (**3-dose initial series Pfizer-BioNTech** at 0, 3 weeks, and at least 4 weeks after dose 2, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - 3 doses (**2-dose initial series Novavax** at 0, 3 weeks, followed by 1 dose Moderna or Novavax or Pfizer-BioNTech 6 months later [minimum interval 2 months]). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
- **Incomplete initial vaccination series before 2024–25 vaccine:**
  - **Previous vaccination with Moderna**
    - **1 dose Moderna:** complete initial series with 2 doses 2024–25 Moderna at least 4 weeks apart (administer dose 1 4 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
    - **2 doses Moderna:** complete initial series with 1 dose 2024–25 Moderna at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - **Previous vaccination with Pfizer-BioNTech**
    - **1 dose Pfizer-BioNTech:** complete initial series with 2 doses 2024–25 Pfizer-BioNTech at least 4 weeks apart (administer dose 1 3 weeks after most recent dose), followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
    - **2 doses Pfizer-BioNTech:** complete initial series with 1 dose 2024–25 Pfizer-BioNTech at least 4 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - **Previous vaccination with Novavax**
    - **1 dose Novavax:** complete initial series with 1 dose 2024–25 Novavax at least 3 weeks after most recent dose, followed by 1 dose 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months later (minimum interval 2 months). May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

Notes

COVID-19 vaccination - *continued*

- **Completed initial 3-dose vaccination series before 2024–25 vaccine with:**
  - **3 or more doses Moderna or 3 or more doses Pfizer-BioNTech:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*
  - **2 or more doses Novavax:** 2 doses 2024–25 Moderna or Novavax or Pfizer-BioNTech 6 months apart (minimum interval 2 months). Administer dose 1 at least 8 weeks after the most recent dose. May administer additional doses of Moderna or Novavax or Pfizer-BioNTech.*

***Additional doses of 2024–25 COVID-19 vaccine for moderately or severely immunocompromised:** based on shared clinical decision-making and administered at least 2 months after the most recent dose (see Table 2 at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#table-02.). For description of moderate and severe immunocompromising conditions and treatment, see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromising-conditions-treatment.

Unvaccinated persons have never received any COVID-19 vaccine doses. There is no preferential recommendation for the use of one COVID-19 vaccine over another when more than one recommended age-appropriate vaccine is available. Administer an age-appropriate COVID-19 vaccine product for each dose.

For information about transition from age 4 years to age 5 years or age 11 years to age 12 years during COVID-19 vaccination series, see Tables 1 and 2 at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html.

For information about interchangeability of COVID-19 vaccines, see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#Interchangeability.

Current COVID-19 schedule and dosage formulation available at www.cdc.gov/covidschedule. For more information on Emergency Use Authorization (EUA) indications for COVID-19 vaccines, see www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

Dengue vaccination (minimum age: 9 years)

Routine vaccination

- Age 9–16 years living in areas with endemic dengue **AND** have laboratory confirmation of previous dengue infection
  - 3-dose series administered at 0, 6, and 12 months
- Endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau. For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm?s_cid=rr7006a1_w and www.cdc.gov/dengue/index.html
- Dengue vaccine should not be administered to children traveling to or visiting endemic dengue areas.

Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix or Quadracel])

Routine vaccination

- 5-dose series (3-dose primary series at age 2, 4, and 6 months, followed by booster doses at ages 15–18 months and 4–6 years)
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

Special situations

- **Children younger than age 7 years with a contraindication specific to the pertussis component of DTaP:** May administer Td for all recommended remaining doses in place of DTaP. Encephalopathy within 7 days of vaccination when not attributable to another identifiable cause is the only contraindication specific to the pertussis component of DTaP. For additional information, see www.cdc.gov/pertussis/hcp/vaccine-recommendations/td-offlabel.html.
- **Wound management in children younger than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine:** For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm.

Haemophilus influenzae type b vaccination (minimum age: 6 weeks)

Routine vaccination

- **ActHIB, Hiberix, Pentacel, or Vaxelis:** 4-dose series (3-dose primary series at age 2, 4, and 6 months, followed by a booster dose* at age 12–15 months)
  - *Vaxelis is not recommended for use as a booster dose. A different Hib-containing vaccine should be used for the booster dose.
- **PedvaxHIB:** 3-dose series (2-dose primary series at age 2 and 4 months, followed by a booster dose at age 12–15 months)
- **American Indian and Alaska Native infants:** Vaxelis and PedvaxHIB preferred over other Hib vaccines for the primary series.

Catch-up vaccination

- **Dose 1 at age 7–11 months:** Administer dose 2 at least 4 weeks later and dose 3 (final dose) at age12–15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at age 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- **Dose 1 before age 12 months and dose 2 before age 15 months:** Administer dose 3 (final dose) at least 8 weeks after dose 2.
- **2 doses of PedvaxHIB before age 12 months:** Administer dose 3 (final dose) at age12–59 months and at least 8 weeks after dose 2.
- **1 dose administered at age 15 months or older:** No further doses needed
- **Unvaccinated at age 15–59 months:** Administer 1 dose.
- **Previously unvaccinated children age 60 months or older who are not considered high risk:** Catch-up vaccination not required.

For other catch-up guidance, see Table 2. Vaxelis can be used for catch-up vaccination in children younger than age 5 years. Follow the catch-up schedule even if Vaxelis is used for one or more doses. For detailed information on use of Vaxelis see www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm.

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Haemophilus influenzae type b vaccination - *continued*

Special situations

- **Chemotherapy or radiation treatment:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.
- **Hematopoietic stem cell transplant (HSCT):**
  - 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant, regardless of Hib vaccination history
- **Anatomic or functional asplenia (including sickle cell disease):**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated* persons age 5 years or older
  - 1 dose
- **Elective splenectomy:**
  Unvaccinated* persons age 15 months or older
  - 1 dose (preferably at least 14 days before procedure)
- **HIV infection:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated* persons age 5–18 years
  - 1 dose
- **Immunoglobulin deficiency, early component complement deficiency, or early component complement inhibitor use:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

Unvaccinated* = Less than routine series (through age 14 months) **or no doses (age 15 months or older)

Hepatitis A vaccination (minimum age: 12 months for routine vaccination)

Routine vaccination

- **2-dose series** (minimum interval: 6 months) at age 12–23 months

Catch-up vaccination

- **Unvaccinated persons through age 18 years should complete a 2-dose series** (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents age 18 years or older may receive HepA-HepB (Twinrix) as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

International travel

- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (www.cdc.gov/travel/):
  - **Infants age 6–11 months**: 1 dose before departure; revaccinate with 2 doses (separated by at least 6 months) between age 12–23 months.
  - **Unvaccinated age 12 months or older**: Administer dose 1 as soon as travel is considered.

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Hepatitis B vaccination (minimum age: birth)

Routine vaccination

- **Mother is HBsAg-negative**
  - 3-dose series at age 0, 1–2, 6–18 months **(use monovalent HepB vaccine for doses administered before age 6 weeks)**
    - Birth weight ≥2,000 grams: 1 dose within 24 hours of birth if medically stable
    - Birth weight <2,000 grams: 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2,000 grams)
  - Infants who did not receive a birth dose should begin the series as soon as possible (see Table 2 for minimum intervals).
  - Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the birth dose.
  - **Minimum intervals (see Table 2):** when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations.
  - **Final (3rd or 4th) dose:** age 6–18 months **(minimum age 24 weeks)**
- **Mother is HBsAg-positive**
  - **Birth dose (monovalent HepB vaccine only):** administer **HepB vaccine** and **hepatitis B immune globulin (HBIG)** in separate limbs within 12 hours of birth, regardless of birth weight.
  - **Birth weight <2000 grams:** administer 3 additional doses of HepB vaccine beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**.
  - Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.

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Hepatitis B vaccination - *continued*

- **Mother is HBsAg-unknown**

  If other evidence suggestive of maternal hepatitis B infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to have chronic hepatitis B infection), manage infant as if mother is HBsAg-positive.
  - **Birth dose (monovalent HepB vaccine only):**
    - Birth weight ≥2,000 grams: administer **HepB vaccine** within 12 hours of birth. Determine mother's HBsAg status as soon as possible. If mother is determined to be HBsAg-positive, administer **HBIG** as soon as possible (in separate limb), but no later than 7 days of age.
    - Birth weight <2,000 grams: administer **HepB vaccine** and **HBIG** (in separate limbs) within 12 hours of birth. Administer 3 additional doses of **HepB vaccine** beginning at age 1 month (total of 4 doses).
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**.
  - If mother is determined to be HBsAg-positive or if status remains unknown, test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.

Catch-up vaccination

- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months. See Table 2 for minimum intervals.
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation **Recombivax HB** only).
- Adolescents age 18 years may receive:
  - **Heplisav-B:** 2-dose series at least 4 weeks apart
  - **PreHevbrio*:** 3-dose series at 0, 1, and 6 months
  - **HepA-HepB (Twinrix):** 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

Special situations

- Revaccination is generally not recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- **Post-vaccination serology testing and revaccination** (if anti-HBs <10mIU/mL) is recommended for certain populations, including:
  - Infants born to HBsAg-positive mothers
  - Persons who are predialysis or on maintenance dialysis
  - Other immunocompromised persons
  - For detailed revaccination recommendations, see www.cdc.gov/mmwr/volumes/67/rr/rr6701a1.htm.
- **Note:** PreHevbrio is not recommended in pregnancy due to lack of safety data in pregnant women.

Human papillomavirus vaccination (minimum age: 9 years)

Routine and catch-up vaccination

- HPV vaccination routinely recommended at **age 11–12 years (can start at age 9 years)** and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated.
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9–14 years at initial vaccination**: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - **Age 15 years or older at initial vaccination**: 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2 = 4 weeks; dose 2 to dose 3 = 12 weeks; dose 1 to dose 3 = 5 months; repeat dose if administered too soon)
- No additional dose recommended when any HPV vaccine series **of any valency** has been completed using recommended dosing intervals.

Special situations

- **Immunocompromising conditions, including HIV infection:** 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
- **History of sexual abuse or assault:** Start at age 9 years
- **Pregnancy:** Pregnancy testing not needed before vaccination; HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant

Influenza vaccination (minimum age: 6 months [IIV3], 2 years [LAIV3],18 years [recombinant influenza vaccine, RIV3])

Routine vaccination

- Use any influenza vaccine appropriate for age and health status annually:
  - **Age 6 months–8 years** who have received fewer than 2 influenza vaccine doses before July 1, 2024, or whose influenza vaccination history is unknown: 2 doses, separated by at least 4 weeks. Administer dose 2 even if the child turns 9 years between receipt of dose 1 and dose 2.
  - **Age 6 months–8 years** who have received at least 2 influenza vaccine doses before July 1, 2024: 1 dose.
  - **Age 9 years or older:** 1 dose
  - **Age 18 years solid organ transplant recipients receiving immunosuppressive medications:** high-dose inactivated (HD-IIV3) and adjuvanted inactivated (aIIV3) influenza vaccines are acceptable options. No preference over other age-appropriate IIV3 or RIV3.
- For the 2024–25 season, see www.cdc.gov/mmwr/volumes/73/rr/rr7305a1.htm.
- For the 2025–26 season, see the 2025–26 ACIP influenza vaccine recommendations.

Special situations

- **Close contacts (e.g., household contacts) of severely immunosuppressed persons who require a protected environment:** should not receive LAIV3. If LAIV3 is given, they should avoid contact with, or caring for such immunosuppressed persons for 7 days after vaccination.

Note: Persons with an egg allergy can receive any influenza vaccine (egg-based or non-egg based) appropriate for age and health status.

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Measles, mumps, and rubella vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination
- 2-dose series at age 12–15 months, age 4–6 years
- MMR or MMRV* may be administered

Note: For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV* may be used if parents or caregivers express a preference.

Catch-up vaccination
- **Unvaccinated children and adolescents:** 2-dose series at least 4 weeks apart*
- The maximum age for use of MMRV* is 12 years.

Special situations
- **International travel**
  - **Infants age 6–11 months:** 1 dose before departure; revaccinate with 2-dose series at age 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.*
  - **Children age 12 months or older:**
    - Unvaccinated: 2-dose series (separated by at least 4 weeks*) before departure
    - Previously received 1 dose: administer dose 2 at least 4 weeks after dose 1*
- In mumps outbreak settings, for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm

***Note:** If MMRV is used, the minimum interval between MMRV doses is 3 months.

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Meningococcal serogroup A,C,W,Y vaccination
(minimum age: 2 months [MenACWY-CRM, Menveo], 2 years [MenACWY-TT, MenQuadfi]), 10 years [MenACWY-TT/MenB-FHbp, Penbraya])

Routine vaccination
- 2-dose series at age 11–12 years; 16 years

Catch-up vaccination
- **Age 13–15 years:** 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- **Age 16–18 years:** 1 dose

Special situations
Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

- **Menveo***
  - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
  - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
  - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- **MenQuadfi**
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

Travel to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj (www.cdc.gov/travel/)**:**

- **Children younger than age 24 months:**
  - **Menveo* (age 2–23 months)**
    - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
    - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
    - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
- **Children age 2 years or older:** 1 dose Menveo* or MenQuadfi

First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits: 1 dose Menveo* or MenQuadfi

Adolescent vaccination of children who received MenACWY prior to age 10 years:

- **Children for whom boosters are recommended because of an ongoing increased risk of meningococcal disease** (e.g., those with complement component deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk.
- **Children for whom boosters are not recommended** (e.g., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

**Menveo has two formulations: lyophilized and liquid. The liquid formulation should not be used before age 10 years. See www.cdc.gov/vaccines/vpd/mening/downloads/menveo-single-vial-presentation.pdf.*

Note: For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Children age 10 years or older may receive a single dose of Penbraya as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day (see "Meningococcal serogroup B vaccination" section below for more information).

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Meningococcal serogroup B vaccination
(minimum age: 10 years [MenB-4C, Bexsero; MenB-FHbp, Trumenba; MenACWY-TT/MenB-FHbp, Penbraya])

Shared clinical decision-making

- **Adolescents not at increased risk age 16–23 years (preferred age 16–18 years)* based on shared clinical decision-making.**
  - **Bexsero or Trumenba (use same brand for all doses):** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer dose 3 at least 4 months after dose 2)

*To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.

For additional information on shared clinical decision-making for MenB, see www.cdc.gov/vaccines/hcp/admin/downloads/isd-job-aid-scdm-mening-b-shared-clinical-decision-making.pdf

Special situations

Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use.

- **Bexsero or Trumenba (use same brand for all doses including booster doses)** 3-dose series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3)

For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Note: MenB vaccines may be administered simultaneously with MenACWY vaccines if indicated, but at a different anatomic site, if feasible.

Children age 10 years or older may receive a dose of Penbraya (MenACWY–TT/MenB–FHbp) as an alternative to separate administration of MenACWY and MenB when both vaccines would be given on the same clinic day. For age-eligible children not at increased risk, if Penbraya is used for dose 1 MenB, MenB-FHbp (Trumenba) should be administered for dose 2 MenB. For age-eligible children at increased risk of meningococcal disease, Penbraya may be used for additional MenACWY and MenB doses (including booster doses) if both would be given on the same clinic day **and** at least 6 months have elapsed since most recent Penbraya dose.

Mpox vaccination
(minimum age: 18 years [Jynneos])

Special situations

- **Age 18 years and at risk for mpox infection:** complete 2-dose series, 28 days apart.

  Risk factors for mpox infection include:
  - Persons who are gay, bisexual, and other MSM, transgender or nonbinary people who in the past 6 months have had:
    - A new diagnosis of at least 1 sexually transmitted disease
    - More than 1 sex partner
    - Sex at a commercial sex venue
    - Sex in association with a large public event in a geographic area where mpox transmission is occurring
  - Persons who are sexual partners of the persons described above
  - Persons who anticipate experiencing any of the situations described above
- **Pregnancy:** There is currently no ACIP recommendation for Jynneos use in pregnancy due to lack of safety data in pregnant women. Pregnant women with any risk factor described above may receive Jynneos.

For detailed information, see www.cdc.gov/mpox/hcp/vaccine-considerations/vaccination-overview.html

Pneumococcal vaccination
(minimum age: 6 weeks [PCV15], [PCV 20]; 2 years [PPSV23])

Routine vaccination with PCV

- 4-dose series at 2, 4, 6, 12–15 months

Catch-up vaccination with PCV

- Healthy children ages 2–4 years with any incomplete* PCV series: 1 dose PCV
- For other catch-up guidance, see Table 2.

Note: For children **without** risk conditions, PCV20 is not indicated if they have received 4 doses of PCV13 or PCV15 or another age appropriate complete PCV series.

Special situations

Children and adolescents with cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; or diabetes mellitus:

Age 2–5 years

- Any incomplete* PCV series with:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23.
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 administer at least 8 weeks after the most recent PCV dose.

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Pneumococcal vaccination - *continued*

Age 6–18 years

- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.**
- Received PCV before age 6 years but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: 1 dose PCV20 or 1 dose PPSV23 administer at least 8 weeks after the most recent PCV dose.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: no further doses of any PCV or PPSV23 indicated.

Children and adolescents on maintenance dialysis, or with immunocompromising conditions such as nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; or sickle cell disease or other hemoglobinopathies:

Age 2–5 years

- Any incomplete* PCV series:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after the most recent PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (at least 8 weeks after the most recent dose and administered at least 8 weeks apart)
- Completed recommended PCV series but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no further PCV or PPSV23 doses needed
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.

Age 6–18 years

- Not previously received any dose of PCV13, PCV15, or PCV20: administer 1 dose of PCV15 or 1 dose of PCV20. If PCV15 is used and no previous receipt of PPSV23, administer 1 dose of PPSV23 at least 8 weeks after the PCV15 dose.**
- Received PCV before age 6 years but have not received PPSV23
  - Previously received at least 1 dose of PCV20: no additional dose of PCV or PPSV23
  - Not previously received PCV20: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV dose. If PPSV23 is used, administer either PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received PCV13 only at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose. If PPSV23 is used, administer 1 dose of PCV20 or dose 2 PPSV23 at least 5 years after dose 1 PPSV23.
- Received 1 dose PCV13 and 1 dose PPSV23 at or after age 6 years: administer 1 dose PCV20 or 1 dose PPSV23 at least 8 weeks after the most recent PCV13 dose and at least 5 years after dose 1 PPSV23.

Pregnancy: no recommendation for PCV or PPSV23 due to limited data. Summary of existing data on pneumococcal vaccination during pregnancy can be found at www.cdc.gov/mmwr/volumes/72/rr/rr7203a1.htm

For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app, which can be downloaded here: wcms-wp.cdc.gov/pneumococcal/hcp/vaccine-recommendations/app.html

**Incomplete series* = Not having received all doses in either the recommended series or an age-appropriate catch-up series. See Table 2 in ACIP pneumococcal recommendations at stacks.cdc.gov/view/cdc/133252

***When both PCV15 and PPSV23 are indicated, administer all doses of PCV15 first. PCV15 and PPSV23 should not be administered during the same visit.*

Poliovirus vaccination (minimum age: 6 weeks)

Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended on or after age 4 years and at least 6 months after the previous dose.

Catch-up vaccination

- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- **Adolescents age 18 years known or suspected to be unvaccinated or incompletely vaccinated:** administer remaining doses (1, 2, or 3 IPV doses) to complete a 3-dose primary series.* Unless there are specific reasons to believe they were not vaccinated, most persons aged 18 years or older born and raised in the United States can assume they were vaccinated against polio as children.

Series containing oral poliovirus vaccine (OPV), either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s_%20cid=mm6601a6_w.
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements.
  - Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
  - Doses of OPV administered on or after April 1, 2016, should not be counted.
  - For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w.
- For other catch-up guidance, see Table 2.

Special situations

- **Adolescents aged 18 years at increased risk of exposure to poliovirus and completed primary series*:** may administer one lifetime IPV booster

***Note:** Complete primary series consist of at least 3 doses of IPV or trivalent oral poliovirus vaccine (tOPV) in any combination.

For detailed information, see: www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

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Respiratory syncytial virus immunization
(minimum age: birth [Nirsevimab, RSV-mAb, Beyfortus])

Routine immunization

- **Infants born October – March in most of the continental United States***
  - Mother did not receive RSV vaccine or mother's RSV vaccination status is unknown or mother received RSV vaccine in previous pregnancy: administer 1 dose nirsevimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **less than 14 days** prior to delivery: administer 1 dose nirsevimab within 1 week of birth—ideally during the birth hospitalization.
  - Mother received RSV vaccine **at least 14 days** prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html)
- **Infants born April–September in most of the continental United States***
  - Mother did not receive RSV vaccine or mother's RSV vaccination status is unknown or mother received RSV vaccine in previous pregnancy: administer 1 dose nirsevimab shortly before start of RSV season.*
  - Mother received RSV vaccine **less than 14 days** prior to delivery: administer 1 dose nirsevimab shortly before start of RSV season.*
  - Mother received RSV vaccine **at least 14 days** prior to delivery: nirsevimab not needed but can be considered in rare circumstances at the discretion of healthcare providers (see www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html)

Infants with prolonged birth hospitalization** (e.g., for prematurity) discharged October through March should be immunized shortly before or promptly after discharge.

Special situations

- **Ages 8–19 months with chronic lung disease of prematurity requiring medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season; severe immunocompromise; cystic fibrosis with either weight for length <10th percentile or manifestation of severe lung disease (e.g., previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable)**:**
  - 1 dose nirsevimab shortly before start of second RSV season*
- **Ages 8–19 months who are American Indian or Alaska Native:** 1 dose nirsevimab shortly before start of second RSV season*
- **Age-eligible and undergoing cardiac surgery with cardiopulmonary bypass**:** 1 additional dose of nirsevimab after surgery. See www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

***Note:** While the timing of the onset and duration of RSV season may vary, administration of nirsevimab is recommended October through March in most of the continental United States (optimally October through November or within 1 week of birth). Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdiction with tropical climate) should follow guidance from public health authorities (e.g., CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

****Note:** Nirsevimab can be administered to children who are eligible to receive palivizumab. Children who have received nirsevimab should not receive palivizumab for the same RSV season.

For further guidance, see www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm and www.cdc.gov/vaccines/vpd/rsv/hcp/child-faqs.html

Respiratory syncytial virus vaccination
(RSV [Abrysvo])

Routine vaccination

- **Pregnant at 32 weeks 0 days through 36 weeks and 6 days gestation from September through January in most of the continental United States*:** 1 dose Abrysvo. Administer RSV vaccine regardless of previous RSV infection.
  - Either maternal RSV vaccination with Abrysvo or infant immunization with nirsevimab (RSV monoclonal antibody) is recommended to prevent severe respiratory syncytial virus disease in infants.
- **All other pregnant women:** RSV vaccine not recommended
- **Subsequent pregnancies:** additional doses not recommended. No data are available to inform whether additional doses are needed in subsequent pregnancies. Infants born to pregnant women who received RSV vaccine during a previous pregnancy should receive nirsevimab.

***Note:** Providers in jurisdictions with RSV seasonality that differs from most of the continental United States (e.g., Alaska, jurisdictions with tropical climate) should follow guidance from public health authorities (e.g., CDC, health departments) or regional medical centers on timing of administration based on local RSV seasonality.

Rotavirus vaccination
(minimum age: 6 weeks)

Routine vaccination

- **Rotarix:** 2-dose series at age 2 and 4 months
- **RotaTeq:** 3-dose series at age 2, 4, and 6 months
- If any dose in the series is either **RotaTeq** or unknown, default to 3-dose series.

Catch-up vaccination

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

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Notes

Tetanus, diphtheria, and pertussis (Tdap) vaccination (minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

Routine vaccination

- **Age 11–12 years:** 1 dose Tdap (adolescent booster)
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36

Note: Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

Catch-up vaccination

- **Age 13–18 years who have not received Tdap:** 1 dose Tdap (adolescent booster)
- **Age 7–18 years not fully vaccinated* with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- **Tdap administered at age 7–10 years:**
  - **Age 7–9 years** who receive Tdap should receive the adolescent Tdap booster dose at age 11–12 years
  - **Age 10 years** who receive Tdap do not need the adolescent Tdap booster dose at age 11–12 years
- **DTaP inadvertently administered on or after age 7 years**:
  - **Age 7–9 years**: DTaP may count as part of catch-up series. Administer adolescent Tdap booster dose at age 11–12 years.
  - **Age 10–18 years**: Count dose of DTaP as the adolescent Tdap booster dose.
- For other catch-up guidance, see Table 2.

Special situations

- **Wound management** in persons age 7 years or older with history of 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons age 11 years or older who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant adolescent, use Tdap.
- For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm.

**Fully vaccinated* = 5 valid doses of DTaP or 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

Varicella vaccination (minimum age: 12 months)

Routine vaccination

- 2-dose series at age 12–15 months, 4–6 years
- VAR or MMRV may be administered*
- Dose 2 may be administered as early as 3 months after dose 1 (a dose inadvertently administered after at least 4 weeks may be counted as valid).

**Note:* For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

Catch-up vaccination

- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have a 2-dose series:
  - **Age 7–12 years**: Routine interval: 3 months (a dose inadvertently administered after at least 4 weeks may be counted as valid)
  - **Age 13 years and older**: Routine interval: 4–8 weeks (minimum interval: 4 weeks)
  - The maximum age for use of *MMRV* is 12 years.

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Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

Guide to Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4-1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions, Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices—United States, 2024–25 Influenza Season | MMWR (cdc.gov), *and* Contraindications and Precautions for COVID-19 Vaccination

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
COVID-19 mRNA vaccines [Pfizer-BioNTech, Moderna]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of an mRNA COVID-19 vaccine[3]	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of an mRNA COVID-19 vaccine[3]; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of an mRNA COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
COVID-19 protein subunit vaccine [Novavax]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a Novavax COVID-19 vaccine[3]	• Diagnosed non-severe allergy (e.g., urticaria beyond the injection site) to a component of Novavax COVID-19 vaccine[3]; or non-severe, immediate (onset less than 4 hours) allergic reaction after administration of a previous dose of a Novavax COVID-19 vaccine • Myocarditis or pericarditis within 3 weeks after a dose of any COVID-19 vaccine • Multisystem inflammatory syndrome in children (MIS-C) or multisystem inflammatory syndrome in adults (MIS-A) • Moderate or severe acute illness, with or without fever
Influenza, egg-based, inactivated injectable (IIV3)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg)	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable (ccIIV3) [Flucelvax]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[4] of ccIIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable (RIV3) [Flublok]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[4] of RIV3	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV3, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated (LAIV3) [Flumist]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[4] (excluding egg) • Children age 2–4 years with a history of asthma or wheezing • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear or any other cranial CSF leak • Children and adolescents receiving aspirin or salicylate-containing medications • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons age 5 years old or older • Persons with underlying medical conditions other than those listed under contraindications that might predispose to complications after wild-type influenza virus infection, e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus) • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should **NOT** be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization.
3. See package inserts and FDA EUA fact sheets for a full list of vaccine ingredients. mRNA COVID-19 vaccines contain polyethylene glycol (PEG).
4. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. See Package inserts for U.S.-licensed vaccines.

Appendix Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

Vaccines and other Immunizing Agents	Contraindicated or Not Recommended[1]	Precautions[2]
Dengue (DEN4CYD)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Lack of laboratory confirmation of a previous dengue infection	• Pregnancy • HIV infection without evidence of severe immunosuppression • Moderate or severe acute illness with or without fever
Diphtheria, tetanus, pertussis (DTaP)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP	• Guillain-Barré syndrome (GBS) within 6 weeks after previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid-containing vaccine • For DTaP only: Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized • Moderate or severe acute illness with or without fever
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Younger than age 6 weeks	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • Pregnancy: PreHevbrio is not recommended due to lack of safety data in pregnant women. Use other hepatitis B vaccines if HepB is indicated[4]	• Moderate or severe acute illness with or without fever
Hepatitis A-Hepatitis B vaccine (HepA-HepB) [Twinrix]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended.*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever • For MMRV only: Personal or family (i.e., sibling or parent) history of seizures of any etiology • If using MMRV, see Varicella/MMRV for additional precautions
Meningococcal ACWY (MenACWY) MenACWY-CRM [Menveo] MenACWY-TT [MenQuadfi]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Men ACWY-CRM only: severe allergic reaction to any diphtheria toxoid— or CRM197—containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	• For MenACWY-CRM only: Preterm birth if younger than age 9 months • Moderate or severe acute illness with or without fever
Meningococcal B (MenB) MenB-4C [Bexsero] MenB-FHbp [Trumenba]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Meningococcal ABCWY (MenACWY-TT/MenB-FHbp) [Penbraya]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction to a tetanus toxoid-containing vaccine	• Moderate or severe acute illness, with or without fever
Mpox [Jynneos]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness, with or without fever
Pneumococcal conjugate (PCV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria-toxoid-containing vaccine or its component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
RSV monoclonal antibody (RSV-mAb)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[5]	• Moderate or severe acute illness with or without fever
Respiratory syncytial virus vaccine (RSV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Rotavirus (RV) RV1 [Rotarix] RV5 [RotaTeq]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe combined immunodeficiency (SCID) • History of intussusception	• Altered immunocompetence other than SCID • Chronic gastrointestinal disease • RV1 only: Spina bifida or bladder exstrophy • Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid–containing vaccine • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized • Moderate or severe acute illness with or without fever
Varicella (VAR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent • For MMRV only: HIV infection of any severity	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever • If using MMRV, see MMR/MMRV for additional precautions

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.
4. For information on the pregnancy exposure registry for persons who were inadvertently vaccinated with PreHevbrio while pregnant, please visit www.prehevbrio.com/#safety.
5. Full prescribing information for BEYFORTUS (nirsevimab-alip) www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf.

Addendum Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger, United States, 2025

In addition to the recommendations presented in the previous sections of this immunization schedule, ACIP has approved the following recommendations by majority vote since October 24, 2024. The following recommendations have been adopted by the CDC Director and are now official. Links are provided if these recommendations have been published in *Morbidity and Mortality Weekly Report (MMWR)*.

Vaccines	Recommendations	Effective Date of Recommendation*
No new vaccines or vaccine recommendations to report		

*The effective date is the date when the CDC director adopted the recommendation and when the ACIP recommendation became official.

EXHIBIT 28

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SECOND SUPPLEMENTAL DECLARATION OF MOLLY O'SHEA, MD

I, Molly O'Shea, M.D., (aka Mary Doherty-O'Shea Gallucci) declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction.

2. I am a graduate of the University of Michigan Medical School and completed residency at Children's Hospital of Michigan. I am a board-certified pediatrician and the owner of two pediatric practices in Michigan with locations in Bloomfield Hills (Oakland County) and Washington Township (Macomb County). I have practiced pediatrics for over 30 years. I care for children from birth through adolescence, including newborns.

3. I am a member of the American Academy of Pediatrics (AAP).

4. I am aware of the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "Secretarial Directive") issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the COVID-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the COVID-19 for pregnant individuals. I am also aware that on or about May 30, 2025, the CDC changed its immunization guidance with regard to children and the COVID-19 vaccine from routine vaccination for all children to "Shared Clinical Decision Making" ("SCDM") without explanation.

5. I am aware of the recommendation issued by the Advisory Committee on Immunization Practices ("ACIP") in September 2025 and subsequently adopted by the acting director of the Centers for Disease Control and Prevention ("CDC") in October 2025, changing the COVID-19 vaccine recommendation for all individuals under the age of 65 from routine to SCDM.

6. As a board-certified pediatrician who has been practicing for more than 30 years, I wholeheartedly and vehemently disagree with the SCDM recommendation for the administration of the COVID-19 vaccine to children. Covid illness is currently on the rise, but this change to SCDM will, unfortunately and very likely, lead to more illness and death.

7. I and other providers at my practices are confused by the CDC's decision to list the COVID-19 vaccine for children as SCDM without explanation or guidance and view this to be an effort by the CDC and the Secretary to discourage parents and caregivers from giving their children the COVID-19 vaccine. When the CDC categorizes a vaccine on its immunization schedule as "routine," not only does it mean that the group of people in the category *should* get the vaccine, but in any health care setting the default decision is to vaccinate. In the past, when the CDC has

issued a SCDM recommendation for a vaccine, the supporting data was published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") in addition to the SCDM recommendation. This data is critical for physician use in consulting with and discussing the risk and benefits of a vaccine categorized as SCDM and, normally, provides clinicians with the evidence base to guide patient counseling. For example, after the ACIP recommended SCDM for the Meningococcal B vaccine, the CDC published guidance on how providers could engage in SCDM with patients.[1] No such data or guidance accompanied the CDC immunization schedule change for children for COVID-19 vaccines from "routine" to "SCDM," leaving us without clear guidance regarding what to discuss with parents and caregivers or how to counsel them regarding the risks and benefits of the COVID-19 vaccine. This lack of clarity and guidance inherently increases the amount of time we spend on unbillable counseling time with patients regarding the COVID-19 vaccine.

8. The change to a SCDM recommendation for the COVID-19 vaccine and the associated messaging from the CDC has injected chaos, confusion, and disruption into the practice and care that I and other providers in my practices provide, and has led to parents and caregivers doubting the safety and efficacy of all vaccinations in general. Designating a vaccine as "routine" signals an unequivocal recommendation from the CDC that a vaccine is recommended to protect patients. A "SCDM" recommendation, however, is the lowest-strength option available to ACIP, and instead signals to parents and caregivers that their children *may* benefit from the COVID-19 vaccine.

9. I have already seen the impact of the downgrade of the recommendation for the COVID-19 vaccine for children from routine to SCDM. This lack of clarity and lack of guidance

[1] *See Shared Clinical Decision Making Meningococcal B Vaccination*, CDC (Dec. 9, 2024), attached hereto as **Exhibit A**.

regarding the SCDM recommendation for the COVID-19 vaccine has left me and my colleagues without a path for employing shared clinical decision-making in practice. As a result, I have had to dedicate time and resources to developing a plan for complying with the SCDM requirement while ensuring we are able to vaccinate as many patients as possible. This has caused a direct financial impact on my practices, as none of that time I've spent developing these plans and protocols is reimbursable or billable.

10. The CDC's downgrade of the recommendation of the COVID-19 vaccine for children to SCDM has also created significant barriers for patients seeking to get a COVID-19 vaccine. Now, in order to engage in SCDM, families must schedule a physician appointment and take time off from work and/or take their child out of school to attend the appointment. Parents and caregivers are also frustrated and strained by the additional co-pay cost required for these visits, which weren't required when the COVID-19 vaccine was recommended as a routine vaccination for children.

11. I and my colleagues use Current Procedural Terminology ("CPT") codes to bill for the professional services that we provide to our patients. Each code is tied to a patient care service and is used to document and receive reimbursement for medical encounters. Vaccine administration has its own family of CPT codes, with the codes tying compensation of doctors to actual counseling and administration of the vaccine during a patient visit—but the time spent meeting with patients in order to satisfy the SCDM requirement far exceeds the typical time counseling for vaccine administration normally takes. By putting COVID-19 vaccine in a different class than other vaccines we routinely give, even parents who accept vaccines willingly are more concerned. As a result of the shift in the COVID-19 vaccine recommendation from "routine" to "SCDM" for children, I and other providers at my practices have been required to spend

significantly more unbillable time counseling families regarding the effectiveness of the COVID-19 vaccine when administered to children and dispelling misinformation regarding all vaccines administered to children. Not only is this time unbillable, but it also infringes on our ability to see additional patients and receive reimbursement for that time, too.

12. My practices have also had to forego our annual flu and COVID-19 vaccination clinics as a result of the CDC's downgrade of the COVID-19 vaccine recommendation for children from "routine" to "SCDM." In years past, I arranged for a flu and COVID-19 vaccination clinic to be held outside of normal office hours at my practices in order to give families the opportunity to obtain these vaccinations quickly and without having to miss school and work. When the flu and COVID-19 vaccinations were both listed as "routine" on the CDC's immunization schedule for children, we were able to quickly and efficiently administer the flu vaccine and/or the COVID-19 vaccine to hundreds of patients at a time that was convenient for the patients and their families. Approximately half of the parents and caregivers who have their child receive a flu vaccine also have their child receive a COVID-19 vaccine; these patients are now receiving the flu vaccine when they set up a SCDM appointment to receive the COVID-19 vaccine. Since the expected participation in a flu-only clinic is approximately halved, my practices were unable to justify the financial burden of holding a flu-only vaccine clinic. Instead, patients must schedule a regular appointment to receive the flu vaccine at my practices, which has led to a significant decline in the number of patients receiving the flu vaccine this year.

13. The removal of the COVID-19 vaccine from the routine vaccination recommendations for children has eroded some families' faith and trust in other vaccines, causing them to refuse or significantly delay a myriad of routine vaccinations. Some families have gone so far as to reject all vaccines now. As a result, fewer parents are getting their children vaccinated on

time for anything, including COVID-19, than was the case before the change to a SCDM recommendation for the administration of the COVID-19 vaccine to children, creating an even more imminent and severe risk of serious illness, hospitalization, and death.

14. On January 5, 2026, Jim O'Neill, Acting Director of CDC, announced the immediate adoption of a completely revised CDC Childhood Immunization Schedule (the "2026 Schedule Change"). The 2026 Schedule Change impacts several routinely administered vaccines, changing them from recommended to SCDM or recommended only for high-risk or certain populations only. These changes were not reviewed or recommended by the ACIP. Instead, the 2026 Schedule Change was implemented unilaterally by political appointees.

15. The 2026 Schedule Change has already disrupted my practice and professional duties. Within 24 hours of the announcement and adoption of the 2026 Schedule Change, my practice carved out time away from our other duties to meet and discuss how the 2026 Schedule Change would impact our practice and what, if any, operational changes would be necessary to ensure compliance. This meeting would not have been necessary but for the announcement and immediate adoption of the 2026 Schedule Change, which required corresponding immediate action by our practice.

16. Based on the 2026 Schedule Change, our practice was forced to change our operations and develop new protocols to ensure compliance with the new categorization of childhood vaccines. These changes will impact how we see patients, our availability to patients, and, ultimately, will harm patient uptake of vaccines.

17. Under our prior model, a patient had the option of receiving a vaccine either during a wellness visit appointment or sometime thereafter. This was prior to the 2026 Schedule Change, which meant the vaccines now classified under SCDM could be given routinely and without the

need to dedicate time to SCDM counseling. For various reasons, such as an ability to compete in an upcoming sporting event or to avoid taking too many vaccines on the same day, patients not infrequently elected to delay vaccination by a few days. This was not problematic for our practice or our patients because, since these vaccines were routinely recommended and *not* subject to SCDM, a patient did not need to see a provider and could quickly get vaccinated by a trained staff member. As a result, our practice was able to provide convenient but competent immunization services to our patients without disruption to our ability to schedule wellness visits or other appointments.

18. Because these previously routinely recommended vaccines are now subject to SCDM, our prior protocol must be replaced with a new, revised protocol. Under the new, revised protocol, the time and professional input of a provider will now be required in order to satisfy and comply with the SCDM component of the 2026 Schedule Change. This means patients will be required to make an appointment to see a provider, who in turn must now dedicate time specifically to SCDM and vaccine administration. Operationalizing this new protocol will require our practice to set aside one dedicated provider every day who will be solely responsible for handling SCDM appointments. This dedicated provider will set aside 30 minutes for any vaccines that now fall under the SCDM category. This staffing change—which is made necessary due entirely to the 2026 Schedule Change—is not made lightly. Changing our office operations will disrupt the workflow of our practice and that of the dedicated provider because at least 2-3 sick children, or 1-2 well children, who would otherwise be evaluated by that dedicated provider in that same time frame will now be displaced by SCDM appointments. Moreover, in my experience, increasing numbers of patients are already requesting to be vaccinated on an alternate schedule. This is happening in greater frequency than in years prior. This trend, combined with the effects of the

2026 Schedule Change and our change in operations, will make it more difficult for our practice to see or treat patients in the regular course and scope of our business.

19. Even with this new protocol in place, our practice will continue to be impacted by the 2026 Schedule Change beyond the time, resources, and effort spent to adopt and operationalize our new appointment-based system for SCDM vaccines. First, the requirement that a patient now make a dedicated appointment whereas before they could get a vaccine on demand will pose a barrier to provider availability. Taking a provider out of rotation for part of a day to handle SCDM-related vaccinations means there will be limited availability of these time slots for patients to make an appointment. This limited availability will make it more difficult for patients to see the dedicated provider, which will ultimately reduce the uptake of vaccines as the inconvenience posed will deter many patients. It will also necessarily impose administrative burden on our practice since we will only have so much time and so many appointment slots available for SCDM sessions. Second, because patients will now need to make an appointment to see a provider for an SCDM-related vaccine, that patient will incur a copay for their office visit. This means patients will now need to spend money that they did not have to pay before. Based on my experience and knowledge of our patients, I reasonably expect that this new cost to patients will serve as a deterrent for many individuals, especially those already struggling with rising costs in general but specific to of health care, ultimately further negatively impacting vaccine uptake and our practice. Third, while there is now a new CPT code as of January 1, 2026, that providers can use for billing SCDM discussions even when a patient refuses a vaccine, I am not aware of *any* health care payer that accepts or recognizes this CPT code or that will reimburse for it. As a result, our practice will suffer financially and *lose* money for every patient who makes an SCDM appointment but ultimately declines vaccination. This is because the CPT code we would use to bill for this time is not

recognized or reimbursed by the health insurers with whom we contract. This will result in denials of claims and require further uncompensated work by our staff and practice as we are left to decide whether to appeal those claim denials and fight for reimbursement. Each of these three impacts will result in financial harm to our practice.

20. These financial harms are not illusory. As referenced above, I have observed more and more of my patients and their families expressing uncertainty or hesitancy over vaccination, and many are opting to vaccinate on an alternate schedule. This is occurring in greater numbers and with greater frequency than in prior years. This has made it challenging to keep patients on pace for their vaccines, and the 2026 Schedule Change and corresponding changes to our practice's operations will only likely cause further impact both to our practice and our patients' health.

21. Even though our practice has developed this new protocol, the 2026 Schedule Change will require further action and analysis to further fine tune operations. Already, we are receiving calls from families about whether our practice's vaccine policy will shift to follow the new CDC recommendations. This is an open matter and will, once again, require our practice to carve out dedicated time to meet and discuss internally and address these issues and determine whether to follow the CDC or the State of Michigan's requirements. Much like other internal meetings or SCDM sessions that do not result in vaccination, this is work that will be done on an uncompensated basis. This is time that could otherwise be spent seeing and treating patients, activities that are compensable and would not result in financial harm to the practice.

22. I am familiar with and have reviewed the memorandum and other supporting documents released with the memorandum articulating the rationale for the CDC's action. Altogether, I find the 2026 Schedule Change to be lacking in any documented or sound scientific or medical support. This puts my colleagues and I in a difficult position as inoculating our patients

against these diseases via vaccination *is* beneficial for *all* children absent a medical contraindication. Our commitment to this position, contrary to the 2026 Schedule Change, and without the ability to explain the medical or scientific aspects or potential justifications of the 2026 Schedule Change will be suggest that my colleagues and I are ill-informed or incapable of answering patients' questions. This will negatively affect the reputation of our practice, thereby causing further harms to me and my colleagues and fostering further vaccine hesitancy and distrust.

23. The lack of scientific grounding behind the 2026 Schedule Change has also been cause for concern among me and my colleagues over health implications both on a macro level and on a micro level for our community and our practice. The 2026 Schedule Change will undoubtedly return us to a pre-1995 environment when rotavirus, RSV, and influenza were prevalent. With decreased vaccination rates, these viruses—all of which are extremely contagious and can survive on surfaces for long periods of time—will be present in our physical space in a way not seen in over a generation. The combined effects of a decrease in vaccine uptake, the heightened presence of these extremely contagious communicable viruses, and their ability to survive on surfaces throughout our office will require more intensive and daily deep cleaning to ensure the health and safety of our staff and our patients. This will prove especially burdensome since health care reimbursements to primary care pediatric practices like ours have not kept pace with labor costs and other costs associated with this kind of work, especially relative to the mid-1990s when our society last dealt with these viruses in such a manner. Investing the additional time and money necessary to ensure a sanitized environment, not just with routine cleaning but with modified deep cleaning between patients and each night, uses resources that would not need to be spent but for the 2026 Schedule Change. This will prove financially burdensome and harmful to our practice. Furthermore, these investments are not optional since failure to ensure a clean and

healthy environment will cause workforce shortages and other operational and financial harms should our staff become infected and unable to work. Lastly, increased threats and levels of virus transmission in our office will also negatively affect our practice's reputation among the community and our patients.

24. Because the 2026 Schedule Change will return us to an environment from more than 30 years ago, we will also likely see increased rates of infection in children of rotavirus, RSV, and influenza. Increased infection in this population will trigger increased community spread of these viruses, which will impact adults who are susceptible to infection, such as the elderly or those who are otherwise immunocompromised. This will undoubtedly result in increased strain on our practice and our local public health infrastructure as more and more patients will require hospitalization and treatment to address illnesses that could have been prevented and avoided by vaccination.

25. My fears over increased spread of these viruses is not academic. During my residency, I witnessed firsthand a child suffer from the scourge of rotavirus. This child was not vaccinated against rotavirus because there was no such vaccine at the time. Over the course of several days, I saw this child suffer and eventually die from rotavirus. This is just one reason why I maintain the rotavirus vaccine and recommend it to my patients.

26. Prior to the rotavirus vaccine, about 70,000 rotavirus-related hospitalizations and approximately 60 infant deaths caused by rotavirus in the United States occurred every year. The level of rotavirus infection will undoubtedly increase due to decreasing rates of vaccination, and tragic illness and death like I witnessed early in my career will become more likely.

27. I also find the stated justifications in the memorandum and supporting documentation for the 2026 Schedule Change to be unpersuasive because they inexplicably

attempt to draw false comparison or equivalencies. Based on my review of these materials, the CDC and proponents of the 2026 Schedule Change suggest that the United States is adopting an approach similar to the vaccine schedule used in Denmark. This is an incorrect and faulty comparison because, unlike the United States, the nation of Denmark has a socialized health care system that does not suffer from the same problems and barriers to accessing health care that we see in the United States. As a result, vaccination against certain viruses in Denmark is less necessary because of the level of preventative screening that occurs in their healthcare system. The system here in the United States is markedly different and does not afford the same level of pre-natal screening or care, thereby making vaccination for certain conditions like Hepatitis B all the more necessary as early as possible and before newborn children enter the world.

28. Since the changes to the CDC immunization schedule recommendations for Covid-19 vaccination for children, I continue to have to respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance. I have to address Covid-19 vaccinations now with my patients throughout my day, and I must repeatedly spend time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption directly interferes with my routine care, diverts my clinical time, and undermines confidence in vaccination recommendations that I rely on daily.

29. The harms to me and my practice as a result of the May 19 Directive, September Schedule Change, and January 5 Schedule Change, and anticipated February 25-26 ACIP actions, are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as their physician. As a physician, I do not regain lost time, trust, or clarity between federal policy shifts. Instead, each new change increases the burden on my practice, amplifies patient

skepticism with my recommendations during my consultation, increases the time I am spending during each visit, and diminishes the effectiveness of my clinical counseling. There is a practical limit to how much uncertainty I can absorb while still providing effective to my patients and counseling their parents, and in my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the imminent February 25-26 ACIP meeting has pushed my clinical practice toward or beyond that limit absent immediate injunctive relief.

30. The harms described above are also compounded by the failure to follow the established GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does not replace prior work, it is added on top of my existing clinical responsibilities. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5 childhood schedule changes, and the anticipated February 25-26 2026 ACIP actions, the harm compounds. I do not have the time or practical ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that I have relied on throughout my entire career as a practicing physician. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in my ability to

answer questions and provide recommendations to my patients on the CDC Immunization Schedule recommended childhood vaccinations, pushing my clinical practice toward a breaking point absent immediate injunctive relief.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of the state of Michigan, that the foregoing is true and correct.

Executed on: January 23, 2026

Molly O'Shea, M.D.

EXHIBIT A

Shared Clinical Decision-Making

Meningococcal B Vaccination

All adolescents and young adults who are at increased risk for serogroup B meningococcal disease should receive Meningococcal B (MenB) vaccine. This includes patients with anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, or complement inhibitor use.

Shared clinical decision-making (SCDM) is recommended regarding MenB vaccination for healthy people 16–23 years of age. SCDM recommendations are meant to be flexible and informed by the characteristics, values, and preferences of the individual patient and the clinical discretion of the health care provider.

When you decide to discuss MenB vaccination with people 16–23 years of age:

Remember:



- MenB vaccine is not routinely recommended for all people in this age group.
- The vaccine series provides short-term protection against most strains of serogroup B meningococcal bacteria circulating in the United States.

Consider:



- Serogroup B meningococcal disease is an uncommon but deadly disease. In recent years, between 20 and 50 cases occurred each year in 16- through 23-year-old people in the United States.
- A low risk of exposure or infection does not mean a person cannot get a MenB vaccine. It is just one potentially important consideration in SCDM.
- Serogroup B meningococcal disease cases most commonly affect young adults who attend a four-year university, are freshmen, live in on-campus housing, or participate in sororities or fraternities.
- MenB vaccines are safe and effective, but they only offer short-term protection (1 to 2 years) to those who get vaccinated.

How to vaccinate:



- If you and your patient decide MenB vaccination is appropriate, administer a 2-dose series of a MenB vaccine, one each at month 0 (the first vaccine appointment) and 6 months later.
  - To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.
- MenB-4C and MenB-FHbp are not interchangeable.
- MenB vaccines should not be administered to a person who has had a severe allergic reaction (e.g., anaphylaxis) to a:
  - Previous dose of MenB vaccine
  - Component of the vaccine
- In pregnant women, delay vaccination until after pregnancy unless the patient is at increased risk and the benefits of vaccination outweigh the potential risks.

Additional information:

CDC Child and Adolescent Immunization Schedule by Age:
www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

CDC Adult Immunization Schedule by Age:
www.cdc.gov/vaccines/hcp/imz-schedules/adult-age.html

CDC Meningococcal Vaccine Recommendations:
www.cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html

EXHIBIT 29

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916

DECLARATION OF SHANNON SCOTT-VERNAGLIA, M.D.

I, Shannon E. Scott-Vernaglia, M.D., declare pursuant to 28 U.S.C. § 1746 under penalty of perjury that the foregoing is true and correct and within my personal knowledge.

1. My name is Shannon E. Scott-Vernaglia. I am a physician and Board Certified in Pediatrics and I am current a Fellow of the American Academy of Pediatrics. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs in this matter and in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction. I am over the age of 18 and make this declaration based on my personal knowledge.

2. I graduated from Harvard University in 1994 with a Bachelor's Degree in Earth and Planetary Science.

3. I went to medical school at the School of Medicine at Stony Brook University Medical School where I graduated in 1999.

4. I completed a residency in Pediatrics at Massachusetts General Hospital where I also was selected to serve as Chief Resident in Pediatrics.

5. I practice medicine and teach at an academic hospital in Boston, Massachusetts.

6. As part of my clinical practice as a pediatrician, I treat pediatric patients on an outpatient basis in a general pediatrics clinic (the "Clinic").

7. As part of my clinical practice, I routinely recommend that children be vaccinated against vaccine-preventable diseases such as measles, mumps, polio, whooping cough, rubella, tetanus, influenza, and COVID-19, among others.

8. I know that recommending routine vaccination of children ages 6 months–17 years against COVID-19 is appropriate evidence-based medicine and is the standard of care for healthy children.

9. Prior to May 19, 2025, the Clinic stocked COVID-19 vaccines to give to patients ages 6 months–17 years in accordance with the FDA's approval and CDC recommendations.

10. Since the May 19, 2025 directive (the "Directive") of the Secretary of the Department of Health and Human Services ("HHS") to rescind previous recommendations that healthy children ages 6 months–17 years be routinely immunized against COVID-19 and, instead, implement shared clinical decision-making ("SCDM"), the Clinic through which I practice medicine has experienced disruptions due to uncertainty about vaccine availability.

11. In general, the Clinic receives most childhood vaccines, including COVID-19 immunizations, through the Vaccines for Children ("VFC") Program. Shortly before the Directive, we were transitioning to buy COVID-19 vaccines through our central pharmacy.

12. The Clinic prioritizes vaccinating children against COVID-19 for their primary series, which are the doses of vaccine needed to provide initial immunity (as compared with later

vaccines that boost immunity and provide better coverage for more recent circulating strains of COVID-19 virus ("Boosters")). Thus, we were planning to stock Boosters updated for the next season when available for older children to provide the best protection for them during the winter respiratory season.

13. When the Directive from HHS came out, we were due to order COVID-19 vaccines for children under the age of 12 to ensure that we could provide primary series vaccines, but had to pause as there was uncertainty about whether the vaccine would be reimbursed by insurance companies due to the Directive. Thus, for a period of just under two weeks, the Clinic did not have any COVID-19 immunizations eligible to be given to healthy patients.

14. On June 11, 2025, one of my patients who is between the ages of 6 months–17 years came to the Clinic for a wellness appointment with a plan to receive the first dose of COVID-19 immunization primary series. Our clinic did not have a stock of COVID-19 immunizations available. When we again had vaccine available, I had to reach out to the patient family and the patient was required to come back on a different day get the COVID-19 immunization. As a result, the patient and the patient's family incurred the significant expense of arranging to be at the Clinic on a separate day and traveling to the Clinic, and I and my staff had to spend additional time caring for the patient through messaging, scheduling, and having the patient return for a second visit.

15. For many of my patients' families, coming to the Clinic to attend a vaccine appointment is logistically difficult. Many of my patients require their parents or caregivers to take time off from work to bring them to the Clinic, and transportation to the Clinic can be costly because there is no free parking near the Clinic. The Clinic is designed to incorporate vaccine administration into our routine care of children coming for their wellness visits. Coming to the

Clinic for a separate, additional appointment when the Clinic has insufficient stock of COVID-19 vaccines is a hardship for my patients that they cannot afford.

16. Before the Directive and the change to SCDM, I recommended that some of my healthy Clinic patients being seen in spring months receive their next COVID-19 Booster, but offered that they might wait to do so until the fall to help ensure maximum protection against COVID-19 during respiratory virus season that occurs in the winter months. When I made that recommendation, the availability of COVID-19 vaccines, updated seasonal Boosters, and whether they would be covered by major insurers was not in question.

17. The Directive has limited the Clinic's ability to consistently stock COVID-19 immunizations for healthy children ages 6 months–17 years. My pediatric patients who chose to wait to receive their COVID-19 Booster until the fall of 2025 may not be able to access it at that time, and they are being put at risk by the Directive. I lose sleep at night thinking about those children and their family members.

18. Given the uncertainty caused by the Advisory Committee on Immunization Practices ("ACIP") and Food and Drug Administration ("FDA"), as derived out of the Directive, my Clinic experienced a delay in vaccine shipments by approximately four to six weeks. Children who were seen in those weeks were unable to receive the COVID-19 vaccine. As a result, children who would have received the COVID-19 vaccine must either return to the Clinic, seek it elsewhere, or have been lost to follow-up.

19. There is clear scientific evidence that missed opportunities for vaccination during regular office visits leads to a greater risk of future under-immunization status for children. Having irregular or uncertain vaccine availability due to the Directive therefore puts my patients at risk of

remaining under-vaccinated in the future and increases their vulnerability to illness and hospitalization.

20. The Directive undermines my ability to professionally serve my patients. The Directive and SCDM recommendation is not the result of evidence-based medicine, and it conflicts with the established standard of care to routinely immunize children ages 6 months–17 years against COVID-19 and to provide annual Boosters in the fall. Statements from governmental authorities such as the Directive and the shift to SCDM dismantles public trust in science and medical-infrastructure, including my physician-patient relationships.

21. Since the Directive, I have had to spend more time counseling patients and family members regarding vaccine recommendations, the safety and efficacy of vaccines, including the COVID-19 vaccine, and correcting misinformation about the COVID-19 vaccine. For example, patients and their family members often have only a vague understanding of changes to the recommendation for COVID-19 vaccines and many believe the vaccine is no longer available to children. This increased time is compounded by the increasing number of patients who require longer and longer discussions to address vaccine misinformation. In my practice I have seen an increased number of families express mistrust in vaccines generally, as a result of both the Directive and persistent misinformation. Even for those vaccines that have retained routine recommendation status, I am often required to spend extra time counseling patients and their families. Additionally, I spend increased time answering concerned parents' questions about the future availability of other vaccines, such as the MMR.

22. For well-child visits, which are regular appointments with pediatric patients in which vaccines are typically administered, I bill as an inclusive visit code. This means that if the visit exceeds the allocated time I am not compensated for that time.

23. Additionally, I lose out on time that I could be spending treating more patients having protracted discussions about misinformation and concerns about the implications for other vaccine availability.

24. There is a well-established shortage of primary care medical providers, including general pediatricians in the country and in Massachusetts. Additionally, there has been a significant drop in the percentage of medical school graduates pursuing Pediatrics as a specialty. HHS directives like the Directive and the SCDM recommendation cause more confusion about appropriate medical recommendations, and erode the relationship between the pediatric physician and patient family exacerbate the difference in the demand and availability of medical resources for children.

25. The Directive and recent actions by the ACIP and CDC downgrading the recommendation for Covid-19 vaccinations to SCDM also puts me at increased risk for contracting COVID-19 by increasing the risk that my patients will be infected with COVID-19 and seek treatment for COVID-19 at the Clinic. My mother is an immunocompromised older adult, and I fear that if I contract COVID-19, I could give it to her and either she or I, or both could suffer devastating long-term consequences from COVID-19. The heightened risk of COVID-19 transmission and infection is a direct result of the Secretary's Directive and the recent actions by ACIP and the CDC, which prevents my patients from being immunized against COVID-19.

26. I am a Fellow of the American Academy of Pediatrics.

27. I make this declaration in my personal capacity and in my capacity as a Fellow of the American Academy of Pediatrics.

28. The harms described above are not confined to past events and are ongoing with respect to the Directive and the ACIP's and CDC's recent changes to the CDC immunization

schedule for Covid-19 vaccination for children and pregnant women. Since the changes to the CDC immunization schedule recommendations for Covid-19 vaccination, I continue to have to respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance about vaccinations. I have to address Covid-19 vaccinations now with my patients throughout my day, and I must repeatedly spend time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption directly interferes with my routine care, diverts my clinical time, and undermines confidence in vaccination recommendations that I make daily. The Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women and children is undermining my physician-patient relationship and causing needless negative health outcomes to my patients. The harms to me set forth above are ongoing and will continue unless the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination are immediately enjoined and the ACIP and CDC return the evidence-based, transparent process for making vaccine recommendations.

29. The harms identified above are compounding rather than isolated. The harms identified above associated with the Directive, CDC's changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women and children, the January 5, 2026 changes to the childhood immunization schedule—as well as the anticipated harms that will result from any additional changes that may result from the upcoming February 26, 2026 ACIP meeting—are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as their physician and my evidence-based health recommendations. As a physician, I do not regain lost time, trust, or clarity between policy shifts. Instead, each new change increases the burden on

my practice, amplifies patient skepticism with my recommendations during my consultation, increases the time I am spending during each visit, and diminishes the effectiveness of my clinical counseling. There is a practical limit to how much uncertainty I can absorb while still providing effective care, and in my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the imminent February 26, 2026 ACIP meeting has pushed my clinical practice toward that limit absent immediate injunctive relief.

30. The harms described above are also compounded by the failure to follow established GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand where the recommendations come from and to ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does not replace prior work, it is added on top of my existing clinical responsibilities. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the anticipated February 2026 ACIP actions, the harm compounds. I do not have the time or practical ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that I have relied on throughout my entire career as a practicing physician. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in my ability to

answer questions and provide recommendations to my patients on these vaccinations, pushing my clinical practice toward a breaking point absent immediate injunctive relief.

I declare under penalty of perjury under the laws of the United States of America and the State of Massachusetts that the foregoing is true and correct.

Executed on January 23, 2026, in Boston, Massachusetts.

Shannon E. Scott-Vernaglia, M.D.

Shannon E. Scott-Vernaglia, M.D.

EXHIBIT 30

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF DR. THOMAS BOYCE, M.D.

I, Dr. Thomas Boyce, M.D., declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction.

2. I reside in Wisconsin and currently practice as a pediatric infectious disease specialist in a large, rural healthcare system, which has 60 locations in 32 counties in Wisconsin and serves about 310,000 patients, including 46,500 children.

3. I completed medical school at the University of Michigan in 1990. I completed my residency in pediatrics at University of Wisconsin in 1993. I then completed my fellowship in pediatric infectious diseases at Vanderbilt University Medical Center in 1999.

4. I am board-certified in pediatric infectious diseases and pediatrics.

5. I am a member of the Infectious Diseases Society of America ("IDSA") and the Pediatric Infectious Diseases Society ("PIDS").

6. As a pediatric infectious disease physician, my primary duty is to consult with providers and patients about infectious diseases and with parents of pediatric patients.

7. In the past, when the CDC classified a vaccine as routinely recommended, that meant that the patient should get the vaccine. A routine recommendation meant that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient and, therefore, should be administered as a standard part of medical care for children. In short, a routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine.

8. During my more than three decades of practice as an infectious disease specialist, I have, until this year, trusted the process that has resulted in vaccines being listed on the CDC immunization schedules as routinely recommended. Up until this year, the CDC's Advisory Committee on Immunization Practices ("ACIP") has likewise been a trustworthy source of non-partisan expertise backed by science and evidence. Based on the trustworthiness of these processes, I had no hesitation in advising providers and patients that a child should receive a vaccine that is a "routine" recommendation on the CDC schedules, including the Covid vaccine.

9. I am familiar with the recent ACIP recommendation that the Covid-19 vaccine be downgraded from routinely administered to one obtained through shared clinical decision making ("SCDM") for individuals under 65 years old and pregnant persons. This approach directly contradicts the standard of care as I know and understand it for safe and quality treatment of patients. This change undermines the patient-provider relationship, just as prior actions by the Secretary did in the Spring of 2025. This change also exposes me and other clinicians to

unnecessary health and legal risks given the sound scientific evidence regarding Covid-19 vaccination and safety.

10. Based on my experience, there is no single definition for "SCDM." Rather, this term can mean different things to different people. In my practice and as it pertains here, SCDM means briefly discussing the benefits of a vaccine that I recommend the patient receive and risks of not being vaccinated. I am not aware of any uniform standard meaning of SCDM for any of the organizations to which I am a member, thus further emphasizing that it is an individual approach that varies from physician to physician.

11. These SCDM conversations are folded into the existing patient exam where there usually are other pressing items to cover and discuss. This means time is reallocated addressing vaccine related concerns. This makes a time pressed examination even more challenging as I do not have an infinite amount of time to spend with any one patient.

12. In addition to patient consults, I am also increasingly being called upon by other providers to assist or guide them in how to interpret the new SCDM framework. Providers have come to me with various questions about how and when a child might qualify for vaccination and whether it would be covered by insurance. Similar to my patient interactions, these consults take time and detract from other pressing work.

13. The time spent engaging in SCDM and counseling colleagues is not separately reimbursable. As a result, I am being called upon and forced to spend more and more time addressing issues caused by the changes to the recommendation of the Covid vaccine. It is not realistic to expect me or other physicians like me to dedicate countless amounts of time to these issues as doing so will detract from other work that must be done. It also deprives me of earnings and forces me to perform uncompensated work since this time is not separately reimbursable.

14. I do not believe the "SCDM" designation is appropriate for the Covid vaccine. Although there is no generally accepted definition of SCDM, in my experience most parents interpret it as a less than full recommendation. This erodes trust in vaccine delivery and immunology, fosters vaccine hesitancy, and spreads misinformation and disinformation. Returning to the previous status quo will help alleviate the harms and adverse impacts I've described above.

15. The harms described above are not confined to past events and are ongoing with respect to the May 19 Directive and September Schedule changes to Covid-19 vaccination for children and pregnant women. Since the changes to the CDC immunization schedule recommendations for Covid-19 vaccination, I continue to have to respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance. I have to address Covid-19 vaccinations now with my patients throughout my day, and I must repeatedly spend time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption directly interferes with my routine care, diverts my clinical time, and undermines confidence in vaccination recommendations that I rely on daily. The Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children is undermining my physician-patient relationship and causing needless health outcomes to my patients.

16. The harms I am experiencing as a result of the May Directive, the September Schedule Change, and the January 5 Childhood Schedule Change, as well as the anticipated February 25-26 ACIP actions,—are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as their physician. As a physician, I do not regain lost time, trust, or clarity between policy shifts. Instead, each new change increases the burden on my

practice, amplifies patient skepticism with my recommendations during my consultation, increases the time I am spending during each visit, and diminishes the effectiveness of my clinical counseling. There is a practical limit to how much uncertainty I can absorb while still providing effective care to my patients, and in my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January childhood schedule changes, and the imminent February 25-26 ACIP meeting has pushed my clinical practice toward or beyond that limit absent immediate injunctive relief.

17. The harms described above are also compounded by the failure to follow the established GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does not replace prior work, it is added on top of my existing clinical responsibilities. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the anticipated February 2026 ACIP actions, the harm compounds. I do not have the time or practical ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that I have relied on throughout my career as a practicing physician. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in my ability to answer

questions and provide recommendations to my patients on these vaccinations, pushing my clinical practice toward a breaking point absent immediate injunctive relief

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Wisconsin, that the foregoing is true and correct.

Executed on January 22, 2026 in Marshfield, Wisconsin.

/s/ Thomas G. Boyce, MD

Dr. Thomas Boyce

EXHIBIT 31

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF SUZANNE BERMAN, M.D.

I, Suzanne Berman, M.D., declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs in this matter and in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction. I am over the age of 18 and make this declaration based on my personal knowledge.

2. I reside in Tennessee and currently co-own Plateau Pediatrics, located in Crossville, Tennessee. I primarily manage the business and compliance aspects of the practice.

3. I completed medical school at the University of Tennessee, Memphis in 1998. I completed my residency in pediatrics at Southern Illinois University in 2001.

4. I am board-certified in pediatrics.

5. I am a member of the American Academy of Pediatrics ("AAP").

6. Ten clinicians, including physicians and nurse practitioners, currently practice at Plateau Pediatrics.

7. Many of the children we treat are medically complex or fragile, including former premature infants, children with G-tubes, and children requiring ventilators. These children require specialty care that family practitioners often cannot provide.

8. I am familiar with the recent changes to the CDC's childhood immunization schedule that were announced on January 5, 2026. Those changes downgraded six immunizations (hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and Covid-19) from routine to shared clinical decision making ("SCDM"). Last year, in September, the Advisory Committee on Immunization Practices voted to downgrade the Covid-19 vaccine from routine to SCDM for everyone under the age of 65. These changes directly contradict the standard of care and clinical guidance that I and other members of our practice rely on to deliver safe and effective care to our patients and undermine the patient-provider relationship. This change also exposes me and other clinicians to unnecessary health and legal risks given the sound scientific evidence regarding the safety and efficacy of the vaccines that were downgraded to SCDM because now, we likely will be treating more children and more parents or caregivers who accompany them who are not vaccinated and, therefore, more likely to be infected when they come in to my office for visits.

9. Based on my training and experience, there is no universal definition or common understanding for what constitutes "SCDM." I similarly am not aware of any definitive guidance on or authoritative definition of SCDM issued by any of the organizations of which I am a member specific to Covid vaccination.

10. In the context of my own practice, SCDM means discussing the vaccine with parent[s.] This usually begins with an initial determination of whether the patient's parent[s] is/are

willing to discuss the topic of the vaccine. Many do not wish to even engage in a discussion. Assuming a discussion is possible, I proceed to discuss the benefits of vaccination and risks of not being vaccinated. The final decision ultimately rests with the patient's parent[s].

11. Usually, these SCDM discussions last anywhere from 7–10 minutes, though some run longer, especially if the family has several questions. In my experience, however, most parents have already made up their minds prior to their child's wellness visit, and no amount of discussion will change their mind.

12. As a result of vaccine hesitancy, which has been fueled by the Secretary's actions, I am increasingly spending more and more time addressing misinformation and disinformation expressed by my patients. This takes away from time that could and should be spent during wellness exams on other, more pertinent details. This vaccine hesitancy has gone beyond Covid and spread over to the flu and other vaccines as well. Some parents have –wrongly—claimed they do not want their children to be vaccinated against influenza because they believe that the flu vaccine also included the Covid vaccine.

13. The time spent engaging in SCDM is not separately reimbursable, and generally SCDM counseling cannot be reimbursed if the patient declines vaccination. Although there are new CPT codes that allow us to bill for this type of discussion, only one insurer is paying for them so far and even then, they are only reimbursing these codes 8% of the time if the patient declines vaccination. As a result, my colleagues and I are spending increasingly more time counseling patients and their parents and performing work that is uncompensated as a result of the change of multiple vaccines from routine to SCDM. This extra time aggregates and amounts to significant time for which my colleagues and I do not receive compensation.

14. In addition to the added uncompensated time my colleagues and I must now invest in SCDM discussions and guidance, our practice has also been materially impacted by the change to SCDM in other ways. For example, because of the lack of a universal definition for SCDM, the practice had to discuss this during weekly administration meetings to determine the meaning of SCDM and develop a standard protocol for our practice. This in turn led to the development of written practice guidance to assist clinicians on navigating these encounters.

15. Our practice has also been adversely impacted with respect to ordering and receiving vaccines. The change of the Covid vaccine to SCDM caused a period of confusion where we were not sure how to proceed and thus could not order or even offer the vaccine until we knew the impact and consequences of the SCDM framework. We have also had to dedicate additional time to training staff, creating new consent forms, and finding and updating resources for clinicians. Overall, the adoption of SCDM now for six vaccines has proved very disruptive to our practice and our ability to provide care, vaccinations, and treatment to our patients. Reversal to the status quo before these changes will alleviate these negative impacts.

16. The harms described above are ongoing. The changes to the CDC's childhood immunization schedule have increased the confusion, hesitancy, and mistrust around vaccines arising from changed federal guidance. We must repeatedly spend time correcting misconceptions created and exacerbated by statements from federal health officials and abrupt policy shifts. This ongoing disruption directly interferes with my physician-patient relationship, diverts my clinical time, and undermines confidence in vaccination recommendations that we provide daily. More importantly, these changes will cause needless negative health outcomes to my patients.

17. Each successive change to the childhood immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me and my

colleagues as their physicians. As physicians, we do not regain lost time, and it is very difficult to restore trust when federal officials are taking action in contradiction of what I believe is the appropriate standard of care. There is a practical limit to how much uncertainty my colleagues and I can absorb while still providing effective care. The cumulative impact of multiple changes to the childhood schedule has pushed my practice toward to the breaking point.

18. Watching national leaders treat our professional expertise with scorn and suspicion unfortunately inspires my patients to do the same. This year, some of our clinicians have asked to work fewer hours, in part so they can take a break from the constant moral injury of patient distrust. Although we are not turning any patients away due to lack of provider availability, these reductions have required us to adjust in other ways. Other clinicians are seeing more patients per day, one clinician has added more hours to her schedule seeing patients that has diverted her time away from doing necessary administrative work such as quality improvement projects, and we ultimately had to hire a new nurse practitioner to maintain coverage. The total reduction in hours across clinicians is about 60% of a full time position. However, it is not feasible to hire a nurse practitioner at 60% capacity, so the nurse practitioner was hired as a full time employee. This means paying for the full cost of salary, benefits, medical malpractice insurance, loan repayment, payroll taxes, and other related expenses, adding up to $130,000 annually. Given that we only needed 60% of this capacity, roughly 40% of the cost, or $52,000 annually, represents excess expense driven by the need to replace lost hours rather than truly growing my practice. In addition, these changes have produced a significant administrative burden for me as I have to shift around schedules, renegotiate clinician days off, and review provider contracts.

19. The harms described above are also compounded by the failure to follow established the GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and

communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without following those frameworks, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does not replace prior work. Instead, it is added on top of my existing clinical responsibilities and diverts from patient care. When this occurs repeatedly, as with the Covid-19 schedule changes and the January 5, 2026 childhood schedule changes, the harm compounds. I do not have the time or practical ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that I have relied on throughout my entire career as a practicing physician. The deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in my ability to answer questions and provide recommendations to my patients on these vaccinations, pushing my clinical practice toward a breaking point.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Tennessee, that the foregoing is true and correct.

Executed on January 23, 2026 in Crossville, Tennessee.

/s/ Suzanne Berman, MD, FAAP

Dr. Suzanne Berman

EXHIBIT 32

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF MARGIE ANDREAE, M.D.

I, Margie Andreae, M.D., declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction.

2. I reside in Michigan and currently practice part-time at the Pediatric Clinic of the Canton Health Center, located in Canton, Michigan.

3. I am the Professor Emerita of Pediatrics and former Chief Medical Officer for Revenue Cycle and Billing Compliance for the University of Michigan Medical Center.

4. I completed medical school at the University of Michigan Medical School in 1991. I completed my residency in pediatrics at William Beaumont Hospital in 1995.

5. I am board-certified in pediatrics.

6. I am a fellow of the American Academy of Pediatrics ("AAP").

7. When the Centers for Disease Control and Prevention ("CDC") classifies a vaccine as routine, that means that the patient should get the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saying lives with minimal risk to the patient and, therefore, should be administered as a standard part of medical care for children. In short, a routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine.

8. During my more than three decades of caring for children, I have paid close attention to the CDC's childhood immunization schedule, the process that is followed by the Food and Drug Administration ("FDA") to authorize a vaccine for use in the United States, and the process that the Advisory Committee on Immunization Practices ("ACIP") and the CDC follow to arrive at recommendations as to how vaccines should be used by different population groups in the United States.

9. I am familiar with the CDC's adoption of new Covid-19 vaccine recommendations in October 2025, which reclassified the Covid-19 vaccine to "Shared Clinical Decision Making" ("SCDM"), a downgrade from the prior recommendation of "routine."

10. In my clinical judgment, this downgrading to SCDM is without justification and is causing confusion and vaccine hesitancy and is undermining public health as well as the public trust in vaccines and the physicians who recommend them. It is additionally causing confusion and strain within the health care field as I see more and more of my colleagues uncertain of how to navigate these changes, practice medicine, and properly engage with patients.

11. In my experience, there is no universal definition for the term "SCDM," and each physician approaches SCDM encounters differently according to how they understand that term. I

am similarly unaware of any universal guidance on SCDM issued by the AAP either in general or as it relates to the Covid-19 vaccine, specifically.

12. I understand SCDM to be a distinct concept from the term "informed consent." As a pediatrician, it is rare to encounter a situation where informed consent is needed. This is because the concept of informed consent – i.e., a process whereby a physician thoroughly discusses and explores the risks and benefits with the patient – is confined mostly to treatments or medical interventions that are new, novel, and/or that present a high risk.

13. SCDM, by contrast, involves discussing options when the standard of care allows for more than one option, and does not focus on the in-depth discussion of the risks and benefits of a single recommended treatment. In an SCDM encounter, a physician shares their knowledge and expertise regarding the options available and considers the concerns and interests expressed by a patient or a patient's parent. Together, the physician and the patient or patient's parent then reach a common or shared decision on the option that best fit with that patient's needs. Furthermore, because the risk of complication from the Covid vaccine is so low, there is little need, if any, to engage in the kind of discussion that constitutes "informed consent." This is the process by which I generally engage in SCDM with my patients.

14. Specific to SCDM for the Covid-19 vaccine, I find the CDC recommendation perplexing because there is only one medically reasonable option that is consistent with the standard of care, and that would be to vaccinate all children. I typically begin my SCDM encounters by referencing the topic of the Covid vaccine and my recommendation that patients receive it. I then solicit the patient or patient's parent for their perspective and engage in a conversation based on what is communicated.

15. Since the downgrade to SCDM, I have observed that fewer patients are electing to receive the Covid-19 vaccine. I have similarly observed that patients or their parents are increasingly coming to wellness visits with preconceived ideas or notions about the Covid vaccine that are usually based on misinformation or disinformation, such as linking the vaccine to autism. Patients or their parents seem to know that the Covid vaccine is no longer routinely recommended and are increasingly concluding that there is little clinical advantage or reason to be vaccinated as a result. This stands in contrast to vaccines that are still routinely recommended, which patients and their parents continue to receive without the same level of skepticism or preconceived notions.

16. These episodes have become much more common since the CDC's adoption of SCDM for the Covid vaccine. Patients or their parents increasingly exhibit incredulity in response to my recommendation that they receive the vaccine and insist—incorrectly—that Covid is no longer a health concern and that it does not affect children. This then compels me to counsel against that misinformation to the best of my ability to ensure that patients and their parents receive the best care possible. On average, these SCDM conversations last approximately 5 minutes, which are folded into the wellness visit with the patient. This means time is taken away from other areas of concern to address issues relating to the Covid vaccine and to provide patients and their parents with the correct information, oftentimes to no avail.

17. To date, I have not had a single pediatric patient receive the Covid vaccine during this season (*i.e.*, in Fall 2025). This is a major departure from this time last year, when roughly 40% of my patients elected to receive the Covid-19 vaccine.

18. Time spent counseling patients on the Covid-19 vaccine is not reimbursable if the patient declines to receive the vaccine. As a result, time spent counseling patients who decline vaccination is time that goes uncompensated because there is no dedicated Current Procedural

Terminology (CPT) billing code that can be used for SCDM counseling alone on the Covid vaccine. Because these episodes are becoming more common, my colleagues and I are increasingly spending more and more time combatting misinformation, which ultimately increases workload. This increased volume and length of SCDM conversations forces me and my colleagues to devote substantial work time after office hours to complete documentation or other tasks not completed during or between wellness visits. In short, the shift to SCDM is causing more and more work to be performed without compensation, resulting in financial harm in the form of lost earnings.

19. The CDC's recent adoption of SCDM has also left me and others in the dark and unsure of how to proceed with counseling patients or their parents who express concerns over the Covid vaccine. I frequently wonder if I have the latest and most reliable data and information to respond to the misinformed or incorrect statements patients or their parents express. This leaves me feeling unsure of how to engage with patients or their parents, especially those who so strenuously cite misinformation or disinformation and who fervently hold to misconceptions about the Covid-19 vaccine because of the lack of reliable or verifiable scientific or medical support for the decisions being made by the CDC, ACIP, and other federal public health entities. Consequently, my ability to provide reliable care consistent with the established standard is compromised.

20. These strident positions by CDC and ACIP place me and my peers at potential risk of liability. As a trained medical professional, I know the standard of care and know that Covid infection still poses a risk to children and that children may face serious health complications as a result of not being vaccinated. As a result, I worry that patients or their parents might come forward in the future and blame or hold me and my colleagues responsible for any adverse health conditions resulting from the lack of vaccination.

21. The harms described above are not confined to past events and are ongoing with respect to the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children and pregnant women. Since the changes to the CDC immunization schedule recommendations for Covid-19 vaccination, I continue to have to respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance. I have to address Covid-19 vaccinations now with my patients throughout my day, and I must repeatedly spend time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption directly interferes with my routine care, diverts my clinical time, and undermines confidence in vaccination recommendations that I rely on daily. The Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children is undermining my physician-patient relationship and causing needless health outcomes to my patients. The harms set forth above are ongoing and will continue unless the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children are immediately enjoined and the ACIP and CDC return to the evidence-based, transparent process for making vaccine recommendations..

22. The harms identified above associated with the Directive, CDC's changes to the CDC immunization schedule for Covid-19 vaccination for children, the January 5, 2026 changes to the childhood immunization schedule,as well as the anticipated harms that will result from any additional changes that may result from the upcoming February 25-26, 2026 ACIP meeting,are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as their physician. As a physician, I do not regain lost time, trust, or clarity between policy shifts. Instead, each new change increases the burden on my practice, amplifies patient skepticism with

my recommendations during my consultation, increases the time I am spending during each visit, and diminishes the effectiveness of my clinical counseling. There is a limit to how much uncertainty I can absorb as a physician while still providing effective care, and in my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the imminent February 25-26, 2026 ACIP meeting has pushed my clinical practice toward or beyond that limit absent immediate injunctive relief.

23. The harms described above are also compounded by the failure to follow the established GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, I must spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology.

24. That burden does not replace prior work, it is added on top of my existing clinical responsibilities. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5childhood schedule changes, and the anticipated February 25-26 ACIP actions, the harm compounds. I do not have the time or ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that I have relied on throughout my career as a practicing physician. Each deviation from those frameworks increases my uncertainty, prolongs my patient counseling, and further erodes confidence in my ability to answer questions and provide

recommendations to my patients on these vaccinations, pushing my clinical practice toward a breaking point absent immediate injunctive relief.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Michigan, that the foregoing is true and correct.

Executed on January 22, 2026 in Canton, Michigan.

/s/ Dr. Margie Andreae

Dr. Margie Andreae

EXHIBIT 33

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF MARY-CASSIE SHAW, MD, FAAP

I, Mary-Cassie Shaw, declare, pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction.

2. I earned a Doctor of Medicine degree from the East Carolina University Brody School of Medicine.

3. I am a Fellow of the American Academy of Pediatrics ("AAP") and a member of the North Carolina Pediatric Society.

4. I have been a practicing pediatrician at Oberlin Pediatrics in Raleigh, North Carolina since 2003.

5. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025, and have read the related May 19, 2025 "Secretarial Directive" (the "Directive") confirming what the Secretary said in the video. I disagree with the decisions announced in the May 27 video and in the Directive to remove recommendations from the Centers for Disease Control and Prevention's (the "CDC's") immunization schedules that pregnant women and children receive the COVID-19 vaccine.

6. I have reviewed the Advisory Committee on Immunization Practices' (the "ACIP's") new recommendation released in September 2025 to change the Covid-19 vaccine recommendation for adults under the age of 65 from routine to shared clinical decision making ("SCDM"). The CDC adopted this recommendation and then improperly conflated SCDM with informed consent. ACIP's recommendation and CDC's adoption of the recommendations provides no guidance to me on how to apply the new recommendations and the lack of guidance to support the change has caused disruption and confusion to me and my practice.

7. These actions (i.e. the Directive and recent actions by ACIP and CDC related Covid-19 vaccines) have personally affected my job and caused disruption to my practice. The Directive has caused chaos and confusion at my practice as to whether we can administer the COVID-19 vaccine to children and has caused confusion and delay as to whether and when we can get the vaccine. This has resulted in me and my colleagues at the practice, including providers and staff, having to spend time that we did not spend before calling drug stores, the health department, other pediatric offices, and hospitals to see if we could get the COVID-19 vaccine from them. This has also caused me and my colleagues to have to spend time doing our own research on the COVID-19 vaccine because the ACIP is not providing us with adequate recommendations and reasonings. Pediatricians and primary care physicians are meant to be foot

soldiers who can rely on the researched recommendations and findings of the ACIP, and instead we are having to fulfill the roles of researchers ourselves. This time is not time we can bill and be paid for.

8. As a result of the Directive and recent ACIP recommendation for Covid-19 vaccines for my pediatric patients, I have had to have longer, more in-depth conversations with parents about the safety and effectiveness of the COVID-19 vaccine, conversations that we did not have to have before the Directive. These conversations take 2–3 extra minutes per visit, and I see 20–25 patients per day. I am not being compensated for this extra time, which results in an hour per day of unpaid time. The cumulative effect between the other providers in my practice is multiple hours a day of unpaid time. Many of these conversations have been about dispelling disinformation that the Secretary and others at the Department of Health and Human Services have spread about the COVID-19 and other vaccines. For example, I have had to tell patients that any trace amount of aluminum in vaccines is not dangerous and that there is ten times more aluminum in breast milk than there is in a dose of a vaccine. I have also had to spend considerable time equating the safety and efficacy of the COVID-19 vaccine and the flu vaccine. Ninety-nine percent of these discussions about vaccines are in preventative visits for which there is no CPT or HCPCS code that I can use to bill this time. The Directive and recent ACIP recommendation for SCDM for Covid-19 vaccines for my pediatric patients, are causing me to work this additional time for free.

9. The Directive and recent ACIP recommendation for Covid-19 vaccines for my pediatric patients has also contributed to patients dropping out of my practice. I treated a mother with eight children, all of whom I have seen since they were born. She came in with her husband and both expressed concern about aluminum in vaccines. These patients have since disappeared

and not brought any of their children into my practice when they were due for their next preventative visits. They have not transferred practices, because if they had, we would have received a request for the children's medical records. This is not the only example of which I am aware of families simply dropping out of the healthcare system because of their mistrust of the COVID-19 and other vaccines. The Directive and recent ACIP recommendation for SCDM for Covid-19 vaccines for my pediatric patients has caused financial harm to my practice by contributing to patients dropping out of my practice.

10. The harms described above are not confined to past events and are ongoing with respect to the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children and pregnant women. Since the changes to the CDC immunization schedule recommendations for Covid-19 vaccination, I continue to have to respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance. I have to address Covid-19 vaccinations now with my patients throughout my day, and I must repeatedly spend time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption directly interferes with my routine care, diverts my clinical time, and undermines confidence in vaccination recommendations that I rely on daily. The Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children is undermining my physician-patient relationship and causing needless health outcomes to my patients. The harms set forth above are ongoing and will continue unless the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children are immediately enjoined and the ACIP and CDC return to the evidence-based, transparent process for making vaccine recommendations for children.

11. The harms identified above associated with the Directive, CDC's changes to the CDC immunization schedule for Covid-19 vaccination for children, the January 5, 2026 changes to the childhood immunization schedule ,as well as the anticipated harms that will result from any additional changes that may result from the upcoming February 25-26, 2026 ACIP meeting,are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as their physician. As a physician, I do not regain lost time, trust, or clarity between policy shifts. Instead, each new change increases the burden on my practice, amplifies patient skepticism with my recommendations during my consultation, increases the time I am spending during each visit, and diminishes the effectiveness of my clinical counseling. There is a practical limit to how much uncertainty I can absorb while still providing effective care, and in my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January 5childhood schedule changes, and the imminent February 25-26, 2026 ACIP meeting has pushed my clinical practice toward or beyond that limit absent immediate injunctive relief.

12. The harms described above are also compounded by the failure to follow the established GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure

from established methodology. That burden does not replace prior work, it is added on top of my existing clinical responsibilities. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5childhood schedule changes, and the anticipated February 25-26 - ACIP actions, the harm compounds.

13. I do not have the time or practical ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that I have relied on throughout my entire career as a practicing physician. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in my ability to answer questions and provide recommendations to my patients on these vaccinations, pushing my clinical practice toward a breaking point absent immediate injunctive relief

I declare under the penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of the State of North Carolina, that the foregoing is true and correct.

Executed on January 23, 2026 in Raleigh, North Carolina.

/s/ Dr. Mary-Cassie Shaw

Mary-Cassie Shaw, MD, FAAP

EXHIBIT 34

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916

DECLARATION OF ANDREW D. RACINE, M.D., Ph.D., FAAP

I, Andrew D. Racine, M.D., Ph.D., FAAP, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' Motion for Preliminary Injunction filed in the above-captioned action.

2. I am board certified in Pediatrics and am a Fellow of the American Academy of Pediatrics and a Professor of Pediatrics at the Albert Einstein College of Medicine.

3. I have over 30 years of clinical experience in pediatrics. I received my medical degree from New York University School of Medicine in 1983, my Ph.D. in Economics from New York University Graduate School of Arts and Sciences in 1987, and served my pediatric internship and residency at Boston Children's Hospital in Boston, Massachusetts.

4. From 2012 – 2025, I served as the Chief Medical Officer of a large health system in New York and from 2012 to present serve as the System Senior Vice President and Executive

Director of a large network of ambulatory primary care practices of that health system that includes one of the largest most comprehensive school health programs in the United States.

5. I also currently serve on the Board of the National Bureau of Economic Research (a non-profit organization dedicated to economics conducting and disseminating research), The Organization for Medical and Psychological Assistance to Children Overseas (a non-profit organization that provides medical and other services to children overseas), The New York Academy of Medicine (a public health oriented coalition of medical professionals), and several committees of the American Academy of Pediatrics (AAP) including the Member Strategic Planning Committee, Member Governance Committee, and the member Engagement Committee.

6. As of January 1, 2026, I am the President of the AAP.

7. Since its establishment in 1930, the AAP has functioned as an independent national voice focused on advancing the health of children. It remains dedicated to promoting the physical, mental, and social well-being of all infants, children, adolescents, and young adults.

8. The AAP has a nationwide membership of more than 67,000 pediatricians, pediatric subspecialists and pediatric surgical specialists. Many of these physicians are actively engaged in the day-to-day delivery of medical care to children and adolescents in a wide range of clinical settings, including hospitals and community-based outpatient practices.

9. In furtherance of its mission, the AAP develops and disseminates scientifically grounded, nonpartisan clinical guidance and policy statements addressing issues that affect pediatric health. These materials are produced through a rigorous review process and are intended to support pediatricians in providing evidence-based care.

10. Pediatricians who are members of the AAP practice in every region of the United States and are directly impacted by federal actions that modify or withdraw established evidence-

based vaccine recommendations for children and adolescents, including changes to federally maintained immunization schedules by the United States Secretary of Health and Human Services Robert F. Kennedy Jr. (the "Secretary"). Since the May 19, 2025 directive issued by the Secretary[1] (the "Directive") continuing through and beyond January 5, 2026, when Jim O'Neill, Acting Director of Centers for Disease Control and Prevention ("CDC"), adopted a completely revised CDC Childhood Immunization Schedule (the "Schedule Change") (collectively, the "Vaccine Changes") there have been immediate consequences for clinical decision-making and patient counseling. If called to testify, I am competent to do so and would testify truthfully under oath regarding the matters stated herein.

11. Alterations to longstanding evidenced-based vaccine policies and recommendations have caused, and will continue to cause, significant harm to AAP's members by undermining evidence-based pediatric practice, creating uncertainty among families, and interfering with the delivery of preventive health care that protects children from vaccine-preventable disease.

12. From my standpoint as President of the AAP and as a physician leader, the issues described below directly affect the AAP and pediatricians nationwide.

13. The AAP has experienced a significant increase in workload as it has been forced to divert substantial resources to address what has become a series of ongoing crises as a result of the Vaccine Changes.

14. For example, the AAP has had to redirect its communications team to deal specifically with these crises, including responding to widespread misinformation related to pediatric health and vaccines.

[1] A true and correct copy of the directive issued by United States Secretary of Health and Human Services Robert F. Kennedy Jr., dated May 19, 2025, is attached to this declaration as **Exhibit A**.

15. Since the Vaccine Changes, a significant portion of the AAP's efforts involves interpreting government recommendations and translating them into toolkits, guidance documents, and communications for pediatricians and the public. This is due to the confusion that the Vaccine Changes have caused. Since the Vaccine Changes, guidance from the Centers for Disease Control and Prevention ("CDC") has not been consistent. For example, there has been confusion regarding whether the birth dose of the Hepatitis B vaccine is recommended under shared clinical decision-making or only for high-risk populations because the CDC website contains statements that suggest both are true. As a result, of these inconsistencies, the AAP must expend additional resources to systematize and clarify recommendations for its members, for practitioners in other medical societies, and for the public at large.

16. Also since the Vaccine Changes, the AAP must also engage extensively with regional and state-level entities to advise them on appropriate messaging to departments of health and to reinforce that there has been no change in disease prevalence or vaccine safety. These efforts must be repeated state by state and district by district, resulting in substantial additional time, labor, and expense.

17. The AAP has also been required to engage in discussions with payors because of uncertainty regarding what services and vaccinations payors are responsible for covering.

18. The AAP has received a high volume of calls from its members seeking clarification, guidance, and tools to help them communicate accurate information to patients and families.

19. Collectively, these activities represent a significant diversion from the AAP's normal mission-driven work and have resulted in increased workload and increased expenses.

20. There are also downstream impacts affecting clinical practice and public health, including changes in vaccination patterns and changes in disease epidemiology. For example, there have been significant measles outbreaks throughout the United States, including in South Carolina. In one instance, a pediatric practitioner in South Carolina who is a member of AAP has been required to evaluate patients with measles-like symptoms in her parking lot to avoid potentially exposing other patients, parents, and staff members to a potential case of measles. These measures are necessary due to a large unvaccinated population in her region prompting serious infection control concerns, as the measles virus is highly contagious. This practitioner has had to forego caring for other patients in order to address these cases, demonstrating how confusion, decreased vaccination rates, and increased disease burden have directly altered the practice of medicine as seasoned practitioners know it.

21. These downstream consequences further increase the strain on pediatricians and healthcare systems.

22. There have been dramatic changes to the vaccines recommended for American children. The CDC childhood schedule now closely resembles that of Denmark. This does not work for a variety of reasons. First, the United States is 3.8 million square miles and Denmark is 16,600 square miles, approximately the size of West Virginia. The United States has 335 million people and Denmark has 6 million, which is fewer than live in the Atlanta metro area. You cannot copy and paste public health as different countries face different disease risks, and it does not make sense to use any other nation's health plan for our kids here in the United States. There is no evidence that skipping or delaying certain vaccinations is beneficial for U.S. children. There is

evidence that any time a child goes without recommended immunizations they are at risk for diseases that we can prevent with very simply, safe, effective interventions.[2]

23. I have reviewed the decision memorandum dated January 5, 2026[3] (the "Decision Memo") and the Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries dated January 2, 2026[4] (the "Assessment").

24. My review of the Decision Memo and the Assessment was conducted for the purpose of evaluating their contents, assumptions, and conclusions as they relate to pediatric care, public health, and the professional activities of pediatricians.

25. My overall impression is that Assessment is written as an advocative opinion piece rather than as a scientific analysis. A scientific document would clearly define its terms, articulate testable hypotheses, systematically marshal data and evidence, and present a comprehensive and balanced review of the relevant literature. This document does not approach the subject in that manner.

26. Throughout the document, the authors rely on narrative assertions rather than empirical analysis. While I highlight several representative examples below, these examples are not intended to be an exhaustive catalog of the ways in which the Assessment departs from accepted scientific standards of evaluation and argumentation.

27. The Assessment's underlying premise is rooted in a directive from the President of the United States instructing the Secretary and the Director of the Centers for Disease Control and

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[2] Sean O'Leary, MD, MPH, FAAP, *What is the difference between the AAP immunization recommendations and other vaccine schedules?*, HEALTHYCHILDREN.ORG (Jan. 16, 2026), https://www.healthychildren.org/English/tips-tools/ask-the-pediatrician/Pages/what-is-the-difference-between-the-AAP-recommended-immunization-schedule-and-other-vaccine-schedules.aspx.

[3] A true and correct copy of the decision memorandum dated January 5, 2026, is attached to this declaration as **Exhibit B**.

[4] A true and correct copy of Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries, is attached to this declaration as **Exhibit C**.

Prevention to "…to update the US core childhood vaccine schedule if they determine that superior practices exist abroad." This framing raises a fundamental question about the responsibilities of these officials: whether their primary obligation is to align U.S. practices with those of other countries or to maximize the safety and health of children in the United States.

28. If conformity with international practices is the objective, the Assessment fails to explain why childhood immunization schedules are singled out for such alignment, as opposed to other public health domains such as dietary guidelines, pediatric surgical practices, or gun safety regulations commonly adopted abroad. The document does not articulate what is uniquely deficient about the current U.S. vaccine schedule that would justify this comparative approach.

29. On page one of the Assessment, the authors introduce the concept of "consensus vaccines," a term that has no established definition or recognized meaning in epidemiology, immunology, molecular biology, or clinical medicine. This construct appears to be invented for the purposes of the argument and lacks empirical content. Nevertheless, it is presented as though it carries weight comparable to the extensive scientific evidence supporting current vaccination recommendations, rendering it essentially a non sequitur in the context of vaccine safety and effectiveness.

30. The Assessment repeatedly asserts that HHS should base vaccination recommendations on both "the best available evidence" and the "best practices of peer, developed nations." These are presented as equivalent criteria, despite being fundamentally distinct. The U.S. vaccination schedule is the product of decades of evidence-based review conducted by expert panels applying transparent and verifiable standards to U.S.-specific data. By contrast, the phrase "best practices of peer, developed nations" has no inherent empirical definition and functions as a rhetorical device rather than a scientifically meaningful benchmark.

31. The authors of the Assessment further claim that the United States is an "outlier" in its vaccination schedule. However, the Assessment's own Table 2 demonstrates that Denmark, not the United States, is the true outlier. The average number of diseases against which children are immunized as represented in this table is 13.8 with a standard deviation of 1.61, and this calculation is not population weighted. If you perform a population-weighted calculation using the OECD Family Database, a data base that provides cross-national indicators on family outcomes and reports child population 14 years of age or younger for each country, the average number of diseases protected against is then 15.22. Even using the lower number with the average of 13.8 and standard deviation of 1.61, the US is two standard deviations above the mean (mean + 2 StD = 17.0) but Denmark is more than two standard deviations below the mean (mean – 2 StD = 10.5). Thus, on a basic level of comparison, the "outlier" country here is Denmark, not the U.S and the Assessment provides no justification for proposing that U.S. policy should be aligned with that of a statistical outlier.

32. On page three of the Assessment, the authors propose that designating certain vaccines as "non-consensus" and limiting them to children with identifiable risk factors would allow vaccination to be better targeted. This is an empirically testable hypothesis, but the document offers no evidence that such risk stratification is feasible or effective. Recent measles deaths in the United States occurred in previously healthy children without identifiable risk factors, illustrating that all children are potentially vulnerable to complications from vaccine-preventable diseases.

33. The Assessment's discussion of hepatitis B vaccination similarly omits critical historical evidence. Prior strategies that limited vaccination to "high-risk" infants failed to prevent thousands of childhood infections in the United States, including those acquired through non-

maternal transmission. These failures directly motivated adoption of the universal birth dose, yet this context is entirely absent from the document.

34. The authors also reference "COVID-19 vaccination mandates with their de facto denial of infection-acquired immunity," a claim made without citation and contrary to established immunologic understanding. Vaccine recommendations were intended to prevent the morbidity and mortality associated with acquiring immunity through infection, not to deny the existence of infection-acquired immunity.

35. The assertion that expanded shared clinical decision-making would "restore trust" in public health recommendations is another unsubstantiated claim. While this hypothesis could be empirically evaluated, the authors provide no evidence that it has been tested or demonstrated. Trust is presented as a justification for policy change without proof that the proposed changes would achieve that goal.

36. The document further discusses vaccine mandates, despite the fact that the CDC issues recommendations rather than mandates, which are determined at the state level. This discussion is tangential to the stated purpose of evaluating vaccination schedules.

37. The document also misrepresents survey data regarding pediatricians who dismiss families refusing vaccination. The citation for this statement comes from a letter to the editor authored by Sean O'Leary, an AAP member, and colleagues from 2020 based on a survey of 303 members of the AAP. While the survey found that many (51%) of practices had policies requiring patients to agree to vaccinate their children, in practice, far fewer (37%) actually enforced the policy "often or always". The way the authors report these findings in the Assessment, therefore, does not accurately reflect what was documented in the survey.

38. When addressing the state of the evidence, the authors of the Assessment call for additional placebo-controlled randomized trials to establish the safety of the childhood immunization schedule. In doing so, they selectively quote a publication of the National Academies of Science Engineering and Medicine that appeared in 2013 entitled: *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence and Future Studies* ("NASEM Study").[5] The authors of the Assessment selectively quote from the NASEM Study while omitting its central conclusions. For example, the authors of the Assessment state that the NASEM study recommended that HHS "incorporate study of the safety of the overall childhood immunization schedule into its processes for setting priorities for research, recognizing stakeholder concerns, and establishing the priorities on the basis of epidemiological evidence, biological plausibility, and feasibility" and "continue to fund and support the Vaccine Safety Datalink project to study the safety of the recommended immunization schedule."[6] However, the Assessment fails to include that the first sentence of the NASEM report states "[v]accines are among the most effective and safe public health interventions available to prevent serious disease and death," that "[e]ach new vaccine considered for inclusion in the immunization schedule is tested within the context of the existing schedule and reviewed by clinical researchers, who analyze the balance of demonstrated benefits and risks. Thus, each new vaccine is approved on the basis of a detailed evaluation of both the vaccine itself and the immunization schedule," and that "[t]he committee found no significant evidence to imply that the recommended immunization schedule is not safe."[7]

[5] The NASEM report is available at: https://www.ncbi.nlm.nih.gov/books/NBK206948/
[6] *Id.* at 12 and 14.
[7] *Id.* at 1-2 and 14.

39. When an external document from the CDC and Department of Health and Human Services misrepresents evidence or advances unsupported conclusions while invoking the authority of established medical practice, AAP is forced to divert substantial staff time and expert resources to reviewing the claims, issuing corrections, and responding to inquiries from clinicians, policymakers, media, and the public. This reactive work displaces core activities such as guideline development, education, research support, and patient safety initiatives, imposing a real and measurable operational burden on the organization.

40. The Vaccine Changes, and the accompanying Decision Memo and Assessment, also create direct reputational harm to AAP by generating confusion about the state of medical consensus. Even when AAP has not endorsed the assessment issuing corrections places AAP in a defensive posture, requiring it to rebut claims that have been widely disseminated. This damages the AAP's reputation as a stable and authoritative source of evidence-based guidance and complicates its relationships with clinicians, public health partners, and policymakers who rely on clarity and consistency. This places AAP in an ongoing cycle of damage control shaped by errors they did not create as each instance of an action by the Secretary, CDC, and the Advisory Committee on Immunization Practice requires action from the AAP to correct the misinformation.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Andrew Racine, M.D., Ph.D., FAAP

Andrew D. Racine, M.D., Ph.D., FAAP
On behalf of the American Academy of Pediatrics

Executed on January 24, 2026

EXHIBIT A

SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN

May 19, 2025

The Department of Health and Human Services (HHS) continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available Food and Drug Administration (FDA) approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

By Secretarial Directive on June 18, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of Pfizer- BioNTech and the Moderna COVID-19 vaccines in the U.S. population for children ages six months through five years, consistent with the parameters of the Emergency Use Authorizations (EUAs) issued by FDA, for the Pfizer- BioNTech and the Moderna COVID-19 vaccines.[1]

By Secretarial Directive on June 24, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of COVID-19 vaccines in the U.S. population for children ages six through 17 years, consistent with the parameters of EUAs issued by FDA.

The CDC also currently recommends the COVID-19 vaccine during pregnancy.[2]

Based on a review of the recommendation of the FDA and National Institutes of Health (NIH), I have determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine. Accordingly, the HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years and are rescinded.

Based on a review of the recommendation of the FDA, I have similarly determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby. Therefore, the CDC recommendation that pregnant women receive the COVID-19 vaccine is rescinded.

Accordingly, the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above.

Robert F. Kennedy, Jr.
Secretary

[1] The Pfizer and Moderna vaccines are currently approved by the FDA for children 12 years of age and older.
[2] https://www.cdc.gov/vaccines-pregnancy/recommended-vaccines/index.html.

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EXHIBIT B

Docusign Envelope ID: 14147443-069C-4B98-B81C-BD6C15B4DB8B

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

Decision Memo

DATE: January 5, 2026

TO: Jim O'Neill, Acting Director, Centers for Disease Control and Prevention (CDC)

FROM: Jay Bhattacharya, MD, PhD, Director, National Institutes of Health
Mehmet Oz, MD, MBA, Administrator, Centers for Medicare and Medicaid Services
Marty Makary, MD, MPH, Commissioner of Food and Drugs

SUBJECT: DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule

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PURPOSE

This memorandum proposes a revised childhood and adolescent immunization schedule for your review and approval.

RECOMMENDATION AND ACTION REQUESTED

After considering the data and recommendations contained in TAB 1, "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries," and your discussions with relevant health officials, you should approve the revised immunization schedule.

BACKGROUND AND SUMMARY OF RECOMMENDED ACTION

On December 5, 2025, the President directed the Department of Health and Human Services (HHS) and the Centers for Disease Prevention and Control (CDC) to review best practices from peer, developed nations regarding core childhood vaccination recommendations and the scientific evidence underlying those practices. The President further instructed that, "if [HHS and CDC] determine that those best practices are superior to current domestic recommendations, update the United States core childhood vaccine schedule to align with such scientific evidence and best practices from peer, developed countries while preserving access to vaccines currently available to Americans."

As part of this review, you discussed childhood immunization recommendations and policy with health officials from Japan, Germany, and Denmark. You also discussed immunizations with CDC and Food and Drug Administration (FDA) officials with duties and responsibilities related to vaccine safety and efficacy, respectively.

TAB 1 is the review of peer nations' best practices and the scientific evidence underlying those practices. Dr. Tracy Beth Høeg, Acting Director of the FDA Center for Drug Evaluation and Research (CDER), and Dr. Martin Kulldorff, Chief Science and Data Officer, HHS Office of the Assistant Secretary for Planning and Evaluation (ASPE), authored TAB 1 in consultation with subject matter

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officials at CDC, FDA, the National Institutes of Health (NIH), and the Centers for Medicare and Medicaid Services (CMS). After a careful review of the current U.S. childhood and adolescent immunization schedule, peer nations' schedules and best practices, and the underlying evidence and data, TAB 1 recommends adopting a revised childhood and adolescent immunization schedule that is based on those vaccines for which there is broad-based international consensus. The consensus vaccines are recommended for all children.

The recommended schedule includes consensus vaccines for measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type B (Hib), pneumococcal disease, human papillomavirus (HPV), and varicella. This vaccine schedule reflects the Danish schedule except that this revised schedule adds the varicella vaccine, which is not currently on the Danish schedule. TAB 1 proposes that the CDC recommend these vaccines for all children.

In addition to the consensus vaccines, the schedule recommended in TAB 1 includes immunizations for high-risk groups and immunizations based on shared clinical decision making. Unlike the consensus vaccines, these are immunizations for which there is not broad-based consensus and TAB 1 discusses the scientific evidence regarding why they should not be recommended for all children.

TAB 1 does not assess and propose any changes to recommendations for high-risk populations. Those immunizations include: Respiratory syncytial virus (RSV) monoclonal antibodies, and hepatitis A, hepatitis B, meningococcal B, meningococcal ACWY, and dengue.

TAB 1 also proposes that CDC's recommended childhood and adolescent immunization schedule list vaccines for hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 be based on shared clinical decision making. The CDC applies shared clinical decision-making recommendations when evidence indicates that individuals may benefit from vaccination based on an analysis of the individual's characteristics, values, and preferences, the provider's medical judgment, and the characteristics of the vaccine being considered.

The recommendation to realign the CDC's immunization schedule under a framework built on 11 consensus vaccines is not a significant departure from the current recommended immunization construct. The current CDC schedule (TAB 2) categorizes routine immunization recommendations into three general categories: (1) population-based (i.e., age-based, including catch-up), (2) risk-based (i.e., immunosuppression, other underlying medical conditions, work-related, or other special circumstances that increase risk of illness), and (3) shared clinical decision-making-based.

Under the new framework, measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib, pneumococcal disease, HPV, and varicella constitute category 1, the population-based category of routine immunizations, and are recommended for all children. Immunizations currently recommended for high-risk groups continue to be recommended for high-risk groups under category 2 in the preceding paragraph. Hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 remain on the schedule based on shared clinical decision-making, category 3 above.

Finally, consistent with the President's direction to "preserv[e] access to vaccines currently available to Americans," all the immunizations listed in the preceding paragraphs are (i) on the current schedule, (ii) will remain on the revised schedule, and, therefore, (iii) continue to be covered without cost sharing by

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private insurance and covered by Medicaid, Children's Health Insurance Program (CHIP), and the Vaccines for Children Program.

*** Figure 1 on pages 2-3 of TAB 1 illustrates the proposed schedule with recommended doses and ages.**

DISCUSSION

Before reviewing and assessing the current childhood and adolescent immunization schedule relative to those of peer nations, it is important to first understand what, if any, problems currently exist with childhood immunization in the United States.

Current Problem: Decreased Vaccine Uptake and Trust

Childhood vaccination rates in America have fallen over the past five years. From the 2019/20 to 2023/24 school year, there was a decline in childhood measles, mumps, and rubella (MMR) vaccination from 95.2% to 92.7%. In the 2024-2025 academic year, 16 states had MMR vaccination rates below 90%, which is below the critical threshold for herd immunity for measles. Consequently, in 2025 there were nearly 50 measles outbreaks and over 1,800 measles cases attributed to those outbreaks. Finally, although the CDC still recommended the COVID-19 booster for all children in 2023, the uptake was less than 10%.

Robust immunization programs are an essential public health tool, but those tools are only effective when there is public trust. Unscientific belief that vaccine-acquired immunity was superior to infection-acquired immunity combined with inaccurate CDC claims that the COVID-19 vaccine would prevent infection and transmission eroded public trust in the COVID-19 vaccine.

The loss of trust in the COVID vaccines coincided with less adherence to the full CDC childhood vaccine schedule, which has resulted in lower immunization rates of well-established vaccines, such as those for measles, rubella, pertussis, and polio.

Current Problem: Knowledge Gaps Concerning Safety

The Institute of Medicine (IOM) stated in a report that "vaccines—like all drugs or medical interventions—are neither 100 percent risk-free nor 100 percent effective." The United States administers significantly more doses of childhood immunizations than its peer nations, yet there is a significant knowledge gap due to a dearth of randomized vaccine trials and limited post-licensure infrastructure for monitoring potential adverse reactions and long-term chronic events.

The U.S. has a limited post-licensure infrastructure focused on monitoring potential adverse reactions that occur within a few days or weeks after vaccination. This includes the Vaccine Adverse Event Reporting System (VAERS), but the two key components are CDC's Vaccine Safety Datalink (VSD) and FDA's Biologics Effectiveness and Safety (BEST) System. These systems typically conduct limited safety review using risk windows after vaccination which inject significant bias and severely limits the potential to detect serious harms, but despite this and other serious limitation, these systems within a year of vaccine approval have confirmed serious harm, including intussusception after rotavirus

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vaccines, febrile seizures after the MMRV vaccine, and anaphylaxis and myocarditis after the mRNA COVID-19 vaccines. Additionally, current surveillance systems are underutilized to detect long-term harms.

International Comparison of Childhood Vaccine Schedules

As illustrated in Table 2 on page 15 of TAB 1, the United States currently recommends more childhood vaccines than any peer nation, and more than twice as many vaccine doses as some European nations.

While a set of consensus vaccines is consistently recommended in all peer countries, several vaccines included in the current CDC childhood and adolescent immunization schedule (e.g., hepatitis A, varicella, influenza, rotavirus and meningococcal vaccines) are limited in their recommendation or excluded in some other developed countries. Each disease addressed by the U.S. child immunization schedule poses a health risk, but the level of threat varies widely by disease and sometimes by individual underlying risk factors. The mere existence of a vaccine does not automatically make it appropriate for every child, nor does it necessarily justify universal vaccination.

There is global variation in the universal use and timing of numerous childhood vaccines. Although these differences sometimes reflect the unique epidemiology of diseases in each region, they more often arise from uncertain science and knowledge gaps, which lead to inadequately informed assessments of risks and benefits that are subject to differing interpretations. Disagreement among states and professional societies in the U.S. further underscores the need and opportunity for a more adaptable childhood immunization schedule.

Broad-based insurance coverage of both consensus and non-consensus immunizations should remain in effect following the updates to the vaccine schedule. Identifying the consensus vaccines on the schedule would help Americans follow the schedule while making all vaccines available for parents also wanting non-consensus immunizations. Through proper vaccine research, it is important to improve our understanding of populations who are most likely to benefit from individual vaccines as well as situations where vaccination may not be needed.

Recommended Immunization Schedule Based on Assessment of Peer Nations and Scientific Evidence

Immunizations Recommended for All Children: These are immunizations that are important for all children to receive. They include measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib and pneumococcal disease vaccines. These are consensus vaccines that are part of the recommended childhood immunization schedules for all 20 peer nations, with the exception of mumps in Japan. While the safety/risk profile is not fully understood, and in need of further study, there is consensus among peer nations that they provide material benefits against the target disease. Focusing on these vaccines is more likely to reverse the declining uptake of these vaccines.

In addition to the vaccines listed above for which there is nearly unanimous peer nation agreement, HPV and varicella vaccines should also be included.

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The scientific evidence for the HPV vaccine—increasingly recognized by peer nations in their own recommendations—supports one dose instead of two when given to children. Australia, parts of Canada, Ireland, Spain, and the United Kingdom have already changed their recommendations to one dose.

The varicella zoster virus causes chickenpox (typically in children) and, for those infected, can reemerge as shingles (typically in adults). The uncertainty of its long-term consequences on adults is one reason why some countries have been cautious about adding the varicella vaccine to the childhood schedule, but similar caution may be warranted regarding a removal once there has been widespread use of this vaccine. The rate of two dose vaccination for varicella among American children is estimated at 92%. Partial population varicella vaccination (60-80% for two doses) could increase the average age at which the population naturally gets chickenpox when this disease could cause more complications, and hence there is a consensus among peer nations that once vaccination for chicken pox has become widespread, stopping use of this vaccine could cause certain complications. For these reasons, the varicella vaccine should remain a consensus vaccine.

Immunizations Recommended for Certain High-Risk Groups or Populations: Like all medical products, vaccines have different risk-benefit profiles for different people. This can either be because of underlying comorbidities, unusual exposure to the disease, or the risk of disease transmission to others. For example, the hepatitis A vaccine when children travel internationally to an endemic area or the birth dose of the hepatitis B vaccine for infants born to mothers that are hepatitis B positive. TAB 1 does not propose any changes in immunization recommendations for high-risk populations.

Immunizations Based on Shared Clinical Decision-Making: Shared clinical decision-making recommendations are individually based and informed by a discussion between the health care provider and the patient or parent/guardian, something that should occur for all vaccines. It is not always possible or pragmatic for public health officials to clearly define who will benefit from a vaccine, who has the relevant risk factors, or who are at risk of exposure. Parents and physicians, who know the child, may be better placed to make that judgement. With shared clinical decision-making, the characteristics of the individual are considered, including their likelihood of being exposed to the diseases, their risks of morbidity and mortality if contracting the diseases, their likelihood of benefitting from the vaccine, their likelihood of vaccine adverse reactions, and their risk of transmitting the disease to others. Sometimes, it is also important to consider personal and family preferences, beliefs, and knowledge, including when a patient presents specific information regarding the pre-and-post licensure safety data of a vaccine or presents specific familial experience with a vaccine. While non-consensus immunizations are not routinely recommended for all children, all these vaccines will continue to be available for anyone who wants them and will be covered by Medicaid, CHIP, the Vaccines for Children Program, and private health insurance.

- Hepatitis A: When hepatitis A vaccines were approved in the 1990s, the primary candidates for vaccination were "travelers to regions of endemic disease, children living in high prevalence areas, homosexual males, users of illicit intravenous drugs, persons working directly with nonhuman primates or hepatitis A virus, patients older than 30 years of age with chronic liver disease, and persons who have received a liver transplant or are awaiting one." Those had disappeared in the U.S. by 2006, at which time a 2-dose regiment at age 12 to 23 months was added to the universally recommended childhood immunization schedule. In 2006, the annual incidence rate of hepatitis A

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was very low at around 1 per 100,000 and it remains similarly low. The annual mortality rate is 1 per 10 million, with the highest rate among older men.

Among peer nations, Greece is the only one with a routine childhood vaccine recommendation. Given the low U.S. incidence and mortality, and the lack of randomized placebo-controlled safety data, the benefit-risk ratio is at best very low for most children. There is a clear benefit, but still undefined risk, for children travelling to high endemic countries in the developing world.

- Hepatitis B: Together with hepatitis B immune globulin, it is important that infants are administered the hepatitis B vaccine at birth if the mother is HBsAg-positive or status is unknown. If the mother tests negative, only two of the 20 peer nations recommend routine vaccination at birth: Australia and Portugal, while two countries do not recommend it at all. At their December 2025 meeting, the ACIP followed the majority of peer nations and voted to no longer recommend the birth dose if the mother tested negative. Instead, it recommended shared clinical decision-making, taking the risk profile of each unique child into account.

- Rotavirus: Rotavirus is a common infection, and prior to the rotavirus vaccine, nearly every child would be infected, both in the U.S. and abroad. In the developing world, many children die from dehydration after catching the virus, and there is a greater opportunity for benefit from vaccination. In the U.S., it can cause hospitalization for gastroenteritis, but the virus poses almost no risk of either mortality or chronic morbidity.

  Data from CDC indicate that among all U.S. children <15 years of age, there were an average of 3.3 deaths per year with the rotavirus diagnostic code listed on the death certificate between 1999 and 2005. This was after the RotaShield vaccine was withdrawn from the market in 1999 and before the RotaTeq vaccine was approved in 2006. Another vaccine, Rotarix, was approved in 2008. After these vaccines were recommended for all children, there were 1.6 deaths per year from 2009 to 2020. There may be many reasons for this very small decrease in mortality that are unrelated to the vaccine, including improved medical care, changes in diagnostic practices, or random fluctuations.

  RotaShield was removed from the market due to an excess risk of intussusception. The newer current vaccines have a lower intussusception risk, at around 1 or 2 per 100,000 vaccinated children. Reasonable people can reach different conclusions about recommending the rotavirus vaccine for all children. Among peer nations, Belgium, Denmark and Portugal do not recommend it. Denmark has cited the very low risk of mortality and chronic morbidity to nearly all children in their rationale for not adding the vaccine to their childhood immunization schedule.

- Meningococcal disease: Among peer nations, 15 recommend meningococcal vaccination for all children while five limit it to high-risk groups. The incidence of meningococcal disease has declined during the past decades, both in countries with and without the routine vaccine recommendations for children, and the magnitude of the decline appears to be independent of vaccination policy. The current incidence in the U.S. is 0.12/100,000 or about one case per million per year.

  In a 2011 position paper, the World Health Organization (WHO) recommended that countries with more than 2 cases per 100,000 population/year maintain a "large scale meningococcal vaccination program," while only vaccinating the high-risk population in countries with lower rates. In the

United States, the current incidence rate is around 0.1 per 100,000 is much lower than the WHO suggested cut-off.

The current meningococcal vaccines recommended for all children (Menveo, Menquadfi, and Penbraya) were not evaluated in large-scale double-blind placebo-controlled randomized trials before FDA approval.

Considering the low incidence rates of meningococcal disease in the U.S., the meningococcal vaccine should not be part of the consensus recommended vaccine schedule. High-risk children and adolescents, such as children with certain types of immune deficiencies, may have a greater chance of benefiting from the vaccine.

- Influenza: The primary purpose of the childhood influenza vaccine in children is to reduce hospitalizations and mortality in children, as well as transmission to the elderly, who are of higher risk for death but there are no randomized controlled trials demonstrating these benefits. There are a few post-licensure randomized placebo-controlled trials for the influenza vaccine. The most comprehensive review was done in 2018 by the Cochrane Collaboration. They found that "in children aged between 3 and 16 years, live influenza vaccines probably reduce influenza (moderate-certainty evidence)" infections while "inactivated vaccines also reduce influenza (high certainty evidence)." Only a few of the trials evaluated school and parental work absenteeism, not finding a statistically significant reduction. There was no evidence about reduced transmission. The trials could not evaluate differences in hospitalizations or mortality, as there were none or few in either group, so they provide no evidence that the vaccines reduce hospitalization or deaths. There was not much information about children under 2 years old.

  The conclusion of the Cochrane systematic review of randomized trials in children was that "Decision-makers' attention to the vaccination of very young children is not supported by the evidence summarised in our review. Although there is a growing body of evidence showing the impact of influenza on hospitalisations and deaths of children, at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza."

  There have been some observational studies with mixed results. A test-negative case-control study claimed to show that childhood influenza vaccine reduces hospitalization, but that is a notoriously biased study design with highly implausible results.

  While there is a scarcity of reliable safety data, the influenza vaccines are not without risk. The seasonal vaccine has been linked to Guillain Barré syndrome. During the 2009/2010 H1N1 influenza pandemic, the Pandemrix pandemic vaccine was found to cause narcolepsy among vaccinated children and adolescents. The Cochrane systematic review, noted that "the lack of safety data for inactive vaccines in younger children is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA and Canada" and that "the manufacturers' refusal to release all safety outcome data from trials carried out in young children, together with obvious reporting bias and inconsistencies in the primary studies, does not bode well for a fair assessment of the safety of live attenuated vaccines."

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Considering the evidence, and lack of evidence, it is understandable that public health agencies in different countries have come to different conclusions about the influenza vaccine for children. Among the 20 peer countries, only Austria and Canada recommend an annual influenza vaccine for all children >6 months and all adolescents. Another six recommend the shot for all children in selected age ranges. The remaining twelve peer nations do not recommend the influenza vaccine for all children in any age group.

Based on both the evidence and uncertainties, the influenza vaccine should not be recommended for all children, but it should be available through insurance for all children >6 months old, through shared-clinical decision making.

- COVID-19**:** In 2022, Denmark became the first peer nation to remove its universal recommendation of the COVID-19 vaccine for children, with the director of its public health authority recognizing that there was little benefit in giving this vaccine to children. Since then, all other peer nations have followed. At their September 2025 meeting, the ACIP voted that shared clinical decision-making should be applied to the COVID-19 vaccine for U.S. children and adolescents.

Finally, if you approve the revised schedule, you should also later recommend to the Secretary that HHS agencies fund and conduct gold standard medical research to assess overall health outcomes related to all immunizations on the revised schedule (i.e., immunizations recommended for all children, immunizations recommended for high-risk groups, and immunizations based on shared clinical decision making), the interaction effects between different immunizations as well as other aspects of the immunization schedule—something that is needed to close the knowledge gap.

EXECUTION

If approved, the revised childhood and adolescent immunization schedule will be published in an upcoming *Morbidity and Mortality Weekly Report*. CDC will also publish the CDC-adopted recommendation on the applicable CDC website and also update the childhood and adolescent schedule in alignment with this decision.

DECISION

After thoroughly reviewing the assessment in TAB 1 and further considering the childhood immunization recommendations based on my discussions with CDC, FDA, and peer, developed nation health officials, I have determined that the CDC will adopt the revised childhood and adolescent immunization schedule, as stated in Figure 1 of TAB 1. Specifically, the CDC immediately recommends: (1) immunization for the measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib, pneumococcal disease, HPV, and varicella for all children; (2) specified immunizations for high-risk groups (Respiratory syncytial virus (RSV) monoclonal antibodies, and hepatitis A, hepatitis B, meningococcal B, meningococcal ACWY, and dengue); and (3) immunization for hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 based on shared clinical decision making, as stated in Figure 1 of TAB 1.

Page 9 - DECISION REQUESTED – Adopting Revised Childhood and Adolescent Immunization Schedule

Approved: ✓ **Disapproved:** _____ **Would like briefing:** _____

Jim O'Neill
Acting Director, CDC

January 5, 2025
Date

TABS

1. "Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries"
2. Current CDC Recommended Childhood and Adolescent Immunization Schedule

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EXHIBIT C

Docusign Envelope ID: 14147443-069C-4B98-B81C-BD6C15B4DB8B

Assessment of the U.S. Childhood and Adolescent Immunization Schedule Compared to Other Countries

January 2, 2026

Tracy Beth Høeg, MD, Ph.D., Acting Director for the Center for Drug Evaluation and Research and FDA Ex Officio member to ACIP, and **Martin Kulldorff, Ph.D.**, Chief Science and Data Officer for the Assistant Secretary for Planning and Evaluation, in consultation with experts at CDC, FDA, NIH, and CMS.

Executive Summary

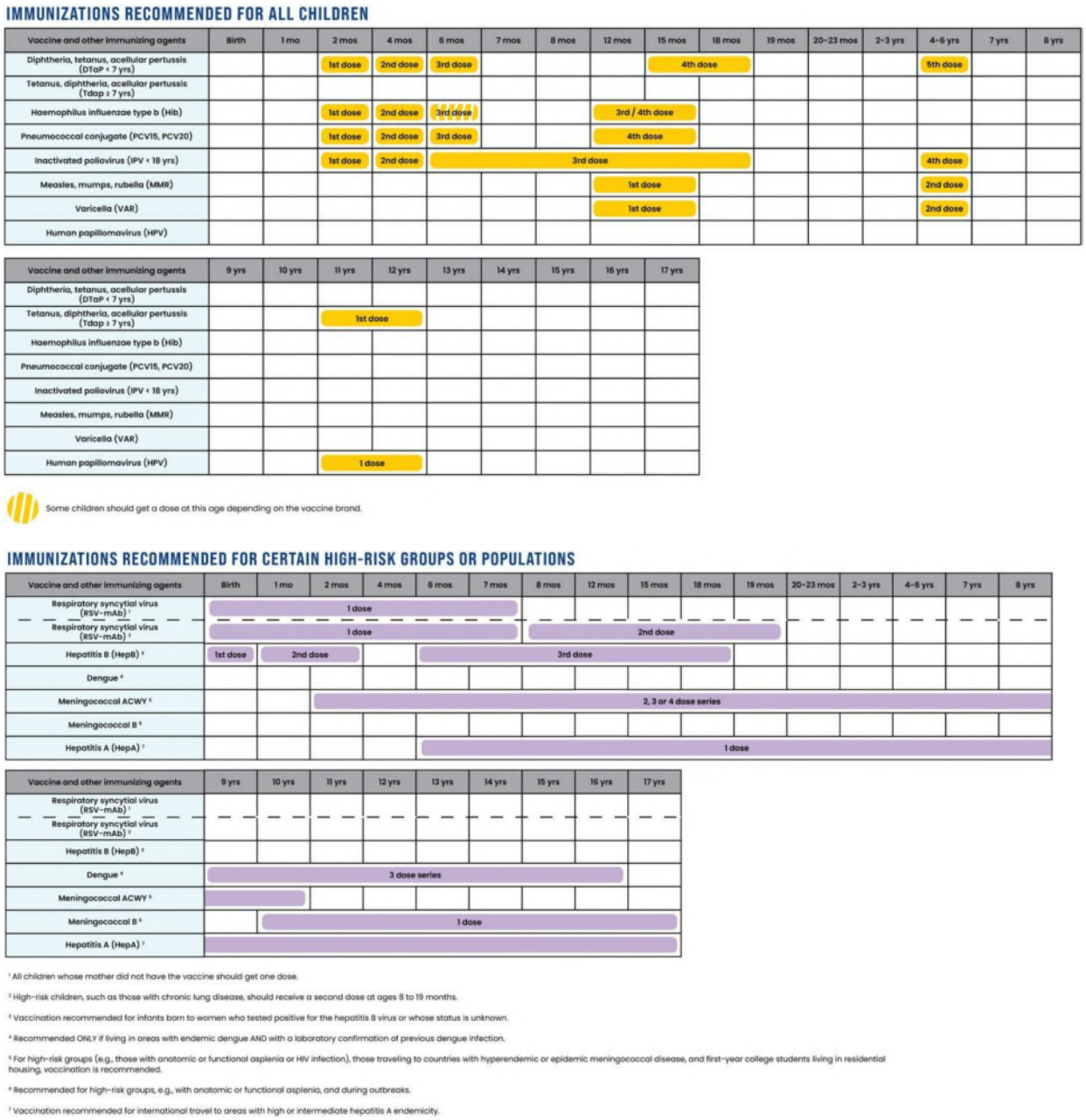
On December 5, 2025, President Trump issued a Presidential Memorandum[1] directing the Secretary of the U.S. Department of Health and Human Services (HHS) and the Acting Director of the Centers for Disease Control and Prevention (CDC) to review best practices from peer, developed nations regarding childhood vaccination recommendations and the scientific evidence underlying those practices. The President instructed them to update the U.S. core childhood vaccine schedule if they determine that superior practices exist abroad.

This assessment is a scientific, evidence-based, data-driven response to the President's directive. It argues that a change in the U.S. childhood vaccine schedule is necessary. It compares the U.S. with peer nations, examines vaccine uptake and trust, addresses clinical and epidemiological considerations and knowledge gaps, analyzes vaccine mandates, and outlines recommendations and next steps for immediate and long-term action.

The U.S. is a global outlier among peer nations in the number of target diseases included in its childhood vaccination schedule and in the total number of recommended vaccine doses.[2]

The Acting CDC Director should immediately consider updating the Childhood Immunization Schedule to keep vaccines for 10 diseases—measles, mumps, rubella, polio, pertussis, tetanus, diphtheria, Haemophilus influenzae type B (Hib), pneumococcal disease, and human papillomavirus (HPV)—for which peer, developed nations share international consensus, as well as varicella (chickenpox) (the "consensus vaccines") in the category of vaccines recommended for all children. These consensus vaccines will represent the core childhood vaccine schedule. This report does not substantively address the consensus vaccines. All other vaccines currently on the U.S. schedule (the "non-consensus vaccines") should be recommended for high-risk groups and populations and/or through shared clinical decision-making, by taking individual patient characteristics into account (Figure 1). No vaccine should be moved to the "not recommended" category.

Therefore, the Acting CDC Director should update the childhood immunization schedule to reflect these three distinct components:



IMMUNIZATIONS RECOMMENDED FOR ALL CHILDREN

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20–23 mos	2–3 yrs	4–6 yrs	7 yrs	8 yrs
Diphtheria, tetanus, acellular pertussis (DTaP < 7 yrs)			1st dose	2nd dose	3rd dose				4th dose					5th dose		
Tetanus, diphtheria, acellular pertussis (Tdap ≥ 7 yrs)																
Haemophilus influenzae type b (Hib)			1st dose	2nd dose	3rd dose			3rd / 4th dose								
Pneumococcal conjugate (PCV15, PCV20)			1st dose	2nd dose	3rd dose			4th dose								
Inactivated poliovirus (IPV < 18 yrs)			1st dose	2nd dose	3rd dose									4th dose		
Measles, mumps, rubella (MMR)								1st dose						2nd dose		
Varicella (VAR)								1st dose						2nd dose		
Human papillomavirus (HPV)																

Vaccine and other immunizing agents	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Diphtheria, tetanus, acellular pertussis (DTaP < 7 yrs)									
Tetanus, diphtheria, acellular pertussis (Tdap ≥ 7 yrs)			1st dose						
Haemophilus influenzae type b (Hib)									
Pneumococcal conjugate (PCV15, PCV20)									
Inactivated poliovirus (IPV < 18 yrs)									
Measles, mumps, rubella (MMR)									
Varicella (VAR)									
Human papillomavirus (HPV)			1 dose						

Some children should get a dose at this age depending on the vaccine brand.

IMMUNIZATIONS RECOMMENDED FOR CERTAIN HIGH-RISK GROUPS OR POPULATIONS

Vaccine and other immunizing agents	Birth	1 mo	2 mos	4 mos	6 mos	7 mos	8 mos	12 mos	15 mos	18 mos	19 mos	20–23 mos	2–3 yrs	4–6 yrs	7 yrs	8 yrs
Respiratory syncytial virus (RSV-mAb) [1]	1 dose															
Respiratory syncytial virus (RSV-mAb) [2]	1 dose						2nd dose									
Hepatitis B (HepB) [3]	1st dose	2nd dose			3rd dose											
Dengue [4]																
Meningococcal ACWY [5]			2, 3 or 4 dose series													
Meningococcal B [6]																
Hepatitis A (HepA) [7]					1 dose											

Vaccine and other immunizing agents	9 yrs	10 yrs	11 yrs	12 yrs	13 yrs	14 yrs	15 yrs	16 yrs	17 yrs
Respiratory syncytial virus (RSV-mAb) [1]									
Respiratory syncytial virus (RSV-mAb) [2]									
Hepatitis B (HepB) [3]									
Dengue [4]	3 dose series								
Meningococcal ACWY [5]									
Meningococcal B [6]		1 dose							
Hepatitis A (HepA) [7]									

[1] All children whose mother did not have the vaccine should get one dose.

[2] High-risk children, such as those with chronic lung disease, should receive a second dose at ages 8 to 19 months.

[3] Vaccination recommended for infants born to women who tested positive for the hepatitis B virus or whose status is unknown.

[4] Recommended ONLY if living in areas with endemic dengue AND with a laboratory confirmation of previous dengue infection.

[5] For high-risk groups (e.g., those with anatomic or functional asplenia or HIV infection), those traveling to countries with hyperendemic or epidemic meningococcal disease, and first-year college students living in residential housing, vaccination is recommended.

[6] Recommended for high-risk groups, e.g., with anatomic or functional asplenia, and during outbreaks.

[7] Vaccination recommended for international travel to areas with high or intermediate hepatitis A endemicity.

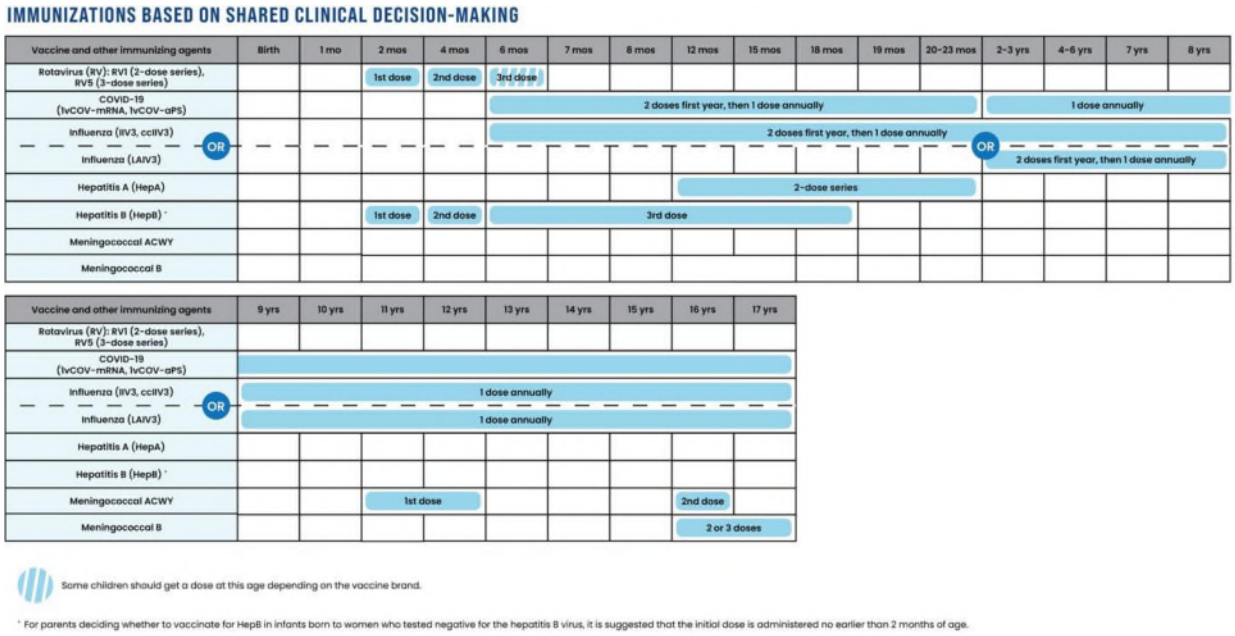


Figure 1: Proposed immunization schedule from birth up to age 18, with recommendations for all children (yellow), recommendations for high-risk groups or populations (purple), and immunizations with shared clinical decision-making (blue), all available and covered by insurance for all children and adolescents without cost sharing.

Importantly, all immunizations recommended by the CDC at the end of 2025—and covered by insurance at that time—should remain covered by insurance without cost sharing, as they should all remain on the schedule. This would include all diseases covered by the 2025 childhood and adolescent immunization schedule. By comparison, in many European countries, vaccines not recommended for routine use are typically not covered. By distinguishing non-consensus vaccines as options based on individual risk factors, we can better define those risk factors and identify the children who are most likely to have a net-benefit from these vaccines.

Between 2020 and 2024, trust in health care declined steeply from 71.5% to 40.1%, coinciding with school closures, other lockdowns, mandatory face masks, COVID-19 vaccination mandates with their de facto denial of infection acquired immunity, and other public health recommendations that lacked scientific rationale and went against basic principles of public health.[3] The distrust of public health agencies during the pandemic has spilled over to other recommendations made by these agencies, including those with respect to vaccines. Over the same period, there was a decline in childhood vaccination rates across the country, with, for example, a reduction in measles, mumps, and rubella (MMR) vaccination from 95.2% to 92.7%.[4,5] This has increased the potential risk for measles cases.[6]

Instead of implementing vaccination mandates, most peer nations maintain high childhood vaccination rates through public trust and education (Table 1). This is in contrast to the U.S.,

where individual states can set mandatory vaccination requirements for children as a requirement to attend school.[7] Among the fundamental principles of public health are respect for personal autonomy and self-determination, and informed consent is a cornerstone of medical care.[8,9,10] While vaccine mandates may increase short-term vaccination rates,[11] coercive measures can also have negative consequences on trust that may decrease long-term vaccination rates for consensus vaccines.[12,13,14] Increased emphasis on personalized medicine would improve informed consent and the doctor patient relationship, leading to a better educated and empowered public. The increased emphasis on shared clinical decision-making would help restore trust in public health recommendations made by CDC.

Vaccines are intended to benefit children by preventing them from being infected by certain infectious diseases. But, like all medicines, vaccines come with risk that must be balanced against their benefits.[15] Before and after licensure, manufacturers have inadequate incentives to study vaccine adverse effects. Regulatory bodies, including the FDA and the CDC have sometimes been slow to identify adverse effects in post-market studies.[16] Vaccine safety and risks are therefore often poorly characterized, quantified, or understood. Scientifically valid rates of adverse events are rarely available to determine the relationship, if any, between our country's immunization schedule and the increasing prevalence of chronic diseases in American children.[17] Medical interventions given to healthy children to prevent diseases, rather than treat or cure them, should have the highest standard of safety pre-and-post marketing.[18]

To address the safety concerns regarding the child and adolescent immunization schedule, HHS should fund gold standard scientific research, including large placebo-controlled randomized trials as needed, both on individual vaccines, combination of vaccines, and vaccination schedules. Putting aside the ethics of administering a medical product that was not properly trialed to affirm its safety, this can be ethically accomplished by, among other methods, randomizing the timing of vaccination.[19] HHS should also fund and conduct observational studies concerning long-term chronic adverse effects of both individual vaccines and the immunization schedule. This will better inform patients/parents and physicians moving forward, increase trust in public health, and improve the state of vaccine science globally.

This assessment only considers immunizations that CDC recommended for all children at the end of 2024. It does not consider the timing or order of vaccines, nor the number of doses, with the exception of the HPV vaccine.

Bringing the U.S. pediatric immunization schedule in line with the consensus of peer nations while keeping non-consensus vaccines available for high-risk groups and populations and/or through shared clinical decision-making is a balanced approach to reform and restore trust in public health. Coupled with an evaluation of potential vaccine harms, this reform seeks to restore

public confidence, provide much-needed clarity for parents of young children, and preserve the benefits of immunization programs.

1. Vaccine Uptake and Trust

In 1980, American children following the CDC immunization schedule received 23 vaccine doses in 7 shots against 7 different diseases (1 MMR, 5 DTP, 1 Td) plus 4 OPV drops. In 2024, the recommended number of routine vaccines had risen to at least 84 vaccine doses in at least 57 shots for 17 diseases, plus the RSV monoclonal antibody immunization for a total of 18 diseases.[20,21,22,23,24,25,26,27] This is more than other developed nations (Table 2).[28]

1.1 Vaccine Uptake

In the decade before the COVID-19 pandemic, the U.S. had high and stable childhood vaccination rates.[29] This changed with the pandemic lockdowns, which generated a drop in childhood vaccine uptake across all age groups (Figure 2). While the vaccination rates have rebounded, the created gaps have never been compensated for through catch-up vaccinations.[30]

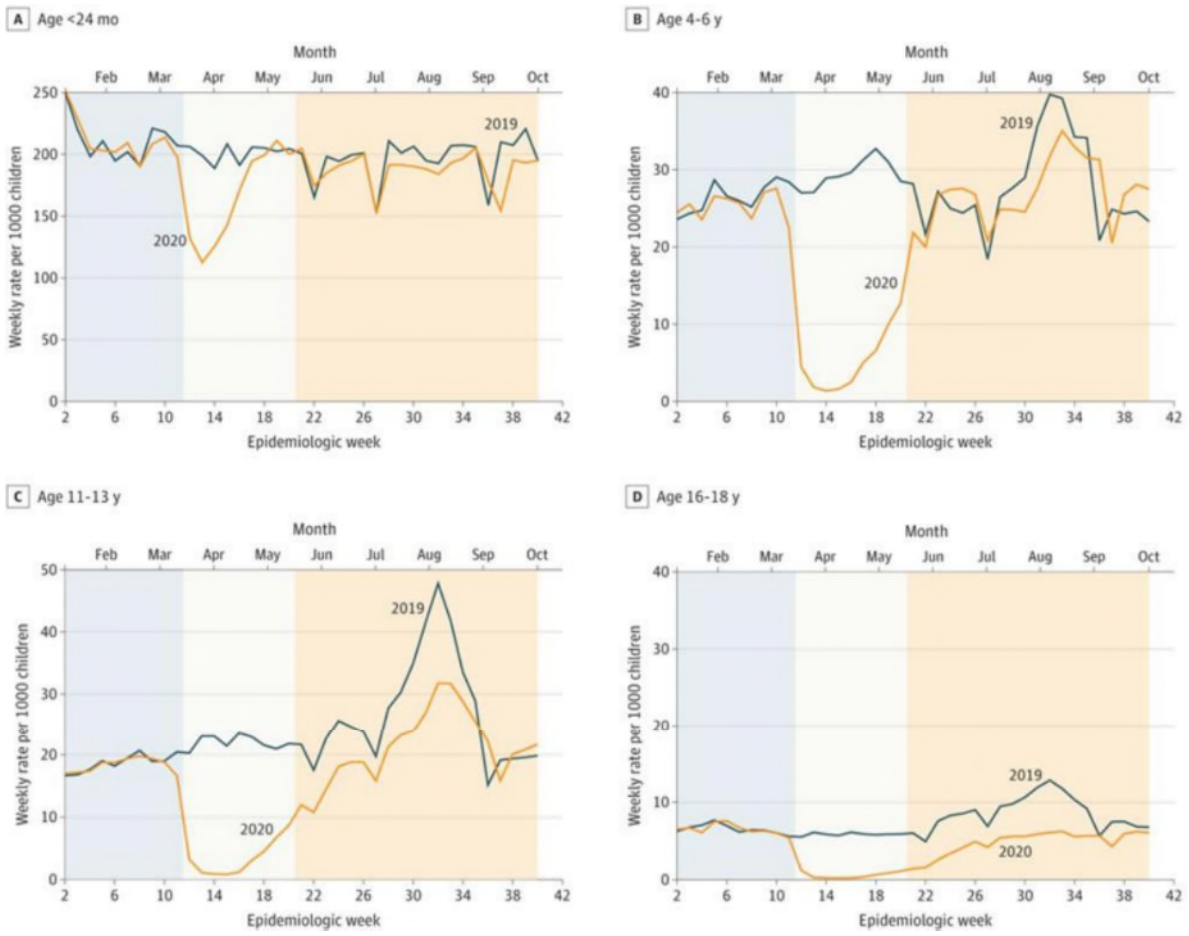


Figure 2: Childhood vaccine uptake by age during the 2020 lockdowns compared to 2019, in health plans providing data to CDC's Vaccine Safety Datalink.[31]

A fundamental principle of public health is trust.[32] For the public to trust public health agencies, those agencies must trust the public, which includes providing accurate information and being honest when the scientific knowledge is incomplete. This particularly fell apart during the COVID-19 pandemic. With COVID-19 vaccine mandates and false CDC claims that vaccine-acquired immunity was superior to infection-acquired immunity[33,34,35,36] and that the COVID-19 vaccine would prevent infection and transmission,[37,38,39] the public lost trust in the COVID-19 vaccine. For example, while CDC still recommended the COVID-19 booster for all children in 2023, the uptake was less than 10%.[40]

The loss of trust during the pandemic not only affected the COVID-19 vaccine uptake. It also contributed to less adherence to the full CDC childhood immunization schedule, with lower rates of consensus vaccines such as measles, rubella, pertussis, and polio.[41] From the 2019-2020 to 2023-2024 school years, childhood vaccination rates against measles, mumps, and rubella (MMR) declined from 95.2% to 92.7%.[42]

Even when the national vaccination rate is very high, lower regional rates can lead to cases of these diseases. Some states have vaccination rates below the estimated community immunity threshold for both measles and rubella.[43] In the 2024-2025 school year, 16 states had MMR vaccination rates below 90% (Figure 3). Rubella has a community immunity threshold of 83-85%,[44] leaving some states, such as Idaho and Wisconsin, at risk of rubella cases.

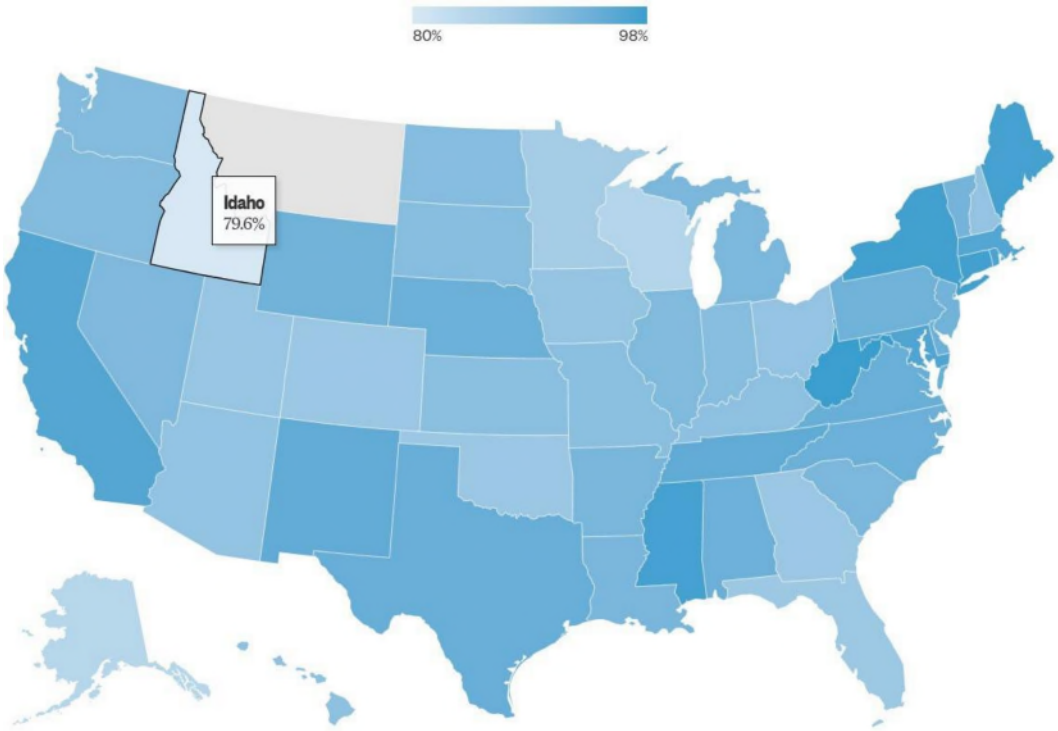


Figure 3: Vaccination rates by state for the second dose of the measles, mumps and rubella vaccination among kindergarteners during the 2023-2024 school year.[45]

1.2 Measles Outbreaks

When vaccine uptake for certain diseases decreases below a certain percentage of the community, it may lead to disease transmission or cases of those diseases.[46] For measles, minimum vaccination coverage threshold is estimated to be above 90%, below which the risk of cases increases.[47,48] Up until December 31, there had been 49 measles outbreaks reported in 2025 across the U.S., noting that an "outbreak" is defined as three or more related cases, and 88% of confirmed cases (1,820 of 2,065) were outbreak-associated[49] (Figure 4).

The U.S., Canada, and much of Europe have recently seen increasing measles cases and Canada recently lost its measles elimination status.[50]

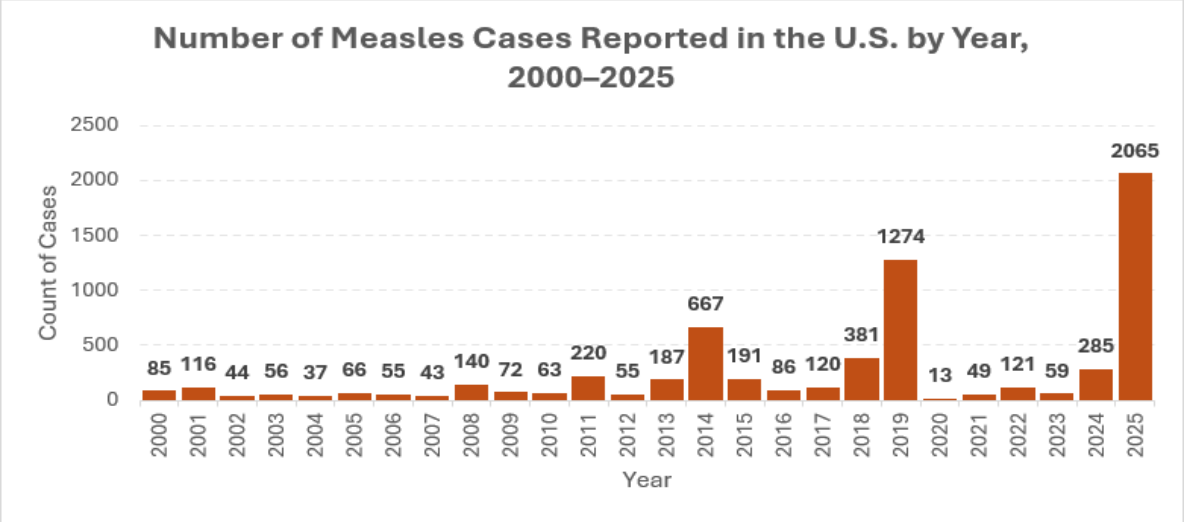


Figure 4: The number of measles cases reported in the U.S. by year, from 2000 to 2025.[51]

1.3 Vaccine Mandates and Trust

With a few exceptions, peer nations do not have childhood vaccination mandates. They have shown that transparent and trustworthy public health authorities can achieve very high voluntary vaccination rates while preserving informed consent (Table 1). The U.S. is among a minority of peer nations with childhood vaccine mandates (enacted by individual U.S. states) for school entry (Table 2). Education is critical to the development of children, and among other things is highly correlated with health and income. Many children lost over a year of schooling during the COVID-19 pandemic, with negative impacts on their academic performance.[52]

	Measles		Rubella	DTP		Polio		Hib	PCV	HPV girls	HPV boys	
dose:	1st	2nd	1st	1st	3rd	1st	3rd	3rd	3rd	1st	1st	Average
Many Vaccine Mandates	**93%**	**91%**	**93%**	**96%**	**94%**	**96%**	**94%**	**94%**	**91%**	**65%**	**59%**	**88%**
Australia (13 vaccines)	91%	92%	91%	93%	93%	93%	94%	93%	95%	73%	70%	89%
France (11)	95%	93%	95%	99%	96%	99%	96%	96%	96%	48%	37%	86%
Italy (10)	95%	84%	95%	94%	94%	94%	94%	95%	90%	66%	59%	87%
United States (# varies by state)	92%	95%	92%	98%	94%	97%	93%	92%	84%	74%	70%	89%
No Vaccine Mandates	**93%**	**89%**	**93%**	**96%**	**94%**	**96%**	**94%**	**94%**	**89%**	**74%**	**71%**	**89%**
Austria	90%	84%	90%	95%	85%	95%	85%	85%	..	53%	42%	80%
Denmark	94%	93%	94%	97%	96%	97%	96%	96%	96%	89%	87%	94%
Finland	94%	92%	94%	97%	91%	97%	91%	91%	87%	71%	63%	88%
Greece	91%	71%	91%	98%	95%	98%	95%	99%	90%	..	..	92%
Ireland	90%	90%	90%	93%	92%	93%	92%	92%	84%	73%	69%	87%
Japan	95%	96%	95%	99%	99%	98%	98%	96%	91%	39%	..	91%
Netherlands	89%	81%	89%	91%	91%	91%	91%	89%	88%	63%	59%	84%
New Zealand	89%	87%	89%	94%	89%	99%	97%	89%	60%	53%	52%	82%
Norway	96%	94%	96%	99%	97%	99%	97%	97%	95%	93%	92%	96%
Portugal	99%	96%	99%	99%	99%	99%	99%	99%	98%	91%	88%	97%
Spain	97%	92%	97%	98%	94%	98%	94%	94%	92%	90%	83%	94%
Sweden	93%	92%	93%	97%	96%	97%	95%	95%	94%	91%	87%	94%
Switzerland	96%	93%	96%	97%	96%	97%	96%	95%	91%	78%	64%	91%
United Kingdom	89%	85%	89%	92%	92%	92%	92%	92%	89%	75%	70%	87%
Partial Vaccine Mandates												
Belgium (only polio)	96%	82%	96%	98%	97%	99%	98%	97%	94%	80%	73%	92%
Canada (2/10 provinces)	92%	79%	92%	92%	92%	92%	92%	90%	85%	86%	81%	88%
Germany (only measles)	96%	92%	96%	97%	89%	97%	88%	88%	75%	68%	46%	85%

Table 1: WHO/UNICEF estimates of national immunization coverage (WUENIC) for some core vaccines in 2024. No estimates available for the other core vaccines, nor for PCV/Austria, HPV/Greece or HPV/boys/Japan. For HPV the percentages are for the vaccination program coverage, that is, the percent of the target population that received the vaccine that year. Note that, if vaccination rates are declining, the uptake of a second or third dose can sometimes be higher than the first dose.[53,54]

It is generally considered contrary to basic medical ethics to coerce or require a medical intervention, and informed consent is a cornerstone of medical care in the U.S. and abroad.[55] In its Code of Medical Ethics, the American Medical Association states that *"Informed consent in medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making."*[56] In its Public Health Code of Ethics, the American Public Health Association asserts that *"the effective and ethical practice of public health depends upon social and cultural conditions of respect for personal autonomy, self-determination, privacy, and the absence of domination in its many interpersonal and institutional forms."*[57]

Some peer countries have recognized that each additional vaccine may erode trust in the entire childhood immunization schedule, resulting in lower uptake of consensus childhood vaccines. Danish health authorities have specifically expressed concerns about adding vaccines to the routine childhood immunization schedule when the opportunity for benefit in non-high-risk populations is low and/or when the disease does not pose a mortality or long-term disability risk.[58] For example, when deciding not to recommend the hepatitis B (HepB) vaccine for all children, the Danish public health authority stated that *"if one includes a vaccine which some consider less important, it could negatively affect the view of vaccines in general. The result of this could be that the current [vaccination] program would have lower uptake,"* and that *"A prerequisite for a successful vaccination program with high uptake has been, in other words, that [the vaccine] is seen as an attractive offer."*[59]

Another key aspect of medicine is mutual trust between patients and physicians.[60] In the U.S., health insurers incentivize physicians with financial bonuses tied to vaccination rates of their patient population,[61] which can encourage coercive vaccination experiences. This can create both distrust in the vaccination schedule and a medical culture which may be reluctant to question vaccine safety. Some children from families who do not consent to certain vaccines have difficulty obtaining medical care because many pediatricians dismiss children from their practice if the parents refuse to have their children vaccinated.[62]

The concomitant administration of multiple separate (not combined into one multivalent product) childhood vaccines on the same day, has raised concerns among some parents about following the recommended vaccines schedules,[63] as there is limited post-market epidemiological research on interaction effects between vaccines in the same schedule.[64] Denmark has managed to minimize the concomitant administration of multiple vaccines by giving a pentavalent (with 5 diseases-targeted-in-one vaccine) three times in the first year of life; separating administration of the MMR and DTaP vaccines into different visits; and vaccinating children for fewer diseases.[65] Without resorting to vaccine mandates, Denmark has achieved consistently high rates of uptake for the consensus recommended vaccines and a lack of serious disease outbreaks.[66,67]

A new U.S. childhood schedule that removes the routine recommendation for non-consensus vaccines could lessen coercion and increase public trust.

A successful childhood vaccination program requires mutual trust between patients/parents and physicians/public health authorities. This is built on four pillars:

1. Scientific honesty about vaccines, including what is known and not known.
2. Informed consent; not coercion.
3. A vaccine approval process using evidence-based science and thorough post-licensure evaluation of vaccine safety and risks.
4. Recommendations that take account of the experience of peer nations.

2. Knowledge Gaps

A 2013 report from the Institute of Medicine (IOM) stated that *"vaccines—like all drugs or medical interventions—are neither 100 percent risk-free nor 100 percent effective."*[68] It is hence essential to have a robust science-based system to detect potential risks, using both pre-licensure placebo-controlled randomized trials and post-licensure observational pharmacovigilance studies. If there is a problem that is not detected in pre-licensure trials, it needs to be detected as soon as possible.[69,70] A robust clinical trial and safety surveillance system is critical to ensure trust in the recommended childhood vaccine schedule.

2.1 State of the Evidence for Childhood Vaccinations

Given the growing distrust that the American people have in the current childhood vaccine schedule, there is a need for more and better science, including gold standard placebo-controlled randomized trials.[71] This could help address knowledge gaps about potential side effects and risk/benefit profiles. Until more studies are completed, the childhood vaccination recommendations must be based on the best available evidence, however limited, and the best practices of peer, developed nations.

To establish a solid scientific basis for the childhood vaccine schedule and to inform global best practices for childhood vaccinations, HHS agencies should fund gold standard science to assess overall health outcomes related to both consensus and non-consensus vaccines, the interaction effects between different vaccines, as well as other aspects of the vaccine schedule. Placebo-controlled randomized trials can be done in an ethical manner by, for example, randomizing the age of vaccination, with the control group getting a placebo at the earlier age but the vaccine at a later time[72] or by studying vaccines for which there is no international consensus about the recommendation.

Those who are convinced that vaccines are safe will welcome randomized, placebo-controlled trials, as they will show that the vaccines are safe if they are safe. Those who are concerned about potential side effects of vaccines will also welcome these trials, as they will detect

problems if problems exist. Prior to completion of these studies, HHS should continue to make determinations about childhood vaccination recommendations based on the best available evidence and the best practices of peer, developed nations.

2.2 Vaccine Safety Surveillance Systems

Safety surveillance systems need to be very robust, minimize bias, and large enough to adequately detect risks which could tip the benefit-risk ratio in a direction that is unfavorable to the vaccine. Number needed to vaccinate (NNV) and number needed to harm (NNH) calculations should be performed for low- and high-risk children for each vaccination on an ongoing basis as harms are identified and as new information is obtained about efficacy against severe disease. These should inform CDC recommendations on an ongoing basis.

The U.S. has a limited post-licensure infrastructure focused on monitoring potential adverse reactions that occur within a few days or weeks after vaccination. This includes the Vaccine Adverse Event Reporting System (VAERS),[73] CDC's Vaccine Safety Datalink (VSD)[74] and FDA's Biologics Effectiveness and Safety (BEST) System.[75] Within a year of vaccine approval, these systems have confirmed serious harm, including intussusception after rotavirus vaccines,[76,77] febrile seizures after the MMRV vaccine,[78] and anaphylaxis[79] and myocarditis[80] after the mRNA COVID-19 vaccines.

However, these systems have serious shortcomings in that they have been underutilized, including for evaluating long-term effects of vaccines and the effect of various combined aspects of the vaccine schedule. Vaccines may cause adverse reactions that occur or are diagnosed months or years after vaccination. For example, a 2023 study from CDC's VSD found that children receiving more aluminum adjuvants had higher rates of persistent asthma, with an estimated hazard ratio of 1.19 per mg of aluminum (95% CI: 1.14-1.25).[81] When comparing mean aluminum exposure to no exposure, this corresponds to a hazard ratio of 2.0 (95% CI: 1.7-2.5), a doubling of the risk. However, this is an exception, and adequate studies of the association between vaccines and long-term health outcomes, including asthma, allergies, auto-immune diseases, neurological disorders, ear infections, or other infectious diseases, have not been performed.[82]

2.3 The Vaccine Schedule

As the childhood vaccination schedule has expanded over the past four decades, the effects of the overall schedule have never been fully evaluated and published by a major institution. The Institute of Medicine (IOM) has called for such studies to be completed.[83,84] A 2013 IOM report recommended that HHS *"incorporate study of the safety of the overall childhood immunization schedule into its processes for setting priorities for research, recognizing stakeholder concerns,*

and establishing the priorities on the basis of epidemiological evidence, biological plausibility, and feasibility." and *"continue to fund and support the Vaccine Safety Datalink project to study the safety of the recommended immunization schedule."*[85] While some important studies have been conducted, on for example the above-mentioned relationship between vaccine adjuvants and asthma,[86] progress has been slow. There are many knowledge gaps, and only a few of the many studies that the IOM sought and deemed feasible have been conducted.

2.4 Filling the Knowledge Gap

In addition to randomized placebo-controlled vaccine trials, HHS should increase and strengthen the use of large population-based observational studies and data to evaluate the safety of vaccines. Any changes in the vaccination schedule should be accompanied by scientific research to evaluate the short- and long-term impact of the updated immunization schedule on the targeted infectious diseases, other infectious diseases, acute adverse reactions and chronic conditions such as asthma, allergies, auto-immune diseases, developmental disorders (including ADHD, developmental delay, learning disabilities, intellectual disabilities, speech disorders, and tics), neurological disorders, seizures, diabetes, fertility issues, and eczema. Some important priorities include observational cohort studies comparing health outcomes between vaccinated and unvaccinated children, and if issues are identified, drilling down to evaluate the ideal number of doses, the timing and order of childhood vaccines; interaction effects of administering multiple vaccines on the same day; multivalent versus monovalent vaccines for the same diseases; vaccine adjuvants; and different immunization schedules.

In order to assess the long-term impacts of vaccines on chronic conditions, both retrospective and prospective cohort study designs should be utilized, with sufficient sample size and follow-up.

Sophisticated statistical methods for large population-based samples can be effectively used to minimize bias in observational studies. Examples include different forms of propensity score matching[87,88] and inverse probability weighting,[89] which can improve the covariate balance between exposed and unexposed groups. Self-control methods are another way to reduce bias in observational vaccine studies, by removing any between person confounding.[90]

With a large sample size, it may also be possible to identify specific population groups that are at increased risk for adverse events, as long as such analyses are carefully and systematically done.

A successful childhood immunization program must be built on solid scientific evidence. This means:

1. Approvals of new vaccines designed for mass uptake should be based on double-blind placebo-controlled randomized trials. This has seldom been the case.
2. For new vaccines, there must be a post-market system in place to quickly detect unexpected adverse reactions.
3. In addition to acute adverse reactions, we must evaluate long-term effects on the immune system, such as asthma, auto-immune diseases, neurological disorders, and non-targeted infections. We have parts of the infrastructure in place to this, but it has been underutilized.
4. In addition to individual vaccines, we must thoroughly evaluate the safety of the immunization schedule, including cumulative effects, vaccine types and ingredients, the timing and order of vaccines, and interaction effects. The IOM has long called for such studies, but progress has been slow.

3. International Comparison of Childhood Immunization Schedules

Table 2 compares the U.S. childhood vaccination schedule[91] to those of 20 peer nations: Australia,[92] Austria,[93] Belgium,[94] Canada,[95] Denmark,[96] Finland,[97] France,[98] Germany,[99] Greece,[100] Ireland,[101] Italy,[102] Japan,[103] Netherlands,[104] New Zealand,[105] Norway,[106] Portugal,[107] Spain,[108] Sweden,[109] Switzerland,[110] and the United Kingdom.[111]

Universal Vaccine Recommendations Funded by the Government	Age at 1st Vaccine (months)	Rotavirus	Diphteria	Tetanus	Pertussis	Polio	Hib	Tuberculosis	Japanese Encephalitis	Hepatitis A	Hepatitis B	Pneumococcal	Measles	Mumps	Rubella	Varicella	HPV	Meningococcal	Influenza	Covid-19	# Vaccine Doses	# Diseases	# Mandated
Australia	0	2	6	6	6	4	4	..	..	..	4	3	2	2	2	1	1	2	5-6	..	50-51	15	13
Austria	2	2-3	5	5	5	5	3	..	..	..	4	3	2	2	2	..	2	1	17-18	..	58-60	14	0
Belgium	2	..	6	6	6	5	4	..	..	..	4	3	2	2	2	..	2	1	..	..	43	12	1
Canada	2	2-3	6	6	6	5	4	..	..	..	2-3	3-4	2	2	2	2	1	2	18-19	..	64-68	15	0
Denmark	3	..	4	4	4	4	3	..	..	..	..	3	2	2	2	..	2	..	..	..	30	10	0
Finland	2	3	5	5	5	4	3	..	..	..	..	3	2	2	2	2	2	..	6-7	..	44-45	13	0
France	2	2-3	5	5	5	5	3	..	..	..	3	3	2	2	2	..	2	6	..	..	45-46	13	11
Germany	1.5	2-3	5	5	5	4	3	..	..	..	3	3	2	2	2	2	2	4	..	..	44-45	14	1
Greece	2	2-3	6	6	6	4-5	4	..	..	2	3	3	2	2	2	2	2	5	5-6	..	56-58	16	0
Ireland	2	2	6	6	6	5	4	..	..	..	4	3	2	2	2	1	1	5	16	..	65	15	0
Italy	3	2	5	5	5	5	3	..	..	..	3	3	2	2	2	2	2	6	..	..	47	14	10
Japan	2	2-3	5	5	4	4	4	1	4	..	3	4	2	..	2	2	2-3	..	..	..	44-46	14	0
Netherlands	1.5	2	6	6	5	5	4	..	..	..	4	3	2	2	2	..	2	2	..	..	45	13	0
New Zealand	1.5	2	5	5	5	4	4	..	..	..	3	3	2	2	2	1	2	3	..	..	43	14	0
Norway	1.5	2	5	5	5	5	3	..	..	..	3	3	2	2	2	..	2	..	..	..	39	12	0
Portugal	0	..	6	6	5	5	4	..	..	..	3	3	2	2	2	..	2	4	..	..	44	12	0
Spain	2	2-3	5	5	4	4	3	..	..	..	3	3	2	2	2	2	1	6	4-5	..	48-50	15	0
Sweden	1.5	2-3	5	5	5	4	3	..	..	..	3	3	2	2	2	..	2	..	..	..	38-39	12	0
Switzerland	2	2	5	5	5	4	3	..	..	..	3	3	2	2	2	2	2	6	..	..	46	14	0
United Kingdom	2	2	6	6	5	6	4	..	..	..	4	2	2	2	2	2	1	4	14	..	62	15	0
# Recommended		17	20	20	20	20	20	1	1	1	18	20	20	19	20	12	20	15	8	0			
# Mandated		1	3	3	3	4	3	0	0	0	3	2	4	3	3	2	0	2	0	0			
USA 2024	0	2-3	6	6	6	4	3-4	..	..	2	3	4	2	2	2	2	2	2	18-19	18-19	84-88	17	12
USA Suggested	2	A	6	6	6	4	3-4	..	..	A	A	4	2	2	2	2	1	A	A	A	38-39	11	0

Table 2: The number of vaccines recommended for all children in peer nations, not including monoclonal antibodies. The number of vaccine doses is more than the number of injections or diseases covered. For example, the MMR shot contains three vaccine doses, one each for measles, mumps and rubella. Red indicates that the vaccine is mandated for e.g. school,[112] and dark green that it is recommended for all children and covered by insurance. For the U.S., "A" means that it should be available through health insurance for all children. In Canada, provincial recommendations may differ for some vaccines, and there are school vaccine mandates in Ontario and New Brunswick. In the U.S., the mandated vaccines vary by state; shown is New York State. The rotavirus vaccine can come in either 2 or 3 doses. For the influenza and COVID-19 vaccines, 2 doses are sometimes given the first time and 1 dose each subsequent year. If it is recommended annually from age 6 months, some children get it 17 times and others 18 times before their 18th birthday. For U.S. infants also receiving the RSV monoclonal antibody injection, the total number of diseases for which protection was provided in 2024 was 18.

In 2024, the U.S. recommended more childhood vaccines than any peer nation, and more than twice as many doses as some European nations. At the lower end is Denmark, which immunizes children against 10 diseases with a total of 30 doses. By using multivalent vaccines, Denmark's schedule only requires 11 vaccine injections/shots/needles: 3 x (diphtheria + tetanus + pertussis + Hib + polio), 1 x (diphtheria + tetanus + pertussis + polio), 3 x pneumococcal, 2 x (measles + mumps + rubella) and 2 x HPV.[113]

By contrast, in 2024 the U.S. recommended routine vaccination against 17 diseases with 84 to 88 vaccine doses, depending on vaccine product and date of birth. Depending on the number of multivalent vaccines used, this required between 57 and 71 vaccine injections, of which the 2 or 3 for rotavirus are oral. For infants also receiving the RSV monoclonal antibody injection, the total number of injections could be 72 to provide protection against 18 diseases.[114]

Many considerations are relevant as countries develop their vaccination recommendations. However, if disease prevalences are comparable and children without underlying risk factors face similar risks from the target disease, variations in practice in terms of doses, number of diseases, and timing of vaccinations often reflects valid uncertainties as to what is the best practice. Such uncertainties and disagreements within the medical community are known as *"clinical equipoise."*[115]

Each disease addressed by the U.S. child immunization schedule poses a health risk, but the level of risk varies widely by disease and sometimes by individual underlying risk factors. Yet the mere existence of a vaccine does not automatically make it appropriate for every child, nor does it necessarily justify routine vaccination.

While a set of consensus vaccines are consistently recommended in all peer countries, several vaccines currently included in the childhood immunization schedule in the U.S. (hepatitis A, varicella, influenza, rotavirus and meningococcal vaccines) are limited in their recommendation or excluded in some other developed countries (Table 2). Another stark difference is that most countries maintain high vaccination rates through trust in public health authorities rather than vaccine mandates (red in Table 2).

There is global variation in the universal use and timing of numerous childhood vaccines. Although these differences sometimes reflect the unique epidemiology of diseases in each region, they more often arise from uncertain science and knowledge gaps, which lead to inadequately informed assessments of risks and benefits that are subject to differing interpretations. Disagreement among states and professional societies[116] in the U.S. further underscores the need and opportunity for a more adaptable childhood immunization schedule.

Countries differ in terms of both disease exposure and health care system. The U.S. provides health care access for children through a combination of private insurance, state Medicaid programs, the Children's Health Insurance Program (CHIP), and the Vaccines for Children (VFC) program.

Broad insurance coverage of both consensus and non-consensus immunizations should remain in effect following the updates to the immunization schedule. Identifying the consensus vaccines on the schedule would help Americans make informed decision while making all vaccines available

for parents also opting for their child to receive non-consensus immunizations. Through proper vaccine research, it is important to improve our understanding of populations who are most likely to benefit from individual vaccines as well as situations where vaccination may not be needed.

A successful childhood vaccination program can learn from successful peer nations. In particular:

1. The U.S. has been an international outlier in the number of vaccines given, and uptake of consensus vaccinations has decreased.
2. One way to restore trust in the U.S. childhood immunization schedule is to better align the country with consensus vaccine components of the schedules of peer nations, while not restricting anyone's access to other immunizations.

4. Recommended Childhood Immunization Schedule

To increase trust, public health agencies should be honest regarding knowledge gaps about vaccines. Without placebo-controlled randomized trials with sufficient sample size and follow-up time for thorough safety evaluation, and post-marketing cohort studies comparing exposed and unexposed populations with long follow-up, we do not have the basic data needed to assess potential vaccine harms. Childhood vaccination recommendations must therefore be based on the best available evidence and the best practices of peer, developed nations. If there is a clear benefit of the vaccine, as for measle vaccines, the risks will need to be more substantial to outweigh the benefit. On the other hand, if the benefits are limited, as for the hepatitis A vaccine, even a small risk will tip the balance, where harms outweigh the benefits. For such vaccines, it is prudent to adopt a more conservative approach. Many peer countries have chosen to limit their core vaccines to diseases where the potential for benefit is understood to be the largest. There can be honest disagreements about where to draw the line, and different countries have made different decisions.

As with all medical procedures, vaccine decisions should never involve coercion but instead should always be the result of informed consent and with the final decision resting with the patient/parents. Coercion renders informed consent invalid and undermines this basic right.

4.1 Immunization Categories

Immunizations Recommended for All Children: These are vaccines, such as the measles vaccine, for which there is consensus among peer nations that all children should receive them. These vaccines should be covered by all forms of health insurance without cost sharing.

Immunizations Recommended for Certain High-Risk Groups or Populations: Like all medical products, vaccines have different risk-benefit profiles for different people. This can either be because of underlying comorbidities, unusual exposure to the disease, or the risk of disease transmission to others. For example, the hepatitis A vaccine when children travel internationally to an endemic area or the birth dose of the hepatitis B vaccine for infants born to mothers that are hepatitis B positive. This document has not assessed and does not propose any changes in vaccine recommendations for high-risk populations. These vaccines should be covered by all forms of health insurance without cost sharing.

Immunizations Based on Shared Clinical Decision-Making: Shared clinical decision-making recommendations are individually based and informed by a discussion between the health care provider and the patient or parent/guardian.[117] It is not always possible for public health to clearly define who will benefit from a vaccine, who has relevant risk factors, or who are at risk of exposure. Parents and physicians, who know the child, may be better placed to make that judgement. With shared clinical decision-making, the characteristics of the individual are considered, including their likelihood of being exposed to the diseases, their risks of morbidity and mortality if contracting the diseases, their likelihood of benefitting from the vaccine, their likelihood of vaccine adverse reactions, and their risk of transmitting the disease to others. Sometimes, it is also important to consider personal and family preferences, beliefs, and knowledge, including when a patient presents specific information regarding the pre-and-post licensure safety data of a vaccine or presents specific familial experience with a vaccine.

While these immunizations are not routinely recommended for all children, they should be available for anyone who wants them and they should be covered by Medicaid, CHIP, the Vaccine for Children (VFC) Program, and private health insurance, without cost sharing. This is in contrast to some peer nations, where such vaccines must be purchased out-of-pocket.[118]

Not Recommended Immunizations: No currently recommended vaccines should be moved into this category. Some vaccines are not recommended for anyone, either because a lack of efficacy, known side effects, or low disease prevalence in the U.S. For example, while the BCG tuberculosis vaccine is used in many countries, it is not recommended for children in the U.S.[119] If approved by FDA, these vaccines may be available for purchase, but they are not covered by Medicaid, the Children's Health Insurance Program (CHIP), or the Vaccine for Children (VFC) Program.

4.2 Immunizations Recommended for All Children

Measles, mumps, rubella, diphtheria, tetanus, pertussis, polio, Hib and pneumococcal disease vaccines (MMR, DTaP, IPV, Hib, and PCV): These are consensus vaccines that are part of the recommended childhood immunization schedules for all 20 peer nations, with the

exception of mumps in Japan (Table 2). As consensus vaccines, they should remain on the immunization schedule in the U.S. as vaccines recommended for all children. While the safety/risk profiles are not fully understood, and in need of further study, there is consensus among peer nations that they provide material benefits against the target disease. Focusing on these vaccines is more likely to reverse the declining uptake[120] of these vaccines.

HPV: There is also international consensus on the HPV vaccine, and it should continue to be recommended for all children/adolescents, but with one dose instead of two. Vaccination with one dose is as or nearly as effective as two doses.[121,122,123,124] Australia, Canada, Ireland, Spain, and the United Kingdom have already updated their recommendations to one dose (Table 2).[125,126,127]

Varicella: The varicella zoster virus causes chickenpox (typically in children), and, for those infected, can reemerge as shingles (typically in adults). The uncertainty of its long-term consequences on adults is one reason why some countries have been cautious about adding the varicella vaccine to the childhood schedule,[128] but similar caution may be warranted regarding a removal once there has been widespread use of this vaccine.[129] The rate of two dose vaccination for varicella among American children is estimated at 92%.[130] Partial population varicella vaccination (60-80% for two doses) could increase the average age at which the population naturally gets chickenpox when this disease could cause more complications, and hence there is a consensus among peer nations that once vaccination for chicken pox has become widespread, stopping use of this vaccine could cause certain complications.[131,132] For these reasons, the varicella vaccine should remain recommended for all children.

4.3 Immunizations Recommended for Certain High-Risk Groups or Populations

Respiratory syncytial virus (RSV) monoclonal antibodies, and Hepatitis A, Hepatitis B, Meningococcal B, Meningococcal ACWY, and Dengue vaccines: This document does not contain an assessment of which high-risk groups and populations should receive which immunizations, and hence, it does not propose any changes to such recommendations.

4.4 Immunizations Based on Shared Clinical Decision-Making

Hepatitis A: There are two FDA approved hepatitis A vaccines: Havrix since 1995 and Vaqta since 1996. At that time, the primary candidates for vaccination were *"travelers to regions of endemic disease, children living in high prevalence areas, homosexual males, users of illicit intravenous drugs, persons working directly with nonhuman primates or hepatitis A virus, patients older than 30 years of age with chronic liver disease, and persons who have received a liver transplant or are awaiting one."*[133] For children, the vaccine was originally only

recommended in high endemic communities. Those had disappeared in the U.S. by 2006, at which time a 2-dose regiment at age 12 to 23 months was added to the universally recommended childhood immunization schedule. In 2006, the annual incidence rate of hepatitis A was very low at around 1 per 100,000 and it remains similarly low. The annual mortality rate is 1 per 10 million, with the highest rate among older men.[134,135,136]

There has been one randomized trial (n=40,119) for Havrix in young children, which used the Engerix-B vaccine for hepatitis B as the control group.[137] For Vaqta, the phase 3 randomized trial for children (n=1037) gave an aluminum and mercury containing diluent to the control group.[138] Hence, without a proper placebo-controlled randomized trial, reliable safety data is limited.

Among peer nations, Greece is the only one with a routine childhood vaccine recommendation (Table 2). Given the low U.S. incidence and mortality, and the lack of randomized placebo-controlled safety data, the benefit-risk ratio is at best very low for most children. There is a clear benefit, but still undefined risk, for children travelling to high endemic countries in the developing world.[139]

The Hep A vaccine should not be recommended for all children, but it should be available for all children whose parents want it through shared clinical decision making, and it should be covered by insurance without cost sharing.

Hepatitis B: Together with hepatitis B immune globulin, infants should be administered the hepatitis B vaccine at birth if the mother is HBsAg-positive or status is unknown. If the mother tests negative, only two of the 20 peer nations recommend universal vaccination at birth: Australia and Portugal, while two countries do not recommend it at all (Table 2). At their December 2025 meeting, the Advisory Committee on Immunization Practices followed the majority of peer nations and voted to no longer recommend the birth dose if the mother tested negative. Instead, it recommended shared clinical decision-making, taking the risk profile of each unique child into account.[140]

Rotavirus: Rotavirus is a common infection, and prior to the rotavirus vaccine, nearly every child would be infected, both in the U.S. and abroad.[141]In the developing world, many children die from dehydration after catching the virus, and there is greater opportunity for benefit from vaccination.[142]

In the U.S., it can cause hospitalization for gastroenteritis, but the virus poses almost no risk of either mortality or chronic morbidity. Data from CDC indicate that among all U.S. children <15 years of age, there were an average of 3.3 deaths per year with the rotavirus diagnostic code listed on the death certificate between 1999 and 2005.[143] This was after the RotaShield vaccine

was withdrawn from the market in 1999 and before the RotaTeq vaccine was approved in 2006. Another vaccine, Rotarix, was approved in 2008. After these vaccines were recommended for all children, there were 1.6 deaths per year from 2009 to 2020.[144] There may be many reasons for this very small decrease in mortality that are unrelated to the vaccine, including improved medical care, changes in diagnostic practices or random fluctuations.

RotaShield was removed from the market due to an excess risk of intussusception.[145] The newer current vaccines have a lower intussusception risk, at around 1 or 2 per 100,000 vaccinated children.[146]

Reasonable people can reach different conclusions about recommending the rotavirus vaccine for all children. Among peer nations, Belgium, Denmark and Portugal do not recommend it. Denmark has cited the very low risk of mortality and chronic morbidity to nearly all children in their rationale for not adding the vaccine to their childhood immunization schedule,[147]

The rotavirus vaccine should not be a consensus vaccine recommended for all children, but it should be available for all children whose parents want it through shared clinical decision making, and it should be covered by insurance without cost sharing.

Meningococcal Disease: Among peer nations, 15 recommend meningococcal vaccination for all children while five limit it to high-risk groups (Table 2). The incidence of meningococcal disease has declined during the past decades, both in countries with and without the routine vaccine recommendations for children, and the magnitude of the decline appears to be independent of vaccination policy (Table 3). The current incidence in the U.S. is 0.12/100,000 or about one case per million per year.

Countries Recommending Menigococcal Vaccine for All Children			
	Incidence 1998-2002	Incidence 2023-2024	Change in Incidence (%)
Australia	2.31	0.52	-78%
Austria	1.02	0.17	-83%
Belgium	3.75	0.72	-81%
Canada	0.76	0.26	-65%
France	0.84	0.86	2%
Germany	0.91	0.36	-61%
Greece	2.13	0.29	-86%
Ireland	12.41	1.01	-92%
Netherlands	3.73	0.73	-80%
Portugal	2.57	0.36	-86%
Spain	2.87	0.64	-78%
Switzerland	2.08	0.42	-80%
United Kingdom	1.36	0.71	-48%
United States	0.83	0.12	-85%
Average	**2.68**	**0.51**	**-72%**
Countries Not Recommending Menigococcal Vaccine for All Children			
Denmark	2.91	0.49	-83%
Finland	1.00	0.14	-86%
Norway	2.10	0.27	-87%
Sweden	0.66	0.37	-44%
Average	**1.67**	**0.32**	**-75%**

Table 3: Annual incidence rates per 100,000 population of meningococcal disease in the U.S. and peer countries, and percent change from 1998-2002 to 2023-2024. International population estimates were obtained from the U.S. Census Bureau, International Programs Center, International Database.[148] *Because historical meningococcal surveillance data are not harmonized across countries, data sources varied by country and time period. To calculate the IR for the U.S., 1998-2002, 2019, and 2024 data were collected from Centers for Disease Control and Prevention.*[149,150] *In the remaining instances, 1998–2002 data were primarily obtained from the European Commission, Health and Consumers Directorate, European Community Health Indicators: Meningococcal Disease report; for Sweden, there existed a probable data error from the source for 2001's count of case reports that resulted in an exclusion of this data point, therefore, the 1998-2002 incidence was calculated as a four-year average with the remaining data points.*[151] *For Australia, 1998–2001 data were compiled from national surveillance publications by The Australian Meningococcal Surveillance Programme and another academic source, with a four-year IR average calculated due to 2002 data unavailability.*[152,153] *For Denmark, 2023-2024 data were from Statens Serum Institut.*[154] *2020-2024 incidence data are reported cases of invasive meningococcal*

disease collected annually through the WHO/UNICEF Joint Reporting Form on Immunization (JRF).[155] *Reliable incidence rates were not found for Italy, New Zealand or Japan.*

In a 2011 position paper, the World Health Organization (WHO) recommended that countries with more than 2 cases per 100,000 population/year maintain a *"large scale meningococcal vaccination program,"* while only vaccinating the high-risk population in countries with lower rates.[156] In the U.S., the current incidence of 0.1 per 100,000,[157] is much lower than the WHO suggested cut-off.

The current meningococcal vaccines recommended for all children (Menveo, Menquadfi, and Penbraya) were not evaluated in large-scale double-blind placebo-controlled randomized trials before FDA approval.[158,159,160]

Considering the low incidence of meningococcal disease in the U.S., the meningococcal vaccine should not be part of the consensus recommended vaccine schedule. High-risk children and adolescents, such as children with certain types of immune deficiencies, may have a greater chance of benefiting from the vaccine, and it should be available and covered by insurance for all children and adolescents through shared-clinical decision making.

Influenza: The primary purpose of the childhood influenza vaccine in children is to reduce hospitalizations and mortality in children, as well as transmission to the elderly, who are of higher risk for death but there are no randomized controlled trials demonstrating these benefits.[161,162,163] There are some randomized placebo-controlled trials for the influenza vaccine. The most comprehensive review was done in 2018 by the Cochrane Collaboration.[164] They found that *"in children aged between 3 and 16 years, live influenza vaccines probably reduce influenza (moderate-certainty evidence)"* infections while *"inactivated vaccines also reduce influenza (high certainty evidence)."* Only a few of the trials evaluated school and parental work absenteeism, not finding a statistically significant reduction. There was no evidence about reduced transmission. The trials could not evaluate differences in hospitalizations or mortality, as there were none or few in either group, so they provide no evidence that the vaccines reduce hospitalization or deaths. There was not much information about children under 2 years old.

The conclusion of the Cochrane systematic review of randomized trials in children was that *"Decision-makers' attention to the vaccination of very young children is not supported by the evidence summarised in our review. Although there is a growing body of evidence showing the impact of influenza on hospitalisations and deaths of children, at present we could find no convincing evidence that vaccines can reduce mortality, hospital admissions, serious complications, or community transmission of influenza."*[165]

There have been some observational studies with mixed results. A test-negative case-control study claimed to show that childhood influenza vaccine reduces hospitalization,[166] but that is a notoriously biased study design,[167] with highly implausible results.[168]

While there is a scarcity of reliable safety data, the influenza vaccines are not without risk. The seasonal vaccine has been linked to Guillain Barré syndrome.[169] During the 2009/2010 H1N1 influenza pandemic, the Pandemrix pandemic vaccine was found to cause narcolepsy among vaccinated children and adolescents.[170,171] The Cochrane systematic review, noted that *"the lack of safety data for inactive vaccines in younger children is particularly surprising given that the inactive vaccine is now recommended for healthy children six months and older in the USA and Canada"* and that *"the manufacturers' refusal to release all safety outcome data from trials carried out in young children, together with obvious reporting bias and inconsistencies in the primary studies, does not bode well for a fair assessment of the safety of live attenuated vaccines."*[172]

Considering the evidence, and lack of evidence, it is understandable that public health agencies in different countries have come to different conclusions about the influenza vaccine for children. Among the 20 peer countries, only Austria and Canada recommend an annual influenza vaccine for all children >6 months and all adolescents. Another six recommend the shot for all children in selected age ranges. The remaining twelve peer nations do not recommend the influenza vaccine for all children in any age group (Table 2).

Based on both the evidence and uncertainties, the influenza vaccine should not be recommended for all children, but it should be available through insurance for all children >6 months old, through shared-clinical decision making.

COVID-19: In 2022, Denmark became the first peer nation to remove its universal recommendation of the COVID-19 vaccine for children, with the director of its public health authority recognizing that there was little benefit in giving this vaccine to children.[173] Since then, all other peer nations have followed (Table 2). At their September 2025 meeting, the Advisory Committee on Immunization Practices voted that shared clinical decision-making should be applied to the COVID-19 vaccine for U.S. children and adolescents.[174] This means that insurance continues to cover this vaccine for all children in the U.S., unlike many peer nations, where insurance only pays for recommended vaccines.

To ensure a successful childhood vaccination program, the proposed updated schedule:

1. Recommends for all children all the vaccines for which there is consensus among peer nations.
2. Allows for more flexibility and choice, with less coercion, by reassigning non-consensus vaccines to certain high-risk groups and populations and/or based on shared clinical decision-making.
3. Ensures that all the diseases covered by the prior immunization schedule would still be available to anyone who wants them through their private health insurance, Medicaid, the Children's Health Insurance Program (CHIP), and/or the Vaccine for Children (VFC) Program. Among peer nations, the U.S. would continue to offer the greatest number of childhood vaccines for free to those who want them.
4. Is accompanied by a strengthening of vaccine research by launching double-blind placebo controlled randomized trials if appropriate and more observational studies to evaluate long-terms effects of individual vaccines and the vaccine schedule.

5. Next Steps

While closely monitoring vaccine safety and risks, vaccine uptake and infectious disease rates, the CDC and its Advisory Committee on Immunization Practices should continue its work revising recommendations based on the latest vaccine developments and scientific research. For example, they should fine-tune the schedule with recommendations for certain populations for those vaccines that are no longer routinely recommended for all children.

HHS should work with states and physician groups to educate parents and physicians on changes to the CDC childhood immunization schedule.

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EXHIBIT 35

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916 District Judge: Brian E. Murphy Magistrate Judge: M. Page Kelley

DECLARATION OF JASON M. GOLDMAN, MD, MACP

I, Jason M. Goldman, MD, MACP, declare pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am a board-certified primary care physician, and I have owned my own private practice in South Florida since 2002. I see close to 2,000 patients per year. I am also an internal medicine specialist and a Master of the American College of Physicians.

2. I graduated from medical school at the University of Miami in 1998. I completed my residency in internal medicine at Jackson Memorial Hospital in Miami, Florida.

3. I am the current President of the American College of Physicians ("ACP"). I previously served as Governor of ACP's Florida Chapter from 2016 through 2020 and a Regent of the College from 2020 through 2024. I served as Chair of ACP's Medical Practice Quality Committee, and I currently serve on ACP's Immunization Committee.

4. ACP was founded in 1915 to promote the science and practice of medicine, and since then, has supported internal medicine physicians by sharing the most updated medical knowledge, offering top-notch educational resources, and providing optimal practice guidelines.

5. ACP is a national organization of internal medicine physicians who specialize in the diagnosis, treatment, and care of adults, and it is the largest medical specialty organization in the United States. ACP has over 162,000 members in more than 172 countries across the globe, which include internal medicine physicians, related subspecialists, and medical students. While most of our physician members treat adults, many of our physician members also currently provide direct care to immunocompromised persons, pregnant women, newborns, and children in both hospital and outpatient settings.

6. In 2018 I became the ACP liaison to ACIP. In 2020, I joined the Advisory Committee on Immunization Practice's ("ACIP") COVID-19 Vaccines Work Group as a liaison member representing the ACP. In 2019 I joined the Pneumonia Vaccine Work Group. I served as the ACP's liaison member to the COVID-19 Vaccines Work Group and Pneumonia Work Group until on or about July 31, 2025, when I received an email that liaison organizations were terminated from participating in ACIP Work Groups because liaison organizations like the ACP allegedly were "special interest groups and therefore are expected to have a 'bias.'"

7. I agree that ACP has a bias, and that bias is "[t]o enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine" and to "apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness."[1]

[1] https://www.acponline.org/about-acp/who-we-are-what-we-do

8. From my five years of service on the COVID-19 Vaccines Work Group, and six years of service on the Pneumonia Vaccine Work Group, I am well-versed in the process and procedure that the COVID-19 Vaccines Work Group, Pneumonia Work Group, and the ACIP followed before Robert F. Kennedy, Jr. became the Secretary of the Department of Health and Human Services (the "Secretary") to make recommendations on how vaccines should be recommended for use in this country and how they should be listed on CDC immunization schedules. I have attended all public meetings of the ACIP since 2018. Attached hereto as Exhibit A is the Final Agenda for the April 15-16, 2025 public meeting, which was the last meeting of the members of the ACIP who were fired on June 9, 2025. At the April 15-16, 2025 meeting, true subject-matter experts presented the results of Evidence to Recommendation ("EtR") framework analyses on a number of different vaccines. At the September and December 2025 meetings of the current ACIP, no one gave an EtR presentation. The EtR framework has been a best practice of the ACIP since before I became a liaison to the Covid-19 Work Group. The current ACIP has abandoned this best practice, without explanation.

9. It has been astonishing who some of the presenters have been at the three meetings of the current ACIP. Robert F. Kennedy, Jr., is the founder of Children's Health Defense, an aggressive anti-vaccine organization. It was incredible to me that the former president of Children's Health Defense, Lyn Redwood, presented at the first meeting of this new ACIP on June 26, 2025, on the alleged danger of thimerosal, a benign form of mercury used as a preservative in some vaccine vials. The theory that thimerosal causes autism, a theory pushed by the Secretary and Children's Health Defense for years, has been thoroughly debunked for over 20 years.

10. At the December 5, 2025 meeting, Aaron Siri, a well-known anti-vaccine lawyer and known associate of the Secretary, presented on the "Childhood/Adolescent Immunization

Schedule." On December 4, Dr. Cynthia Nevison and Mr. Mark Blaxill presented on the hepatitis B vaccine. Dr. Nevison is a climate scientist, not a vaccine scientist. Mr. Blaxill is not a doctor and works in finance. Neither of them have training or education in vaccine-related science. Attached hereto as Exhibit B is an article reporting on Mr. Blaxill, Ms. Redwood, and other known anti-vaxxers being hired for positions at the CDC, which is frightening. The presentations were misleading, biased, and not reflective of true scientific inquiry or factual information.

11. I have been a practicing physician for almost 30 years. For the last 10 years, I have served in a governance position for the ACP. For the last eight years, I attended every public meeting of the ACIP and a countless number of Covid-19 and Pneumonia Work Group meetings. Based on this experience, it is my professional opinion that another public meeting of this ACIP would be dangerous to the general public and poses an existential threat to the public health, welfare, and safety of my patients. Public meetings of the ACIP are streamed real-time on YouTube. News of what was said and what was voted on at ACIP meetings spreads fast. One piece of false or misleading misinformation presented at an ACIP meeting is one too many. Too much false and misleading information has been presented at the last three ACIP meetings to let this ACIP publicly meet again to spread more false and misleading information.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 25, 2026, in Coral Springs, Florida



Jason M. Goldman, MD, MACP
President, American College of Physicians

EXHIBIT A

Docusign Envelope ID: DBE72992-0BD5-47CD-9C49-8B0EF3F6E552 Case 1:25-cv-11916-BEM Document 185-35 Filed 01/26/26 Page 7 of 19

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)
Centers for Disease Control and Prevention
Atlanta, Georgia 30329

Tuesday, April 15, 2025

8:00	**Welcome & Introductions**	Dr. Keipp Talbot (ACIP Chair) Dr. Melinda Wharton (ACIP Executive Secretary, CDC)
8:15	**Mpox Vaccine**	
	Introduction	Dr. Faisal Minhaj (CDC/NCEZID)
	Presentation on immunogenicity and safety of JYNNEOS in 12-17 year olds	Dr. Buddy Creech (Vanderbilt University)
	EtR for JYNNEOS in outbreaks and due to the 2022 global outbreak	Dr. Faisal Minhaj (CDC/NCEZID)
9:55	**Lyme Disease Vaccine**	Dr. Grace Marx (CDC/NCEZID)
10:00	**Influenza Vaccines**	
	Introduction	Dr. Jamie Loehr (ACIP, WG Chair)
	Influenza vaccine effectiveness update	Dr. Aaron Frutos (CDC/NCIRD) Dr. Sophie Zhu (California DPH and CDC/PHIC), Dr. Joshua Quint (California DPH)
	FluMist self/caregiver administration	Dr. Allyn Bandell (AstraZeneca)
11:15	***Break***	
11:30	**COVID-19 Vaccines**	
	Introduction	Dr. Robert Schechter (ACIP, WG Chair)
	Moderna mRNA-1283 COVID-19 vaccine	Dr. Bishoy Rizkalla (Moderna)
	Epidemiology and risk factors for COVID-19 hospitalizations	Dr. Fiona Havers (CDC/NCIRD)
	Vaccine effectiveness update	Dr. Ruth Link-Gelles (CDC/NCIRD)
	Workgroup considerations for use of 2025-2026 COVID-19 vaccines	Dr. Lakshmi Panagiotakopoulos (CDC/NCIRD)
1:30	**Pneumococcal Vaccines**	
	Workgroup Next Steps and Proposed Work Plan	Dr. Miwako Kobayashi (CDC/NCIRD)
1:45	***Break***	
2:00	**Human Papillomavirus (HPV) Vaccines**	
	Introduction	Dr. Oliver Brooks (ACIP, WG Chair)
	Update on literature related to reduced number of doses for HPV vaccination	Dr. Carla DeSisto (CDC/NCIRD)
	KEN SHE trial	Dr. Ruanne Barnabas (Harvard University)
	HPV vaccination coverage	Ms. Cassandra Pingali (CDC/NCIRD)
	Modeling of reduced number of doses for HPV vaccination	Dr. Jane Kim (Harvard University)
	Modified EtR: wording of the age for routine HPV vaccination	Dr. Ruth Stefanos (CDC/NCIRD)
	Workgroup next steps and considerations	Dr. Lauri Markowitz (CDC/NCIRD)
4:00	**Cytomegalovirus (CMV) Vaccines**	
	Introduction	Dr. Denise Jamieson (ACIP, WG Chair)
	CMV and cCMV epidemiology and disease burden	Dr. Tatiana Lanzieri (CDC/NCIRD)
	CMV vaccine safety and immunogenicity data	Dr. Robert Paris (Moderna)
	Initial workgroup considerations for CMV vaccine policy	Dr. Tatiana Lanzieri (CDC/NCIRD)
5:00	**U.S. Measles Update**	Dr. David Sugerman (CDC/NCIRD)
5:30	**Adjourn**	

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Wednesday, April 16, 2025

8:00	**Welcome & Introductions**	Dr. Keipp Talbot (ACIP Chair)
8:15	**Meningococcal Vaccines**	
	Introduction	Dr. Jamie Loehr (ACIP, WG Chair)
	GSK pentavalent vaccine: update of EtR and workgroup considerations	Dr. Sarah Schillie (CDC/NCIRD)
	Updates to Meningococcal vaccines VFC resolution	Dr. Jeanne Santoli (CDC/NCIRD)
	Introduction to MenQuadfi label change for infants	Dr. Sarah Schillie (CDC/NCIRD)
	MenQuadfi in infants: safety and immunogenicity	Dr. Rachel Dawson (Sanofi)
	Workgroup considerations regarding MenQuadfi in infants	Dr. Sarah Schillie (CDC/NCIRD)
9:30	***Break***	
9:45	**Respiratory Syncytial Virus (RSV) Vaccines - Adults**	
	Introduction	Dr. Albert Shaw (ACIP, WG Chair)
	Manufacturer Presentation: mRNA-1345 (Moderna) Immunogencity in Adults 18-59 at Increased Risk; 24-Month Re-Vaccination	Dr. Frances Priddy (Moderna)
	Manufacturer Presentation: Arexvy (GSK) 36-Month Re-Vaccination	Dr. Susan Gerber (GSK)
	Economic Analysis of Adult RSV Vaccination, including benefits and risk discussion	Dr. Ismael Ortega-Sanchez (CDC/NCIRD)
	Comparison of Economic Analyses of Adult RSV Vaccination	Dr. Ismael Ortega-Sanchez (CDC/NCIRD)
	Evidence to Recommendations	Dr. Diya Surie (CDC/NCIRD), Dr. Michael Melgar (CDC/NCIRD)
	Clinical Considerations	Dr. Diya Surie (CDC/NCIRD)
12:15	***Break***	
12:30	**Chikungunya Vaccines**	
	Introduction	Dr. Edwin Asturias (ACIP/WG Chair)
	EtR for use of virus-like particle chikungunya vaccine among adolescent and adult travelers	Dr. Susan Hills (CDC/NCEZID)
	EtR for use of virus-like particle chikungunya vaccine among laboratory workers	Dr. Erin Staples (CDC/NCEZID)
	Surveillance for adverse events following use of live attenuated chikungunya vaccine and its use among travelers	Dr. Susan Hills (CDC/NCEZID), Dr. Erin Staples (CDC/NCEZID)
	Clinical guidance for use of virus-like particle chikungunya vaccine among pregnant and breastfeeding women	Dr. Susan Hills (CDC/NCEZID), Dr. Dana Meaney-Delman (CDC/NCBDDD)
3:00	***Break***	
3:10	**Public Comment**	
3:40	**VOTES**	
	Meningococcal Vaccines	Dr. Sarah Schillie (CDC/NCIRD)
	Meningococcal Vaccines VFC	Dr. Jeanne Santoli (CDC/NCIRD)
	RSV Adult	Dr. Michael Melgar (CDC/NCIRD)
	Chikungunya Vaccines	Dr. Susan Hills (CDC/NCEZID)
4:10	**Respiratory Syncytial Virus (RSV) Immunizations- Maternal/Pediatric**	
	Introduction	Dr. Helen Chu (ACIP, WG Chair)
	EtR: Clesrovimab	Ms. Danielle Moulia (CDC/NCIRD)
	Clinical considerations	Dr. Jefferson Jones (CDC/NCIRD)
5:10	**Adjourn**	

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Acronyms

cCMV	Congenital cytomegalovirus
CDC	Centers for Disease Control and Prevention
CMV	Cytomegalovirus
COVID-19	Coronavirus disease 2019
DPH	Department of Public Health
EtR	Evidence to Recommendations Framework
HPV	Human papillomavirus
NCBDDD	National Center on Birth Defects and Developmental Disabilities
NCIRD	National Center for Immunization & Respiratory Diseases
NCEZID	National Center for Emerging and Zoonotic Diseases
PHIC	Public Health Infrastructure Center
RSV	Respiratory Syncytial Virus
WG	Work Group
VFC	Vaccines for Children

EXHIBIT B

Sep. 26, 2025, 1:50 PM EDT

By Brandy Zadrozny

The Centers for Disease Control and Prevention has hired anti-vaccine activist and author Mark Blaxill as a senior adviser, according to three current and former senior CDC officials and an internal profile reviewed by MSNBC.

Neither a physician nor a scientist, Blaxill claims without evidence that every child who takes vaccines is in some way injured, and has written books and articles promoting the disproven claim that childhood shots cause a broad range of health conditions and that autism is a consequence purely of environmental exposures. Blaxill once helped lead the advocacy group, SafeMinds, which funded research aimed at proving a link between vaccines and autism and served as editor-at-large of the anti-vaccine website, Age of Autism. Blaxill has long and wrongly blamed thimerosal, a preservative in some vaccines, for what he calls an autism "epidemic." His claims have been refuted by decades of rigorous research. The Institute of Medicine officially rejected any causal relationship between thimerosal-containing vaccines and autism in 2004.

Blaxill's quiet hiring is the latest in a series of staffing moves by Kennedy aimed at reshaping federal vaccine policy.

Blaxhill's role and remit at CDC is unclear. The internal profile showed he will be working directly under CDC chief of staff Matthew Buzzelli. One of the senior CDC officials said Blaxill's name had been floated for weeks as a potential leader for a program that tracks autism within the Center on Birth Defects and Developmental Disabilities.

The current and former CDC officials were granted anonymity due to fears of retaliation.

Blaxill's employment began last week, according to his internal profile. His hiring comes before the expected release of a report on autism and on the heels of President Donald Trump signaling that autism, its causes and treatments, would be a defining policy of the administration. On Monday,

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Kennedy. "These are people who believe what Kennedy believes, that want to to promote an agenda, that vaccines cause autism. And so Mark Blaxill will be perfect, right?"



Kennedy's principal deputy chief of staff, Stefanie Spear, previously worked for Children's Health Defense, the anti-vaccine nonprofit Kennedy founded. In February, Stuart Burns, a former congressional aide and key ally of the anti-vaccine movement in the 1990s, was named senior adviser to the CDC director and has been managing Kennedy's vaccine-related projects inside the agency. David Geier, an anti-vaccine researcher who alongside his physician father conducted experiments on autistic children, was hired in March to review vaccine safety data. In June, Lyn Redwood, a former president of Children's Health Defense, joined the CDC's Vaccine Safety Office with the title of "expert."

Senior CDC officials who recently resigned in protest have said Kennedy doesn't speak with career CDC officials or receive expert briefings. When asked who he consults, Kennedy named Bill Thompson, a longtime agency scientist inside the CDC's division of viral hepatitis. Thompson is well

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Blaxill is also featured in the film, which was directed by Andrew Wakefield, a British physician whose retracted 1998 study in The Lancet helped launch the modern anti-vaccine movement.

Senior CDC officials who recently resigned in protest have said Kennedy doesn't speak with career CDC officials or receive expert briefings.

Kennedy's recent hires have already helped enact stark policy shifts around vaccines. According to former senior CDC leaders, Kennedy told the CDC director to work solely with his appointees, who set the agenda and determined the working groups for recent meetings of an advisory committee deciding which vaccines the CDC will recommend and on what schedule. That committee was gutted and remade with vaccine critics and activists who recently voted against flu shots containing thimerosal and declined to recommend universal Covid shots.

Recommended



MS NOW Opinion

RFK Jr. is targeting aluminum in vaccines — and children could pay the price

Alex Morozov, Helen Petousis-Harris, Stephan Lewandowsky



Latest

Trump, without new evidence, tries to link Tylenol and autism

Brandy Zadrozny

Blaxill, the chief financial officer for a Minnesota company that buys and sells computer servers and IT equipment, is the self-described "warrior dad" of an autistic daughter. He ran as a Republican for Congress in Minnesota in 2022 but ultimately suspended his campaign.

Blaxill did not respond to emails and voicemails requesting comment. Health and Human Services declined to respond to questions about Blaxill's hire.

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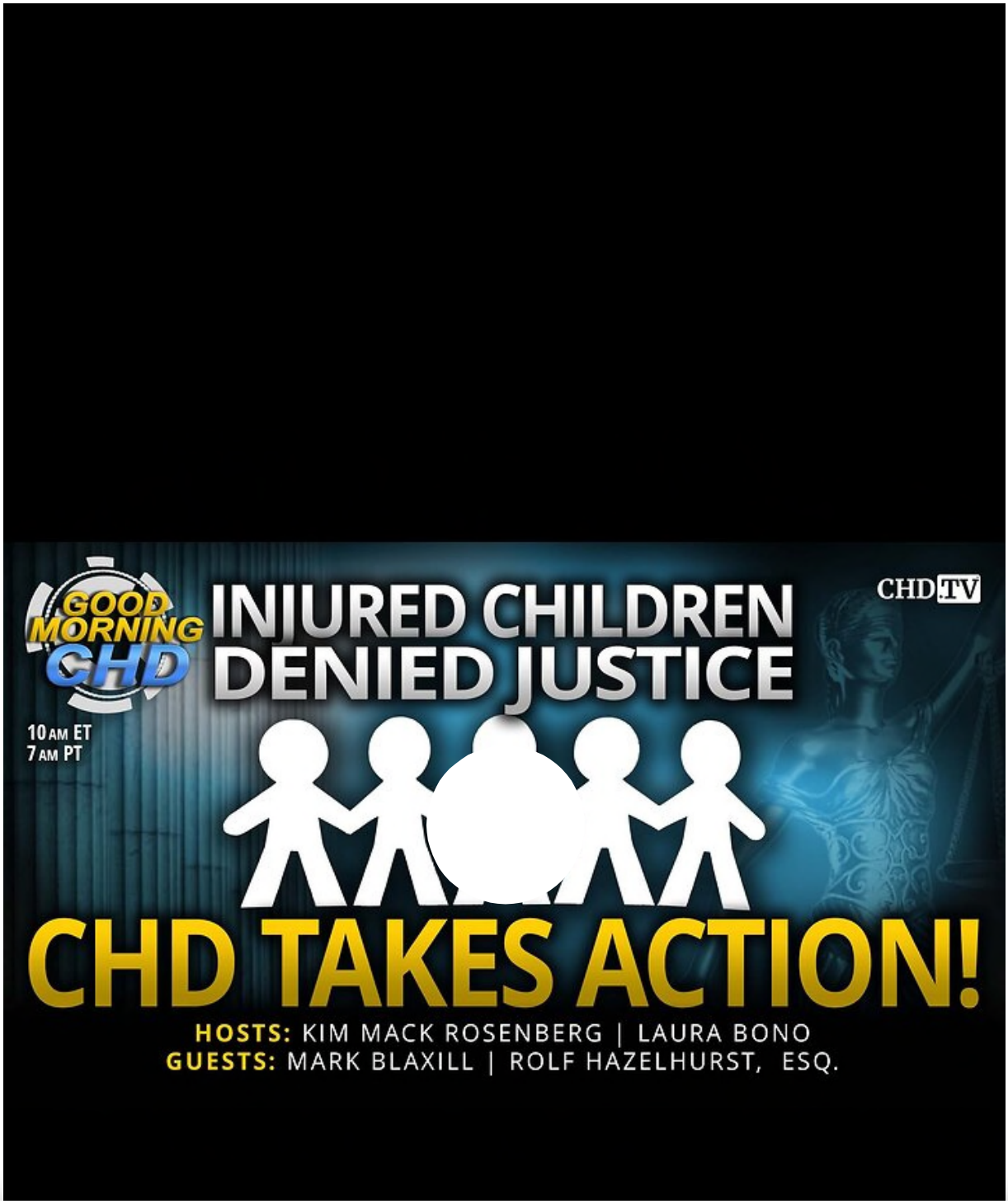
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this is the sort of thing that should cause you to be skeptical," Blaxil said, according to The Washington Post.

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'The Rate of Injury is 100%'



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In a video interview posted last year by Children's Health Defense, Blaxill asserted that "of the children that receive the recommended childhood vaccine schedule, the rate of injury is 100%," and linked vaccines to anxiety, food allergies and attention-deficit/hyperactivity disorder.

Though not a statistician or epidemiologist, Blaxill authored a 2021 paper titled "Autism Tsunami," which projected a trillion-dollar cost to treat autism in the U.S. by 2030. Kennedy cited the paper at a recent press conference, where he exaggerated the severity of autism and parroted Blaxill's argument that "genes do not cause epidemics." Kennedy failed to mention that the Journal of Autism and Developmental Disorders had retracted Blaxill's paper in 2023, citing misrepresentation of the incidence in autism, unrepresentative data, unjustified assumptions that inflated costs, and undisclosed conflicts of interest. Blaxill has publicly said the paper was retracted for "no good reason" and, in a formal response, said it was targeted for "ideological" reasons.

A formal report on the causes and answers to what Blaxill and Kennedy describe as the "autism epidemic" was expected this month. After Trump's rushed news conference to blame Tylenol and vaccines, it's not clear whether an official report is coming. But with Blaxill on board, any report would likely include the same disproven theories that anti-vaccine activists have spent decades promoting — this time under the CDC seal.



Brandy Zadrozny

Brandy Zadrozny is a senior enterprise reporter for MS NOW. She was a previously a senior enterprise reporter for NBC News, based in New York.

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EXHIBIT 36

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF
ANDREW T. PAVIA, MD, FAAP, FACP, FIDSA

I, Andrew T. Pavia, MD, FAAP, FACP, FIDSA, declare pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. Based on my over-30-year career as an infectious disease expert, the Secretary of Health and Human Services Robert F. Kennedy, Jr.'s dangerous and unsupported decisions regarding COVID-19 vaccines are causing preventable suffering and death to Americans.

2. I received my medical degree at Brown University. I trained in internal medicine at Dartmouth Hitchcock Medical Center and served as chief resident.

3. At the Centers for Disease Control and Prevention ("CDC"), I was trained in Public Health Epidemiology as an Epidemic Intelligence Service officer and a Preventive Medicine Resident.

4. I completed a fellowship in pediatric and adult infectious diseases at the University of Utah, and joined the faculty at the University of Utah in 1991. I later became the George and Esther Gross Presidential Professor and Chief of the Division of Pediatric Infectious Diseases.

5. I also currently serve as Director of Hospital Epidemiology at Primary Children's Hospital and Associate Director of Antimicrobial Stewardship.

6. I am a member of the Society for Pediatric Research, and a Fellow of the American Academy of Pediatrics, the American College of Physicians, the Infectious Diseases Society of America, and the Society for Healthcare Epidemiology of America. I have served as a member of the National Vaccine Advisory Committee, where I chaired the Vaccine Safety Working Group, and the National Biodefense Science Committee.

7. I have also been a member of the Advisory Committee on Immunization Practices ("ACIP") working group on Anthrax and a consultant to CDC on several expert groups.

8. I served as a member of the National Institutes of Health ("NIH") COVID-19 Treatment Guidelines Panel, where I led the Pediatric Working Group.

9. I served as a member of the Board of Directors for the Infectious Diseases Society of America ("IDSA") from 2009 to 2012 and was the IDSA's past chair of the Pandemic Influenza Task Force, past Chair of the National and Global Public Policy Committee and past Chair of the IDWeek Program Committee. I am still an active member of IDSA as the Chair of the Avian Influenza Task Force and co-Chair of the IDSA Influenza Treatment Guidelines Committee.

10. IDSA was formed in 1970 in Washington, DC with the goal to cultivate the growing knowledge of infectious diseases, endorsing scientific programs, and retaining a membership of persons whose work showed significant contributions to the field.

11. IDSA is currently the leading medical society representing more than 13,000 infectious disease ("ID") physicians, scientists, and other health professionals devoted to patient care, prevention, public health, education, and research in infectious diseases.

12. IDSA's mission is to bring together the curiosity, compassion, and knowledge of our members to strengthen the field of infectious diseases, advance science, and advocate for health equity.

13. IDSA offers robust training, education, and resources regarding immunization, which is one of the most important things people can do to protect their families and communities from infectious diseases, such as COVID-19, measles, polio, whooping cough, bacterial meningitis, and cervical cancer.

14. Our membership includes infectious disease ("ID") physicians nationwide, many of whom are currently providing direct care to adults under the age of 65, pregnant patients, newborns, and children in both hospital and outpatient settings. Across specialties, ID physicians are tasked with treating patient with vaccine-preventable illness and their serious, and often, life-threatening complications.

15. IDSA has adopted clinical practice guidelines that are considered the standard of care for our physician members and are in place to optimize and protect the care provided to our members' patients. Clinical practice guidelines are informed by a systematic review and quality assessment of peer-reviewed research and evidence; the professional judgment of our members and relevant experts from other specialties; and an assessment of the benefits and harms of alternative care options. Clinical practice guidelines follow a sound, transparent methodology to translate best evidence into clinical practice for improved patient outcomes. They are a key component of patient-centered care.

16. IDSA maintains regular guidance for clinicians regarding COVID-19, including related to the treatment and management of patients with COVID-19, infection prevention for health care personnel, and various diagnostic testing methodologies.

17. The recent actions of the Department of Health and Human Services related to the COVID-19 vaccine have injected chaos, confusion, and disruption into the practice and care that I and other IDSA physician members deliver to patients.

18. I am aware of and disagree with the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "Secretarial Directive") issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the COVID-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the COVID-19 for pregnant individuals. The Directive was arbitrary and not supported by the evidence. In fact, no data presented by the COVID-19 Vaccines Work Group for the ACIP—before or after the issuance of the Directive—has suggested that vaccines should not be routinely recommended for pregnant persons or children. Indeed, pregnancy and recent pregnancy are considered risk factors for severe illness of COVID-19.

19. I am aware of and disagree with the recommendation issued by the newly reconstituted ACIP in September 2025 and subsequently adopted by the acting director of the CDC in October 2025, changing the COVID-19 vaccine recommendation for adults under the age of 65 from routine to SCDM. This change by the ACIP and the CDC was made without the usual transparent presentation of GRADE tables or Evidence to Recommendation ("EtR") framework for evaluating the quality of evidence, nor was this change accompanied by a clear, contemporaneous explanation in the MMWR. In my practice and in conversations with IDSA physician members, this change to the CDC immunization schedule for COVID-19 vaccines for adults has significantly disrupted the prior harmonious system and created multiple layers of confusion and harm.

20. I am aware of and disagree with the revisions to the Childhood Immunization Schedule, issued by the Acting Director of the Centers for Disease Control and Prevention through a Decision Memo ("Schedule Change") on January 5, 2026. This overhaul circumvented established policy by foregoing consideration by ACIP. Neither the Decision Memo nor accompanying materials included a fulsome explanation or analysis of the available scientific evidence to support the revision. This revision to the Immunization Schedule builds on growing confusion and harm experienced by IDSA physicians.

21. I am aware of and disagree with ACIP's intention to meet on February 25-26. The newly reconstituted ACIP has shown an increased willingness to broadcast messaging fueled by theory and personal vendettas against vaccines. At the same time, ACIP has shut the door on its liaisons, including IDSA and other scientific organizations, signaling that it has no intention to operate with any regard to established evidence or policy.

22. IDSA has historically endorsed the ACIP's COVID-19 vaccine recommendations. That is no longer the case. The ACIP appointed by the Secretary has abandoned the careful, comprehensive, and transparent review historically undertaken by the ACIP that weighs all the factors that go into developing and issuing a vaccine recommendation. In reaching the decision to change the COVID-19 vaccine recommendation from "routine" to "SCDM," the ACIP appointed by the Secretary excluded the opinions of liaison groups who care for patients and who have relevant expertise necessary to develop an effective, reliable vaccine recommendation; included minimal participation in deliberations from CDC experts; and failed to consider peer-reviewed, evidence-based data.

23. When the CDC classifies a vaccine as routine, that signals to patients that there is no ambiguity about the effectiveness and safety of a vaccine and enables providers to administer

the vaccine with the backing of an unequivocal recommendation from the CDC and that the vaccine is recommended in order to protect their patients' health. That is because a routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient and, therefore, should be administered as a standard part of medical care for the patient. A routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine. Routine recommendations do not in any way compel or mandate that the patient receive the vaccine. Rather, they provide clear, evidence-based medical advice and patients can discuss any questions they may have with providers.

24. The CDC immunization schedule change for adults for the 2025-2026 COVID-19 vaccines from "routine" to "SCDM" and the subsequent revision of the Childhood Immunization Schedule, resulting in a shift from "routine" to "SCDM" for rotavirus, influenza, hepatitis A, and meningococcal MenACWY vaccines is a downgrading of the CDC's recommendation and sends a message to patients discouraging uptake. As a recent article published by several distinguished IDSA physician members succinctly explained, "In contrast to an explicit recommendation to vaccinate is SCDM, which is the lowest-strength option available to ACIP. Rather than a recommendation, it is a 'perhaps.'"[1]

25. In the past, when the CDC has issued a SCDM recommendation for a vaccine, the supporting data was published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") in addition to the SCDM recommendation. This data is critical for physician use in consulting with and discussing the risk and benefits of a vaccine categorized as SCDM and, normally, provides

[1] Thomas R. Frieden, MD, MPH, et al., *CDC's Failure to Recommend COVID-19 Vaccination—"Shared Clinical Decision-Making" Is Abdication of Responsibility*, JAMA (November 13, 2025). A true and correct copy of this article is attached to this declaration as **Exhibit A.**

clinicians with the evidence base to guide patient counseling. No such data or guidance accompanied the CDC immunization schedule change for adults for the 2025-2026 COVID-19 vaccines from "routine" to "SCDM," leaving me and other IDSA physician members without clear guidance regarding what to discuss with patients or how to counsel them regarding the risks and benefits of the COVID-19 vaccine. In addition, as revisions made to the Childhood Immunization Schedule in January of 2026 were published via Decision Memo, the CDC did not provide supporting data or implementation guidance. Neither did IDSA physicians benefit from transparent discussions regarding data and ultimate recommendations, as customarily occurs through ACIP. This lack of clarity and guidance inherently increases the amount of time I and other IDSA physician members spend on unbillable counseling time with patients regarding the COVID-19 vaccine and those vaccines subject to changes in the Schedule Change.

26. As it relates to the COVID-19 vaccine, IDSA physician members have informed me that this lack of clarity and lack of guidance regarding the SCDM COVID-19 vaccine recommendation has left them without a path for employing shared clinical decision-making in practice, including whether it requires face-to-face time with a healthcare provider or if it allows for consultation with pharmacists.

27. This lack of standardized recommendations and practices has required states to fill in the gaps and determine how the SCDM recommendation for the COVID-19 vaccine fits within their state's laws. Consequently, states have had to hastily convene committees to interpret and develop guidance and regulations founded on evidence-based vaccine recommendations. As a result, instead of a single, trusted voice providing vaccine recommendations—as was the case prior to the Secretary's reconstitution of the ACIP—the public is receiving messages and recommendations regarding the COVID-19 vaccine that vary significantly on a state-by-state

basis. As a resource for physicians on all issues and considerations related to vaccines, the IDSA has had to devote significant time and resources to keeping up with the rapidly-changing patchwork of state requirements and laws related to the administration of the COVID-19 vaccine in order to address the influx of inquiries received from IDSA physician members following the downgrading of the CDC immunization schedule change for adults for the 2025-2026 COVID-19 vaccines from "routine" to "SCDM."

28. The CDC's downgrade of the recommendation of the COVID-19 vaccine for adults under age 65 to SCDM has created significant barriers for patients seeking to get a COVID-19 vaccine. For example, in order for a patient to engage in SCDM with a physician, a patient must schedule a physician appointment, incur copay costs, and potentially take time off work. Further, limited healthcare provider availability remains a significant obstacle for patients seeking access to the COVID-19 vaccine.

29. The downgrading of the recommendation of the COVID-19 vaccine for adults under age 65 to SCDM also requires me and other IDSA physician members to spend more time counseling patients about the safety and effectiveness of the COVID-19 vaccine. Before the new ACIP recommendation was issued, when the COVID-19 vaccine was a routine recommendation for adults under 65, I spent very little time counseling my patients regarding the COVID-19 vaccine because patients generally trusted the well-supported, evidence-based recommendations published by the CDC. Although studies establishing the safety and effectiveness of the COVID-19 vaccine and the risk-benefit analysis of receiving the COVID-19 vaccination has not changed, the new ACIP recommendation, adopted by the CDC acting director, has created significant confusion and distrust about the COVID-19 vaccine among patients. This confusion and distrust

require me to spend significantly more time counseling patients and educating colleagues in order to dispel the misinformation the Secretary has spread about the COVID-19 vaccine.

30. IDSA physician members have informed me that the change in the COVID-19 vaccine's classification from routine to one requiring shared clinical decision-making and the CDC's and the Secretary's associated messaging has left their patients confused and concerned regarding the vaccine's efficacy and safeness. Patients are seeking clarity from IDSA physician members regarding why this change is necessary and what additional risks have been identified necessitating the change, while providers are left without answers because there are no studies or data indicating that this change was necessary. As a result, the change in the COVID-19 vaccine recommendation from "routine" to "SCDM" has created a sense of chaos and instilled a lack of confidence among patients regarding a vaccine that is proven to be safe and effective at preventing the spread of COVID-19.

31. IDSA physician members use Current Procedural Terminology ("CPT") codes to bill for the professional services that they provide to their patients. Each code is tied to a patient care service and is used to document and receive reimbursement for medical encounters. Vaccine administration has its own family of CPT codes, with the codes tying compensation of doctors to actual administration of the vaccine during a patient visit.

32. IDSA physicians report that, ACIP's COVID-19 recommendation, adopted by the CDC, which shifts the recommendation for COVID-19 vaccines to SCDM for adults under the age of 65, they have been required to spend significantly more unbillable time counseling patients and answering questions from primary care physicians regarding COVID-19 vaccinations.

33. Confusion and the need to spend increased time consulting patients regarding the COVID-19 vaccination has persisted as a challenge for IDSA physicians through the current

respiratory season. These challenges have only been compounded by the Schedule Change and ongoing actions by ACIP. IDSA physicians have reported that the Schedule Change and actions taken by ACIP to present debunked evidence as scientific authority have impacted not only those vaccines that have been downgraded, but all currently and previously recommended vaccinations. IDSA physicians have reported spending increased time with patients, discussing the scientific evidence behind each of the vaccinations. These actions have sown doubt into the patient-provider relationship, which providers must amend in short, allotted patient visits. Not only is this time often unbillable, but it also infringes on the ability of IDSA physician members to see additional patients and receive reimbursement for that time.

34. IDSA has meaningfully engaged with ACIP in years preceding its current membership. During these times, IDSA was provided an opportunity to share insight on practical implications of recommendations, based on the collective knowledge of IDSA physicians. This collaborative relationship created recommendations which adequately and effectively served the patient population. The Schedule Change's obversion of procedure stripped IDSA of any ability to provide input. This disenfranchisement and continued disregard to evidence and clinical perspective is poised to continue as ACIP resumes its efforts to dismantle the immunization schedules.

35. Peer-reviewed and evidence-based studies consistently show that the COVID-19 vaccine provides substantial protection against severe illness, long COVID-19, hospitalization, and death for adults under the age of 65. Unless the COVID-19 vaccine is given to children, especially those younger than 5, and adults under the age of 65, including pregnant patients, then vaccination rates will fall and the risks of severe illness, hospitalization, and mortality will increase for these patient populations and their families. Moreover, increased rates of infection among

adults under 65 and children who care for elderly and immunocompromised patients will increase the risk of COVID-19 related morbidity and mortality in these highly vulnerable patients.

36. Peer-reviewed and evidence-based studies have further demonstrated the importance of pediatric vaccines in curbing hospitalizations and mortality. For example, the rotavirus vaccine and RSV immunization have both proved to be successful in reducing the rates of hospitalization amongst children. Before implementation of these vaccines, each disease caused more than 50,000 pediatric hospitalizations annually. Downgrades in recommendations to the vaccines threaten to lower uptake, thereby increasing hospitalization rates.

37. ACIP and CDC's continued subversion of this scientific evidence has demonstrated disingenuity. As a result of the repeated dismissal of evidence-based science, IDSA physicians have been tasked with the uphill battle of responding to governmental misinformation.

38. Across the United States there has been a growing shortage of ID physicians. Misinformation, paired with significant, targeted action to revise the immunization schedules, continues to pose a threat to the ability to of the ID specialty to stay afloat. IDSA physicians have reported increased mental burden and burnout as a result of the now constant need to rebuild trust with patients, both in their relationship with patients and in their patient's relationship with science. In addition, IDSA physicians have reported difficulty carrying out their responsibilities, which typically involves caring for patients with serious and life-threatening infections, and those students interested in the ID profession are increasingly reevaluating their options.

39. IDSA physicians are charged with responding and guiding their communities through outbreaks, in addition to treating the complications which may arise as a result of these infections. Many of IDSA's members serve in local and state public health roles. Responding to outbreaks places a significant burden on the thinned ID specialty nearly every respiratory season.

Vaccination prevents not only death, but serious complications, in the event of breakthrough cases. An increase in children who are not vaccinated for common respiratory illnesses, such as flu and RSV will have an immediate, devastating effect, which will overburden an already limited and strained workforce. Furthermore, there is a critical shortage of pediatric hospital beds in the United States, and the increase in rotavirus, influenza and Covid-19 admissions will lead to overcrowding, cancelled surgeries and delays in care. The reality of which is an unsupportable burden on IDSA physicians, who face burnout and exhaustion when caring for more critically ill patients with fewer resources.

40. The CDC actions identified above also inflict immediate harm on IDSA itself by compelling the organization to abandon planned mission-critical work and operate in an ongoing response mode so that we can respond to questions from members and the public surrounding the May 19 Directive, September CDC immunization schedule for Covid-19 vaccination, and the January 5, 2026 changes to the CDC childhood immunization schedule. IDSA leadership, staff, and communications teams are spending hours each day responding to misinformation, correcting federal shifts in vaccination pronouncements, and briefing IDSA members on the internally inconsistent CDC materials. IDSA is being forced to divert staff time to review and understand these abrupt unscientific changes to the CDC immunization schedule so that it can review its publications that utilized the evidence-based ACIP framework that the process for May 19 Directive, September Schedule Change for Covid-19 vaccination, and January 5 Childhood Schedule Change completely abandoned. IDSA also must expend additional resources to correct the misinformation being presented at the ACIP meetings to rebuild trust with members and their patients on vaccination recommendations.

41. The harms to IDSA and IDSA members associated with the May 19 Directive, September Schedule Change for Covid-19 vaccination, and the January 5 changes to the childhood immunization schedule—as well as the anticipated harms that will result from any additional changes that may result from the upcoming February 26, 2026 ACIP meeting—are immediate, ongoing, and compounding. I have seen first had how each successive change to CDC immunization schedule is building on unresolved confusion from the prior changes and further erodes patient confidence their ID physician. Each new change amplifies patient skepticism and diminishes the effectiveness of ID physician's clinical counseling. The cumulative impact of the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the imminent February 26, 2026 ACIP meeting has pushed ID physician's clinical practice toward or beyond that limit absent immediate injunctive relief.

42. The harms described above are also compounded by the failure to follow established the GRADE and EtR frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. Practicing ID physicians rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations they discuss with their patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, ID physicians are forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the anticipated February 2026 ACIP actions, the harm compounds. ID physicians do not have the time or practical ability to reconstruct population-level

evidence analyses that the ACIP processes are designed to perform and that they have relied on throughout their entire career. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in vaccinations, pushing ID physician's clinical practice toward a breaking point absent immediate injunctive relief.

43. The newly constituted ACIP meetings are now a platform for spreading information on vaccination that is directly impacting the ID physician's consultations with their patients every day, forcing ID physician's into a daily crisis-mode as they spend hours of their time now correcting misinformation that is spread at ACIP meetings and trying to rebuild trust with their patients as their recommendations on infectious disease prevention and vaccination that relied on the prior evidence based EtR review process have been discredited and abandoned by this ACIP. If the February 25-26, 2026 ACIP meeting proceeds as scheduled, this ACIP meeting will spread more misinformation and confusion throughout the United States to the public, thereby causing more harm to ID physicians already in a crisis mode trying to rebuild trust with their patients. ID physicians are frontline clinicians who will be forced to divert substantial time away from actual patient care and disease prevention to address the confusion, misinformation, and erosion of trust caused by an illegitimate ACIP. Each additional meeting of this ACIP, and each vote this ACIP takes, compound the injury: ID physicians must counsel patients amid uncertainty created by unstable federal guidance; ID physicians must spend additional uncompensated time counseling patients and explaining ACIP changes to the CDC immunization schedule that fail to follow the established GRADE and EtR evidence framework; ID physicians must respond to and prepare materials that have relied on the CDC immunization schedule and EtR framework to prevent the spread of infectious diseases across the country; and IDSA must redirect staff and funding to crisis response rather than their core missions. These harms occur the moment ACIP meeting occurs and

ACIP votes to endorse or ratify changes to the CDC immunization schedule, which are immediately treated as authoritative federal guidance nationwide. Once the ACIP meeting takes place and guidance issues, the resulting damage to vaccine confidence and the ID physician-patient relationship cannot be fully reversed through later litigation or post-hoc agency reconsideration. Absent immediate injunctive relief, IDSA and IDSA members will remain in a perpetual crisis-response mode, sustaining ongoing injuries to IDSA missions and IDSA members across the United States.

44. I am over the age of 18 years old. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Utah, that the foregoing is true and correct.

Executed on: January 22, 2026

Andrew T. Pavia, MD, FAAP, FACP, FIDSA
On behalf of Infectious Disease Society of America

EXHIBIT A

VIEWPOINT

CDC's Failure to Recommend COVID-19 Vaccination—"Shared Clinical Decision-Making" Is Abdication of Responsibility

Thomas R. Frieden, MD, MPH; William Schaffner, MD; Joshua M. Sharfstein, MD

The acting Centers for Disease Control and Prevention (CDC) director recently endorsed making COVID-19 vaccination of older adults and other high-risk individuals a matter of so-called shared clinical decision-making (SCDM) rather than a definitive recommendation. This difference has important implications for clinicians and patients and will have unfortunate consequences for health in the US. The new direction, based on a proposal from the reconstituted Advisory Committee on Immunization Practices (ACIP), may foreshadow a new and troubling era of vaccine policy.

Guidance from ACIP forms the backbone of US immunization efforts. When evidence is clear that a vaccine's benefits exceed its risks, ACIP has historically issued—and the CDC director has endorsed—an explicit recommendation to vaccinate. A recommendation from CDC is not a vaccine mandate, nor does it keep patients from asking questions about vaccines or declining vaccination; all vaccines are given only after informed consent. A recommendation is a statement, based on evidence, that for individuals in the designated group, vaccination's benefits exceed the risks and will reduce the risk of serious illness.

For clinicians, an unequivocal CDC recommendation makes it possible to tell patients, "This vaccine is recommended to protect you." For patients, there is no ambiguity about the actions likely to protect their health. For policymakers, a CDC recommendation creates momentum to improve vaccine access, including coverage by health care payers.

In contrast to an explicit recommendation to vaccinate is SCDM, which is the lowest-strength option available to ACIP. Rather than a recommendation, it is a "perhaps." SCDM calls for patients to consult with their physicians about the risks and benefits of a vaccine in their individual circumstances before making a decision. CDC has stated that SCDM is appropriate "when individuals may benefit from vaccination, but broad vaccination of people in that group is unlikely to have population-level impacts" and when benefits and risks may be different based on "the individual's characteristics, values, and preferences; the health care provider's clinical discretion; and the characteristics of the vaccine being considered."[1]

The concept of SCDM originates from areas of medical practice where there are judgment calls that require careful discussions about risks and benefits of treatment. For example, for men aged 50 to 69 years, deciding whether to have a prostate-specific antigen test balances a small chance of reducing prostate cancer death against the risk of false-positive results and overtreatment. Similarly, for adults with borderline cardiovascular risk, starting a statin weighs modest prevention benefits against the burden and potential adverse effects of daily medication. A key criterion for the use of this approach is equipoise, meaning that there is no evidence-based best choice of action.[2]

Historically, CDC has used SCDM in certain situations, including hepatitis B vaccination for adults aged 60 years or older and human papillomavirus vaccination for adults aged 27 to 45 years, in which the benefits are uncertain or small. But this ambiguity does not exist for COVID-19 vaccination for individuals at the highest risk of serious illness or death, for whom the benefits are substantial and the risks minimal.

The benefits of COVID-19 vaccination, analogous to those of influenza vaccination, are likely to vary from year to year but have been substantial in recent seasons. High-risk individuals are less likely to be hospitalized and to die if they receive updated COVID-19 vaccinations. The most recent finding, during the 2024 to 2025 season, was a 39% reduction (95% CI, 22%-55%) in COVID-19–related hospitalization and 64% reduction (95% CI, 23%-86%) in COVID-19–related death among more than 160 000 veterans with a mean age of 71 years (SD, 11 years). The benefit of vaccination was even greater among veterans with cardiovascular disease, cerebrovascular disease, chronic kidney disease, chronic lung disease, and immunocompromised status.[3]

Adverse events from COVID-19 vaccination are rare, as documented by clinical trials, high-quality research reports, and large clinical studies. For example, in a 2024 study of more than 170 000 older adults from the Canadian National Vaccine Safety Network, the rate of serious health events, defined as emergency department visits or hospitalizations within 7 days of vaccination, was less than 0.3% across all messenger RNA vaccine products and doses and was not higher than in unvaccinated control participants; most symptoms were mild and self-limited.[4]

When a vaccine is routinely recommended, systems align: standing orders, pharmacy practices, payer rules, nursing home protocols, and outreach all reinforce uptake. By contrast, a switch to SCDM confuses patients and physicians about whether the underlying rationale for vaccination has changed and increases friction and inefficiency at each stage of the vaccination process.

If fewer clinicians make clear, strong recommendations for COVID-19 vaccination to people at high risk for illness, fewer patients will be vaccinated, which is a particular concern among older adults.[5] Although the absolute death rate from COVID-19 is declining, Loo and colleagues[6] projected for the 2024-2025 respiratory season that COVID-19 vaccination of high-risk individuals at current rates would prevent 70 000 COVID-19 hospitalizations and more than 7000 deaths; even 10% less vaccination of this group would lead to thousands more hospitalizations and hundreds more deaths.

SCDM for COVID-19 vaccination of high-risk individuals may seem to encourage patient autonomy, but it actually misinforms and does not support informed decision-making. As examples, clinicians

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do not use SCDM when they recommend tetanus vaccination after a dirty wound, folic acid for women who could become pregnant, or vitamin K for newborns because the benefits are well established and, as with vaccination against COVID-19, the risks are minimal. Instead, they give crisp and strong recommendations, providing the clarity that patients deserve.

Patients deserve this clarity about COVID-19 vaccination, too. A definitive CDC recommendation to vaccinate would support the consent process and the patient-clinician relationship; an agency recommendation is not equivalent to a clinical conversation. Rather, it is an essential resource to support such discussions. For vaccines whose benefits far exceed the risks, CDC failure to provide an unambiguous, strong recommendation abdicates the responsibility to share with clinicians and US families what they can do to avoid unnecessary illness and death.

CDC's endorsement of SCDM also assumes that patients have equal access to clinicians who can spend time to discuss vaccination. Yet those most at risk—people with limited access to care, lower health literacy, or other priorities—may not have regular sources of care. An explicit recommendation encourages clinicians to make special efforts to reach such patients, thereby promoting higher vaccination rates and better health protection in all groups.

In recent weeks, major professional associations have moved to fill the vacuum left by CDC. In September 2025, the American Academy of Family Physicians issued recommendations for COVID-19 vaccination of individuals, especially those aged 65 years and older and at higher risk for severe disease.[7] The American College of Obstetricians and Gynecologists recommends COVID-19 vaccination during pregnancy, and the American Academy of Pediatrics has issued its own recommendations for children at higher risk of serious illness from COVID-19. For many clinicians and patients, it is now possible to rely on these recommendations rather than CDC's guidance, and many US states and insurers are using these alternative recommendations to set policy, including for insurance coverage. Doing so may reduce unnecessary preventable hospitalizations and death.[6]

Yet these actions are not a full substitute for a clear and direct CDC recommendation. Making vaccination contingent on SCDM for people at high risk for serious illness from COVID-19 is the opposite path from making the US healthier. The administration may now be tempted to apply SCDM to other important vaccinations, including childhood vaccinations. If CDC proceeds in this direction, professional societies, state health departments, and clinicians should continue to respect patient autonomy by providing unambiguous recommendations for vaccination where the benefit far exceeds risk.

A better path would be for the administration to rethink its abandonment of a critical tool for public health communication and restore straightforward recommendations for people who would benefit from the COVID-19 vaccine.

ARTICLE INFORMATION

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Published Online: November 13, 2025. doi:10.1001/jama.2025.22473

Conflict of Interest Disclosures: None reported.

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EXHIBIT 37

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF RAVI JHAVERI, M.D.

I, Ravi Jhaveri, M.D., declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction.

2. I am a physician, presently practicing in Chicago, Illinois, and am Board Certified in Pediatrics and Infectious Diseases. I am a member and elected fellow of both the Pediatric Infectious Disease Society (PIDS) and the Infectious Disease Society of America (IDSA). I make this declaration based on my personal knowledge and experience, in my personal capacity, and as a member of PIDS and IDSA. This declaration is further informed and supported by my over-20-year career as an infectious disease expert and my training and education, which includes a Doctor of Medicine degree from Mt. Sinai School of Medicine in 1996, residency in Internal Medicine at

the University of Chicago Hospitals in 1999, and a fellowship in infectious diseases at the University of California – Los Angeles Medical Center in 2003.

3. The actions of the Department of Health and Human Services that include (i) the Directive issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the Covid-19 for pregnant individuals, and (ii) the Advisory Committee on Immunization Practices ("ACIP") new recommendation in September of this year to change the Covid-19 vaccine recommendation for adults from routine to SCDM, which the Centers for Disease Control and Prevention ("CDC") later improperly inflated with informed consent, has injected chaos, confusion, and disruption into my practice and care that I am delivering to my patients.

4. I currently practice medicine as an infectious disease specialist in Chicago, Illinois. In that capacity, I serve as a consulting physician for pediatric patients on an inpatient basis.

5. I have personally treated children who contracted Covid-19 which led them to contract other superimposed infectious, like complicated bacterial pneumonia and orbital cellulitis, that required invasive medical treatments, surgery, and extended inpatient and intensive care stays.

6. I also presently treat pediatric patients in our outpatient clinic which includes treating post-Covid patients. The patients I treat in my clinic are children ages 3 – 17 years old who suffer prolonged symptoms of Covid-19, such as chronic fatigue and persistent fevers. Many of the patients I currently treat in my clinic have such severe lingering Covid-19 symptoms or damage resulting from their initial or subsequent Covid-19 infection that they are unable to fully return to their pre-Covid activities. For instance, I have had numerous patients whose Post-Covid symptoms prevented them from consistently attending school and/or participating in the

extracurricular activity (*e.g.*, sports or dance) that they loved. Part of the work I do in my clinic is to help these patients' families to develop plans to help the affected children reintegrate into the activities they miss out on due to their Post-Covid symptoms.

7. In my professional experience, children ages 6 months to 17 years are less likely to receive vaccines that are not affirmatively recommended as routine vaccinations for that age group by the Centers for Disease Control and Prevention (the "CDC"). Like many of my colleagues, I depend on ACIP and the CDC to conduct deep, time-intensive review of scientific evidence regarding vaccines, including the Covid-19 vaccine, and to make informed, evidence-backed recommendations in light of that intensive review. Throughout my entire practice of medicine, I have relied on ACIP recommendations, which I previously knew were supported by a team of experts at the CDC, whose job is to spend most of their time reviewing the literature, analyzing clinical trial data, evaluating safety and effectiveness, and then issuing well-reasoned recommendations based on the highest quality clinical evidence.

8. I understand that at the September 2025 ACIP meeting, the new ACIP (appointed by the Secretary) changed the Covid-19 vaccine recommendation for essentially all adults under age 65 to shared clinical decision-making instead of the prior straightforward routine recommendation. I further understand that the CDC adopted this changed recommendation.

9. Based on my training and experience, when the CDC classifies a vaccine as routine, that means that the patient should get the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient and, therefore should be administered as a standard part of medical care for the patient. A routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine. I consider the CDC

immunization schedule change for adults for the 2025-2026 Covid-19 vaccines from "routine" to "SCDM" to be a downgrading of the CDC's recommendation and sending a message to patients discouraging this vaccine

10. In my clinical judgment, this downgrading to SCDM is without justification and is causing confusion and vaccine hesitancy and is undermining public health as well as the public trust in vaccines and the physicians who recommend them. It is additionally causing confusion and strain within the health care field as I see more and more of my colleagues uncertain of how to navigate these changes, practice medicine, and properly engage with patients.

11. The confusion and problems caused by downgrading to SCDM are further compounded by the fact that there is no shared or common understanding of what constitutes "SCDM." Based on my training and experience, I am not aware of any universally agreed upon or accepted definition for or guidance on the term "SCDM." To the contrary, it is my belief and understanding that "SCDM" can mean different things to different individual physicians and that individual professional organizations are left to their own devices to determine what "SCDM" means, how to engage in it, or if they want to develop or adopt a common understanding within their specialty field of medicine or organization. For example, I am unaware of any guidance or authoritative literature from the AAP defining "SCDM" for all its members, much less for the specific topic of the Covid-19 vaccine.

12. Because there is no common or universal definition for "SCDM," each physician must develop their own sense of what that term means and how to engage in it. Drawing from my training and experience, I understand "SCDM" to mean the process of discussing with a patient or their parent[s]/legal guardian their concerns about receiving the Covid-19 vaccine, no matter how factually unsupported those concerns might be, but that view might not be shared by other

physicians. As a result, patients are seeing inconsistent care delivery, furthering fragmentation and a lack of uniform standards in the practice of medicine.

13. I have been personally affected by the downgrading of the Covid vaccine to SCDM. Since that action, I have spent considerable time counseling colleagues across the Chicago metro area on how they should engage in and document their Covid-related SCDM process. Before the new ACIP recommendation was issued, when the Covid-19 vaccine was a routine recommendation for adults under 65, I spent very little time counseling on the Covid-19 vaccine because there was very little to debate about the safety and effectiveness of the Covid-19 vaccine. However, the new ACIP recommendation and CDC adoption has contributed significantly to the confusion and distrust about the Covid-19 vaccine and has increased the frequency for which I must counsel on this topic to correct the misinformation the Secretary has spread about the Covid-19 vaccine.

14. Based on my interactions with colleagues across the Chicago metro area who turn to me for guidance and advice on how to engage in SCDM discussions, it is my understanding that SCDM conversations typically can last 10 minutes or longer. Unfortunately, there is no dedicated time for these conversations, which means they are folded into the existing wellness visit for the patient. This means the physician must dedicate valuable time during that wellness visit to counsel on and address questions relating to the Covid-19 vaccine, including explaining the disconnect and fragmentation within the public health world, such as why the Covid vaccine is no longer routinely recommended or why the state might have different standards and recommendations from the federal government. This eats up time that should be spent on the primary purpose of the wellness visit, such as depression screenings, completing the necessary examination for school physicals, chronic disease management, or other treatment to address the needs of patients, especially those who present with complex conditions. As a result, the quality and quantity of the time spent on

issues at the core of the wellness visit suffer because of the downgrading of the Covid-19 vaccine from routinely recommended to SCDM.

15. The time spent engaging in SCDM is not separately billable or reimbursable as there is no dedicated CPT code for that work. This means physicians are being forced to engage in work that is not compensated. While these SCDM discussions might seem like a minor inconvenience on an individual basis, the cumulative effect of engaging in SCDM with multiple patients every day results in more time spent engaging in work that is not compensable and that detracts from other more pressing work. This places further strain the physician's time and schedule as there is more to do and cover in the wellness visit. As a result, an SCDM discussion that takes 10 or even 20 minutes is 10 or 20 minutes of time that is not reimbursed and that accumulates into hours of additional work over the course of seeing and treating multiple patients. Unlike other vaccines subject to SCDM, the ACIP's and CDC's change to SCDM for the Covid-19 vaccine for adults under the age of 65 was issued without publication of supporting data in the CDC's Morbidity and Mortality Weekly Report ("MMWR"). Normally, the MMWR provides clinicians with the evidence base to guide patient counseling and serves as the trigger for payer coverage. No such data or guidance accompanied this change, leaving me and my colleagues without a clear basis to counsel patients, which also contributes to the increased amount of time spent on unbillable counseling time on the Covid-19 vaccine.

16. I am also concerned about the CDC equating "informed consent" with SCDM. In my view, informed consent refers to participation in research or other novel and untested treatments involving experimental interventions that require thorough discussion and disclosure of the risks involved, which may be unknown. Using that term makes it sound as if Covid-19 vaccines are experimental, thus causing vaccine hesitancy and distrust. Shared clinical decision-making, on

the other hand, refers to discussing the uses and application of known and approved agents that are routine and not experimental. Conflating the two concepts adds confusion for both physicians and patients.

17. Since the ACIP's and CDC's change to SCDM for Covid-19 vaccines for adults under the age of 65, I have spent additional and unreimbursed time counseling physicians and patients, interpreting ACIP's recommendation myself, and addressing increased confusion. These harms are related directly to ACIP's September 2025 recommendation for Covid-19 vaccines, which was adopted by the CDC. If the decision were vacated or corrected, these harms would be reduced or eliminated.

18. On January 5, 2026, Jim O'Neill, Acting Director of CDC, announced the immediate adoption of a complete revised CDC Childhood Immunization Schedule (the "2026 Schedule Change"). The 2026 Schedule Change impacts several routinely administered vaccines changing them from "Recommended" to "SCDM" or recommended only for certain high-risk individuals or populations only. The 2026 Schedule Change was not reviewed or recommended by ACIP or any of its Work Groups. To the contrary, the 2026 Schedule Change was unilaterally adopted by political appointees without any sound scientific evidence in pursuit of an anti-vaccine agenda.

19. I believe that the 2026 Schedule Change is harmful both in terms of how it impacts my practice directly and how it will negatively impact public health and society at large.

20. Like so many other actions by federal public health officials, which I have spoken to in my prior Declaration and in this Supplemental Declaration, the 2026 Schedule Change appears to put politics over policy and pursue an anti-vaccine agenda. Like many other recent changes to federal public health policy, the 2026 Schedule Change lacks any scientific or medical

rationale or evidence. This is worsened by the fact that there is no reason or basis to reject or abandon prior studies or findings that supported the status quo before these series of changes by the Secretary and members of the current federal Administration. Altogether, these changes, coupled with their lack of scientific or medical evidentiary support, further sow and foment confusion within the medical profession and among the patients that my colleagues and I serve.

21. The confusion wrought by the 2026 Schedule Change plays a material role in increasing the spread of misinformation and disinformation with respect to vaccines. This ultimately causes unsupported and harmful vaccine hesitancy and skepticism. This confusion also negatively impacts me, my practice, and my day-to-day activities and work as a physician and educator. Since the announcement of the 2026 Schedule Change, I have fielded calls from providers and parents of patients who have expressed confusion and requested assistance and guidance. These repeated requests for my expertise intrude upon other pressing work and require me to re-direct time, effort, and resources away from those other duties. This reallocation of work and turning away from other important tasks would not be occurring but for actions like the 2026 Schedule Change and other disruptions to federal vaccine policy.

22. To further counteract the confusion sown by the 2026 Schedule Change, my colleagues and I have had to dedicate time and resources towards mapping out how we will respond to yet another unsupported change by the federal government. Thankfully, because the State of Illinois has taken proactive steps to not be bound by CDC or ACIP action, my colleagues and I are able to counsel patients that we will continue to vaccine children as we did before January 5, 2026. Nevertheless, this does not change the fact that time and effort are still required to address patient and parent confusion, investments that would not be necessary but for the 2026 Schedule Change.

23. The 2026 Schedule Change is also harmful from a public health perspective. Again, it bears repeating that the 2026 Schedule Change was made without sound scientific or medical backing. This becomes apparent when one considers the fact that the 2026 Schedule Change materially changes access to the influenza vaccine for children ***during*** a severe flu season. Why the federal government or any public health official would issue or support such a directive defies logic, common sense, or well-established principles of medical science. These changes will contribute to lower rates of uptake for the influenza vaccine, which will in turn result in significantly higher rates of influenza infections and complications.

24. Like influenza, rotavirus is another condition that will spread and become more prevalent among children due to the 2026 Schedule Change. This is particularly concerning to me given my firsthand experience with rotavirus during my pediatric training in the late 1990s. At that time, there was no vaccine for rotavirus. As a result, I personally witnessed infants fall ill with rotavirus and suffer greatly from rotavirus complications. I also saw many infants die because of catastrophic rotavirus infections.

25. Since approximately 2008, we have managed to avoid a repeat of these severe outcomes through routine and widespread vaccination against rotavirus. The 2026 Schedule Change guarantees that we will go backwards in terms of public health and vaccine science with rotavirus, resulting in the spread and rise of tragic sickness like what I witnessed more than 25 years ago. Just like the decision regarding the influenza vaccine, turning away from the rotavirus vaccine with knowledge of its efficacy and the stakes and likely consequences of reduced uptake illustrates how these decisions are being made without any real regard or concern for sound medical science.

26. Lower rates of vaccine uptake for these conditions will inevitably result in greater incidents of infection. Many children will likely face severe complications and outcomes, including lifelong health problems. Some children will die. Our health care infrastructure and ecosystem will be severely burdened in meeting these needs, as so many will require care. Health care providers will further be strained because they will be increasingly exposed to individuals who are sick with these conditions, be them unvaccinated children or immunocompromised adults who were exposed to infected children. These adults will likely face their own health complications and adverse outcomes.

27. I am further troubled by the 2026 Schedule Change because it draws a false equivalency between the United States and Denmark, two nations that are very different from each other. As a large, diverse nation without a fully integrated national healthcare system, the United States is unique in terms of epidemiology. It would therefore be unwise and incorrect to compare our system to that of Denmark, a smaller, more homogenous nation whose vaccine policy is built on a completely different healthcare delivery system model. Efforts to compare the two and say that what works for Denmark will work for the United States further illustrates the lack of nuance in developing and issuing the 2026 Schedule Change.

28. Widespread and persistent vaccine uptake over the decades has yielded meaningful declines in influenza, RSV, rotavirus, meningitis, hepatitis A and B, and the other conditions referenced in the 2026 Schedule Change. Turning away from what has worked so well for so long will jeopardize that progress. These outcomes are preventable, but only if the 2026 Schedule Change is prevented from full, unfettered implementation.

29. For these reasons, ACIP should not be permitted to meet or take action on the 2026 Schedule Change. The current ACIP, constituted of like-minded individuals who share in the

Secretary's anti-vaccine agenda, has already demonstrated a willingness to take actions or make decisions that are contrary to established medical science. If given the opportunity to convene for the February 25-26, 2026, I believe ACIP will serve as a *post hoc* rubber stamp on the 2026 Schedule Change, voting to adopt it and further cementing its place in federal public health policy. This would all but guarantee the harms I describe above.

30. ACIP adoption of the 2026 Schedule Change would also likely have serious consequences for other federal public health efforts, like the Vaccines for Children (VFC) program, which ensures that poor children throughout the country have access to vaccines. I fear that action by ACIP adopting the 2026 Schedule Change will increase barriers to vaccine access for the poorest and most vulnerable children in America, only worsening health disparities in our country. As a result, the 2026 Schedule Change should be reversed, and ACIP should be prevented from formally adopting it.

31. Since the May 19 Directive and September Schedule Change changing the CDC immunization schedule recommendations for Covid-19 vaccinations, I have to continuously respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance, which is time I am not reimbursed for and will never get back. I have to address Covid-19 vaccinations now with my patients throughout my day, and I must repeatedly spend unreimbursed time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption directly interferes with my routine care, diverts my clinical time, and undermines confidence in vaccination recommendations that I rely on daily.

32. The harms I am experiencing as a result of the May Directive, the September Schedule Change, and the January 5 Childhood Schedule Change, as well as the anticipated February 25-26 ACIP actions,—are immediate, ongoing, and compounding. Each successive

change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as their physician. As a physician, I do not regain lost time, trust, or clarity between these federal policy shifts. Instead, each new change increases the burden on my practice, amplifies my patient's skepticism with my recommendations during our consultation, increases the time I am spending during each visit, and diminishes the effectiveness of my clinical counseling. There is a practical limit to how much uncertainty I can absorb while still providing effective patient care to my patients, and in my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January childhood schedule changes, and the imminent February 25-26 ACIP meeting actions has pushed my clinical practice toward or beyond that limit absent immediate injunctive relief.

33. The harms described above are also compounded by the failure to follow the established GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does not replace prior work, it is added on top of my existing clinical responsibilities. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the anticipated February 2026 ACIP actions, the harm compounds. I do not have the time or practical ability to reconstruct population-

level evidence analyses that the ACIP processes are designed to perform and that I have relied on throughout my career as a practicing physician. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in my ability to answer questions and provide recommendations to my patients on these vaccinations, pushing my clinical practice toward a breaking point absent immediate injunctive relief.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Illinois, that the foregoing is true and correct.

Executed on January 22, 2026 in Chicago, Illinois.

/s/ Ravi Jhaveri

Dr. Ravi Jhaveri

EXHIBIT 38

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF DAVID A. WHEELER, M.D.

I, David A. Wheeler, M.D., declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction.

2. The actions of the Department of Health and Human Services that include (i) the Directive issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the Covid-19 for pregnant women; (ii) the Advisory Committee on Immunization Practices ("ACIP") new recommendation in September of this year to change the Covid-19 vaccine recommendation for adults from routine to SCDM, which the Centers for Disease Control and Prevention ("CDC") later improperly

conflated with informed consent; and (iii) the recent announcement on January 5, 2026 and implementation of changes to the pediatric vaccine schedule have injected chaos, confusion, and disruption into my practice and care that I am delivering to my patients.

3. I am board certified in Infectious Diseases.

4. I completed medical school at the University of Virginia, and I completed my residency in internal medicine at University of Colorado. I completed a fellowship in infectious diseases fellowship at the University of Maryland.

5. I am a fellow of the Infectious Diseases Society of America ("IDSA") and fellow of the American College of Physicians ("ACP").

6. I have over 30 years of clinical experience in treating patients with infectious diseases. I have also served as the managing partner for a private clinical practice that serves patients throughout Northern Virginia. My practice is focused on the care of adults with serious and complex infections, both hospitalized and in the outpatient setting. I routinely counsel patients under the age of 65 on prevention of infectious diseases, including the role of vaccination.

7. I, along with my fellow infectious disease physicians, depend heavily on ACIP and the CDC to conduct the deep, time-intensive review of scientific evidence regarding vaccines, including the Covid-19 vaccine. As a practicing clinician, I spend the vast majority of my time caring for sick patients. I simply do not have the bandwidth to independently and comprehensively review every study relevant to each vaccine or vaccine policy change. Throughout my entire practice of medicine, I have relied on ACIP recommendations, which I previously knew were supported by a team of experts at the CDC, whose job is to spend most of their time reviewing the literature, analyzing clinical trial data, evaluating safety and effectiveness, and then issuing well-reasoned recommendations based on the highest quality clinical evidence.

8. During my more than three decades of taking care of patients suffering with infectious diseases, I have paid close attention to several government resources, including (i) the CDC's immunization schedule, (ii) the process that is followed by the Food and Drug Administration ("FDA") to authorize a vaccine for use in the United States, and (iii) the process that ACIP and the CDC follow to arrive at recommendations as to how vaccines should be used by different population groups in the United States. In my experience, ACIP, supported by CDC staff—function as the brain of the system. I have relied on their synthesis of the evidence for vaccine recommendations in a transparent, organized, and methodologically sound way. Community infectious disease physicians like me serve as the arms and fingers of that system. Our role as physicians is to take those carefully developed, evidence-based recommendations from ACIP and the CDC and implement them in the real world by counseling patients and advising primary care physicians who turn to us for guidance. Over many years, there has been a harmonious relationship between ACIP and community physicians like me.

9. I understand that at the September 2025 ACIP meeting, the new ACIP (appointed by the Secretary) changed the Covid-19 vaccine recommendation for essentially all adults under age 65 to shared clinical decision-making instead of the prior straightforward routine recommendation. CDC adopted this change. I am also aware that this change by the ACIP and the CDC was made without the usual transparent presentation of GRADE tables or Evidence-to-Recommendation ("EtR") framework for evaluating the quality of evidence, or a clear, contemporaneous explanation in the MMWR. In my practice and in conversations with colleagues, this change to the CDC immunization schedule for Covid-19 vaccines for adults has not functioned as a neutral or minor adjustment to how we talk with patients. Instead, it has

significantly disrupted the prior harmonious system and created multiple layers of confusion and harm to me and my practice.

10. When the CDC classifies a vaccine as routine, that means that the patient should be offered the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient. A routine recommendation also indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive it. I consider the CDC immunization schedule change for adults for the 2025-2026 Covid-19 vaccines from "routine" to "SCDM" to be a downgrading of the CDC's recommendation and sending a message to patients discouraging this vaccine.

11. The effect of downgrading the recommendation of the Covid-19 vaccine for adults under age 65 to SCDM requires me and my colleagues to spend more time counseling patients about the safety and effectiveness of the Covid-19 vaccine. Before the new ACIP recommendation was issued, when the Covid-19 vaccine was a routine recommendation for adults under 65, I spent very little time counseling my patients on the Covid-19 vaccine because there was very little to debate about the safety and effectiveness of the Covid-19 vaccine. However, the new ACIP recommendation and CDC adoption has contributed significantly to the confusion and distrust about the Covid-19 vaccine. This confusion and distrust requires me to spend more time building trust with my patients and telling them the truth about the Covid-19 vaccine to correct the misinformation the Secretary has spread about the Covid-19 vaccine.

12. One recent example illustrates the problem clearly. A patient under the age of 65 wanted to get a Covid-19 vaccine at a pharmacy. The patient's insurance company indicated it would not cover the vaccine unless there was a written prescription. The patient's primary care

physician was unsure whether to write such a prescription because ACIP had moved the Covid-19 recommendation to shared clinical decision-making. Unsure how to proceed, the primary care physician contacted me. In order to answer these questions, I had to spend non-trivial time explaining the rationale for the Covid-19 vaccination. This interaction was not part of a scheduled clinic visit and was not billed as a separate service. In effect, I was doing ACIP's work for them: interpreting a vague recommendation and translating it into a concrete decision without compensation. Since the SCDM change, I have had multiple conversations with patients and primary care physicians about Covid-19 vaccines. These unscheduled interactions represent a diversion of time and resources and an uncompensated burden that directly results from ACIP's changed recommendation for Covid-19 vaccines to SCDM.

13. The lack of evidence to support ACIP's recommendation for Covid-19 vaccines to be downgraded to SCDM (and CDC's adoption of this recommendation) has also caused a shift of the burden to physicians to research and interpret data that was previously synthesized and communicated by ACIP. In other words, I rely on the ACIP to do the work to synthesize, analyze, and interpret the data to arrive at sound recommendations with regard to vaccines. Before the current ACIP, I trusted the recommendations that came out of the ACIP. Now, the current ACIP did not do the work to analyze and interpret the data to support the change to SCDM for Covid-19 vaccines for adults under the age of 65 and the current ACIP did not provide me with the guidance I need to understand the change and apply it. This has further complicated my counseling process with patients and other providers who ask me for guidance on the Covid-19 vaccine in my community.

14. I am also concerned about the CDC equating "informed consent" with SCDM. Informed consent refers to participation in research involving experimental interventions; using

that term makes it sound as if Covid-19 vaccines are experimental. Shared clinical decision-making refers to discussing the risks and benefits of an accepted, standard intervention. Conflating the two concepts adds confusion for both physicians and patients.

15. Further compounding these harms is the January 5, 2026 announcement by Jim O'Neill, Acting Director of CDC, which immediately adopted a completely revised CDC Childhood Immunization Schedule (the "2026 Schedule Change"). The 2026 Schedule Change, which impacts various routinely administered childhood vaccines, was adopted and approved outside of the normal procedure involving careful study and consideration of medical or scientific evidence, ACIP review of said evidence, and ACIP's recommendation. Instead, the 2026 Schedule Change was implemented by fiat of political appointees.

16. While the 2026 Schedule Change concerns childhood vaccines, adults will also be impacted by these changes. Because of the 2026 Schedule Change, fewer children will be vaccinated against conditions like influenza and RSV. Lack of vaccination means children will be a greater risk for contracting these viruses and experiencing complications from them. These infected children will then serve as carriers for these illnesses and will spread these viruses to adults whom they encounter, including their parents, grandparents, teachers, and the healthcare workers who treat them. This risk of harm is even greater for adults who are immunocompromised, who will be especially at risk for complications or even death from influenza or RSV. These risks become even more heightened if we experience greater vaccine hesitancy and uptake among adults.

17. I am also concerned by the 2026 Schedule Change because of the health impacts it will have on a large scale. Not vaccinating children against diseases like hepatitis B, meningitis, or HPV will have rippled effects that will last a lifetime. Hepatitis B and HPV are both preventable

through vaccination, but a child who is not vaccinated will be at greater risk for contracting these viruses. A child who contracts either hepatitis B or HPV will be at greater risk for complications that require treatment well into adulthood. Failure to vaccinate for these conditions can also lead to serious adverse outcomes, such as cancer. Indeed, HPV is known to be a risk factor that increases one's risk of developing anal, throat, or cervical cancers later in life. This will result in high cost and burdensome care for patients, further strain on our healthcare infrastructure, and increased demands and pressures on providers like myself who will not have a corresponding increase in time to handle these increased needs.

18. The 2026 Schedule Change seeks to justify its existence by comparing the United States's childhood schedule to that of Denmark's. This is a false comparison. Denmark is very different from the United States in terms of demographics and how it provides for medical care and coverage for its citizens. Overall, Denmark does a much better job of comprehensively integrating its citizenry into a healthcare system where there are few barriers to access, virtually universal screenings for prenatal care, and far better health outcomes for adults. The United States, however, is a much larger and more diverse nation that lacks a strong, centralized, social medicine infrastructure. Our model of providing healthcare treatment and coverage is entirely different, and our rates of prenatal screening or adult healthcare outcomes are not similar to those of Denmark. Overall, while both might be industrialized Western nations, they are very different and not similar when it comes to underlying healthcare delivery systems and methodologies.

19. The harms I am experiencing as a result of the May Directive, the September Schedule Change, and the January 5 Childhood Schedule Change, as well as the anticipated February 25-26 ACIP actions,—are immediate, ongoing, and compounding. Each successive

change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as their physician.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Virginia, that the foregoing is true and correct.

Executed on January 23, 2026 in Annandale, Virginia.

/s/ Dr. David Wheeler

David A. Wheeler, MD

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

DECLARATION OF RICHARD MARTINELLO, M.D.

I, Richard Martinello, M.D., declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction in the above-captioned action.

2. I am board certified in adult and pediatric Infectious Diseases.

3. I completed medical school at the Loyola University Chicago, and I completed my residency in internal medicine and pediatrics at Indiana University School of Medicine. I completed fellowships in infectious diseases in both internal medicine and pediatrics at the Yale School of Medicine.

4. I am a fellow of the Infectious Diseases Society of America ("IDSA").

5. I am the current Chief Medical Officer of Yale Medicine, located in New Haven, CT. In addition to this role, I am a Professor of Internal Medicine and Pediatrics at Yale School of Medicine.

6. I serve both as a clinician and an educator in my role at Yale. In my clinical practice, I care for both adults and children suffering from infectious diseases and their complications. My practice includes providing consultative services to other physicians for the treatment and management of infectious diseases. In my role as a professor, I am responsible for teaching medical students and other trainees on a range of topics related to infectious diseases, including vaccines. Both roles are informed by my more than 20 years of practice in infectious disease, infection prevention and public health, including caring for patients with vaccine-preventable diseases.

7. In my clinical practice, I have relied upon the guidance and data issued by the Advisory Committee on Immunization Practices ("ACIP") and Centers for Disease Control and Prevention ("CDC") to inform my decision-making related to vaccines. In this role I am trusted by patients and my physician colleagues who turn to me for advice and guidance on infectious disease and vaccination matters, to distill this information into a communicable and understandable form. Similarly, in my role as a professor my students rely upon me to present clear, reliable, and evidence-based instruction.

8. As part of my responsibilities as a professor of internal medicine and pediatrics, I devote a portion of my coursework to vaccines. In preparing this material, I have historically relied upon ACIP recommendations and corresponding CDC guidance. The CDC website has served as a comprehensive repository of vaccination data and past-ACIP recommendations. The ACIP and CDC have served as cornerstones to building curriculum through their promulgation of evidence-based vaccine best practices. Those resources have been substantially diminished. The CDC

website is frequently outdated and now includes false statements and unreliable materials. Similarly, ACIP recommendations no longer reflect guidance developed with rigorous scientific evaluation. As a result of these changes, I am required to spend significantly more time independently reviewing and parsing through available information to identify the most accurate and fact-driven sources for instructional purposes.

9. The actions of the ACIP have caused disruption, not only to clinical practice amongst physicians, but to the classrooms of the future generation of medical professionals. ACIP's focused discussions on debunked theories, including those related to adjuvants, paired with recommendations which have no basis in rigorous science have retracted from other meaningful vaccine topics. Frequent changes and shifts and rhetoric have created additional burdens in preparing for class and determining which material is true and which is false.

10. Historically, ACIP recommendations have been imperative to providing medical students and other trainees with up-to-date vaccination guidance and best practices. The newly reconstituted ACIP has diminished the reliability of its recommendations and has instead espoused previously debunked theories, which inject confusion and distrust into the administration of vaccines. ACIP has broadcast regarding the safety and efficacy of vaccines, often using its authority to promote rhetoric supporting vaccine skepticism. As a result, the vaccine-related curriculum in my course has been considerably condensed to allow time to address misinformation and reassert the scientific evidence supporting vaccination.

11. While they possess specialized training and knowledge, medical students are just like any other person: they are products of the environments in which they are raised and educated. At a foundational-level, medical school, which aims to be holistic in nature, affords only a limited amount of time to vaccines. Many of these students will enter specialties in which they will not

routinely administer vaccines or be required to keep up-to-date on best practices. Accordingly, the instruction provided during medical school serves as a critical baseline for their future clinical practice.

12. By my observations, the current generation of medical school students came of age in an environment where vaccine-related misinformation was common and widespread. As a result, vaccine skepticism and hesitancy among medical students is higher than I have ever seen before. Decades of exposure to this environment has harmed my students' education by diverting time away from other critical aspects of my medical education duties. For example, in a November 2025 class, I replaced planned instruction on vaccines with the topic of vaccine reimbursement, prompted by changes made by the ACIP to the Immunization Schedules. Similarly, in a December 2025 course to physician associates on hepatitis, I removed materials on the epidemiology of hepatitis in order to devote additional time to reviewing data on hepatitis vaccines to reestablish the factual foundation regarding their safety, efficacy, and importance.

13. ACIP's promulgation of these topics harms not only me, by requiring additional time and effort to sift through and correct unreliable information in preparing coursework, but also medical students and other trainees, broadly. These students represent the future of medicine and are increasingly exhibiting skepticism towards established public health measures that has only been amplified by statements and materials issued by the ACIP and the CDC.

14. Parallel to this effect is the increasing patient-level impacts. Of recent, my hospital has experienced numerous unvaccinated patients with severe illnesses brought on by complications from vaccine-preventable diseases. These impacts underscore the importance of establishing evidence-based vaccine instruction in the future generation of medicine.

15. I am concerned that by continuing to meet, the ACIP will further erode trust in vaccines and established recommendations, creating challenges for myself as a professor and for the future generation of medical professionals, who will continue to face misinformation.

Executed on January 24, 2026 in Connecticut.

/s/ Richard A Martinello

Richard Martinello, M.D.

EXHIBIT 40

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

DECLARATION OF RONALD NAHASS, MD, MS, FIDSA

I, Ronald Nahass, M.D., M.S., FIDSA declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiff's Fourth Amended Complaint and Motion for Preliminary Injunction filed in the above-captioned action.

2. I am board certified in Infectious Diseases and a Fellow of the Infectious Diseases Society of America ("IDSA").

3. I have over 30 years of clinical experience in infectious diseases, during which I joined with other infectious disease physicians to establish a single-specialty practice of infectious disease. Together, this practice spans across nearly every aspect of infectious disease, including many of which are preventable via vaccination.

4. I received my medical degree from the Robert Wood Johnson Medical School and served my residency at Robert Wood Johnson University Hospital. I received my master's in Healthcare Management from the Harvard T.H. Chan School of Public Health.

5. I am the current president of IDSA, wherein I serve as an advocate and resource for IDSA's 13,000 members, comprising of infectious disease physicians, scientists, and other professionals devoted to patient care, prevention, public health, education, and research in infectious diseases. In serving in my role, I maintain operational knowledge of the organization and monitor member's needs.

6. IDSA was formed in 1970 in Washington, DC with the goal to cultivate the growing knowledge of infectious diseases, endorsing scientific programs, and retaining a membership of persons whose work showed significant contributions to the field.

7. IDSA's mission is to bring together the curiosity, compassion, and knowledge of our members to strengthen the field of infectious diseases, advance science, and advocate for health equity. To further this mission, IDSA has adopted clinical practice guidelines that are considered the standard of care for our physician members and are in place to optimize and protect the care provided to our members' patients. Our clinical practice guidelines follow a sound, transparent methodology, enabling our physician members to easily translate best evidence practices into clinical care. They serve as a valuable resource to our physician members, as a tool to improve patient care and outcomes.

8. IDSA and its members have suffered significant and direct consequences due to the frequent, unsupported changes to both the Childhood Immunization Schedule and Adult Immunization Schedule. In its capacity as the body charged with making vaccinations recommendations, the Advisory Committee on Immunization Practices ("ACIP") has repeatedly used its meetings as a sounding board of misinformation, resulting in hurried recommendations which appear to have no deference to scientific or clinical standards. Since its reformation by Health and Human Services Secretary, Robert F. Kennedy Jr., ACIP has revised recommendations

to the Covid-19 and HepB vaccine recommendations. In addition, ACIP has removed the recommendation for the combination vaccine for MMRV and for flu vaccines containing thimerosal. ACIP has also hosted discussions detracting from its purpose, in support of fringe science and theory. These discussions include unsupported criticism of the U.S. Childhood Immunization Schedule and pushes for placebo-controlled vaccine trials by a lawyer whose career is dedicated to suing manufacturers.

9. ACIP's actions have been compounded by the actions of the Acting Director of the CDC, Jim O'Neill, in his adoption of a wholesale revision of the CDC Childhood Immunization Schedule (the "Schedule Change"). This newly revised Schedule, downgrades recommendations for several routinely recommended vaccines, advising instead that these vaccines be given only to those populations at high-risk or those evaluated under a shared clinical decision-making framework ("SCDM"). These changes have no basis in science, neither do they represent clinical realities or scientific consensus.

10. IDSA's members have faced ongoing difficulties at the hands of ACIP's misinformation and revised vaccination recommendations. These difficulties have compounded, creating strain on IDSA, as an organization, and on the profession, as a whole.

11. Infectious disease ("ID") physicians serve in a multitude of critical roles. ID physicians serve as community experts, answering questions about infectious diseases from primary care physicians and other specialists. ID physicians inform, and in some cases lead, the developmental of hospital and health system policies regarding infectious diseases and prevention methods. ID physicians care for patients with infectious diseases, including vaccine-preventable diseases, and lead hospitals and health system responses to outbreaks or surges of infectious diseases. ID physicians also care for the immunocompromised, who, in addition to receiving

recommended vaccines themselves, must rely upon herd immunity for certain preventable diseases. ID physicians also conduct research to support the development and use of vaccines.

12. IDSA has promised to be a trusted resource, convener and advocate for those committed to reducing the burdens of infectious diseases. To further this promise, IDSA provides resources to communities in the event of an infectious disease outbreak. As a result of continued misinformation by ACIP and the recent Schedule Change IDSA has had to reevaluate where to deploy its limited resources. The consequences of misinformation are no longer theoretical; as a result of growing vaccine skepticism children going unvaccinated for measles. As a result, IDSA and its members have had to divert resources to ongoing measles outbreaks. These outbreaks will continue to occur and amplify in twofold due to both the actions of ACIP and the Schedule Change.

13. IDSA as an organization and the ID profession, as a whole, is limited in the resources it can provide. Beginning during the COVID-19 pandemic and exacerbated by increased societal hesitancy regarding vaccination, ID professionals are rapidly burning out. As a result of ACIP, in its capacity as once-trusted resource, spreading false rhetoric and publishing recommendations lacking scientific basis, existing ID physicians are facing additional psychological, emotional, and professional stress arising from the need to continuously serve on the defensive in efforts to provide evidence-based recommendations.

14. I have witnessed the first-hand effects of the uncertainty and distrust ACIP and the CDC have injected into the practice of medicine. Many of IDSA physicians are encountering patients who still trust their physician's judgment but are increasingly suspicious of established medical practices, including vaccines. These patients are inclined to believe the government would not recommend policies which are harmful.

15. Patients have also suffered at the hands of the ambiguity of ACIP's recommendations. In my own practice, I have been told by a patient that their child is "not high risk" for meningococcal and therefore, will not require the vaccination. IDSA members, including myself, are therefore faced with an uphill battle of explaining the factual evidence and providing context to recommendations and risk categories. These conversations take a significant amount of time, for which ID physicians do not get paid. Moreover, these conversations can be physically and mentally exhausting, a fact exacerbated by the fact that the opponent is the federal government, a previously trusted resource. As a result, I have been told by IDSA members that they can no longer maintain an active practice and are considering working part-time to lessen stress.

16. The decline in practicing ID physicians has been accelerated not only by burnout but by difficulty recruiting new physicians to the practice. This past year IDSA expended a great number of resources to recruitment. Despite these efforts, the ID profession faced an abysmal outcome through the National Resident Matching Program. The continued onslaught by ACIP on vaccinations and the recent Schedule Change has further disenfranchised the practice of infectious diseases. IDSA anticipates spending an increased amount of time and resources rebuilding the reputation of ID in efforts to recruit residents to the field. While the lack of recruitment and burnout harms the entire profession, it also harms IDSA as an organization. In addition to expending limited resources to address these issues, IDSA is a membership-based organization, meaning that a downturn in members will only cause further harm to the organization's operations and ability to provide adequate resources.

17. As a result of schedule changes instituted by the ACIP, IDSA resources have also been diverted to rapidly develop vaccine guidelines in advance of the 2025-2026 respiratory season. IDSA had not previously developed a set of such comprehensive vaccination guidelines

and was forced to expend a significant amount of resources to do so. These efforts, however, were necessary to serve members. This is particularly true as a large number of IDSA physicians treat immunocompromised patients who rely upon herd immunity. IDSA physicians reported treating immunocompromised patients fearful for their lives as a result of changes to the immunization schedules. Further unsupported changes to the immunization schedules will force IDSA to again spend its already thin resources reasserting evidence-based practices.

18. IDSA is concerned that ACIP's actions and the Schedule Change have and will continue undermine public health to a degree which threatens the safety of all Americans. ACIP's rhetoric has made it all the more difficult for IDSA physicians to ensure they are doing part to keep their communities healthy.

19. IDSA has been and continues to be disenfranchised and prohibited from engaging meaningfully with the government in forming vaccination recommendations. The Schedule Change obverted any public comment process, thereby foregoing the valuable exercise of receiving input from those with firsthand knowledge and decades of scientific experience. This action has not only worked as a step to discredit and disempower medical societies and organizations, such as IDSA, but has worked against the principle of collaboration, a pillar of public health. Public health recommendations work best when they represent a unified voice. The failure of collaboration has compounded challenges in addressing vaccine hesitancy and has caused confusion amongst providers, including IDSA members.

20. I am concerned that if ACIP is continues to meet in its current form it will continue to provide recommendations and information which are inconsistent with scientific evaluation and medical practice.

21. Further, I am concerned that the Schedule Change will have detrimental effects to the ID practice and therefore, IDSA's ability to fully serve its community.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 20, 2026, in New Jersey.

Dr. Nahass

Ronald Nahass, M.D., M.S., FIDSA
On behalf of IDSA

EXHIBIT 41

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

DECLARATION OF WILBUR CHEN, M.D.

I, Wilbur Chen, M.D., declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old and not under any disability. All of the facts set forth in this declaration are based on my personal knowledge. I submit this declaration in support of Plaintiffs' Fourth Amended Complaint and Motion Preliminary Injunction in the above-captioned action.

2. The actions of the Department of Health and Human Services that include (i) the Directive issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the Covid-19 for pregnant women, (ii) the Advisory Committee on Immunization Practices ("ACIP") new recommendation in September of this year to change the Covid-19 vaccine recommendation for adults from routine to SCDM, which the Centers for Disease Control and Prevention ("CDC") later improperly conflate with informed consent, and (iii) the revision to the childhood vaccination schedule

announced by the CDC on January 5, 2026 have injected chaos, confusion, and disruption into my practice and care that I am delivering to my patients.

3. I am board certified in Infectious Diseases.

4. I completed medical school at the Howard University College of Medicine and I completed my residency in internal medicine at Johns Hopkins University. I completed a fellowship in infectious diseases at the University of Maryland.

5. I am a fellow of Infectious Diseases Society of America ("IDSA").

6. I have over 30 years of clinical experience in treating patients with infectious diseases. My practice is focused on the care of adults with serious and complex infections, both hospitalized and in the outpatient setting. I routinely counsel patients under the age of 65 on prevention of infectious diseases, including the role of vaccination.

7. I formerly served as a voting member of ACIP from December 2020 through June 2024. My appointment to ACIP was formally approved by the CDC Director and the Secretary of the U.S. Department of Health and Human Services ("HHS"). During my tenure, I served under both the Trump and Biden Administrations.

8. As an ACIP member, I participated in multiple vaccine workgroups, collaborated directly with CDC scientists, reviewed epidemiologic and clinical evidence, and contributed to national vaccine policy recommendations. Throughout my time as an ACIP member, ACIP strictly adhered to its long-standing scientific and procedural standards.

9. ACIP operates pursuant to written Standard Operating Procedures ("SOPs") that establish the required structure, conflict-of-interest controls, evidence review process, and methodology for all ACIP recommendations. These SOPs serve as a binding internal framework, similar to a codebook, and govern everything from membership vetting to scientific evaluation.

Historically, CDC has treated these SOPs as essential to ensuring transparency, rigor, and public trust. In recent meetings under Secretary Robert F. Kennedy Jr.'s administration, these SOPs have been disregarded.

10. Each ACIP vaccine area has an associated workgroup led by CDC scientists. These workgroups include epidemiologists, statisticians, health economists, infectious disease specialists, and subspecialists such as OBGYNs and pediatricians. Workgroup deliberations historically involve confidential, rigorous, systematic review of all available evidence. Workgroups vote internally on whether to support a recommendation before the issue is brought to the full ACIP. These internal deliberations ensure that the full ACIP committee reviews vetted, methodologically grounded evidence. In my tenure, workgroup deliberation and internal votes were the backbone of ACIP's recommendations.

11. Under Secretary RFK Jr.'s leadership, this structure collapsed. At recent ACIP meetings, including the September 2025 meeting that resulted in the Covid-19 vaccination changed recommendation to shared clinical decision-making, non-CDC individuals with unclear expertise presented material, while many long-serving CDC scientists were absent.

12. Historically, ACIP members submit conflict-of-interest disclosures annually to the CDC Ethics Office via a secure internal server. These forms are reviewed by dedicated ethics personnel who issue written assessments. ACIP members, working group members, and external consultants must also disclose new conflicts immediately. This system no longer appears to be functioning. Under Secretary RFK Jr.'s leadership, the ethics infrastructure has been bypassed or abandoned. The ethics infrastructure is critical to the recommendations coming out of ACIP to ensure the recommendations are unbiased, and can be trusted by the public and practicing physicians.

13. ACIP's scientific evaluation has relied on two formal, transparent methodologies: (i) GRADE (Grading of Recommendations, Assessment, Development and Evaluation): a systematic assessment of quality and biases across all available studies and (ii) Evidence-to-Recommendations (EtR) Framework: a structured, public matrix assessing benefits, harms, feasibility, acceptability, and implementation considerations. These frameworks ensure that any member of the public can trace policy back to data. It is transparent and reproducible, so the public, including practicing physicians, can trust and apply the vaccine recommendations.

14. At the September 2025 ACIP meeting, which resulted in the downgrade of Covid-19 vaccination for adults under 65 to shared clinical decision-making ("SCDM"), no GRADE tables were presented, no EtR framework was used, and no systematic evidence review was shown. Instead, the committee received slide decks containing unsourced, ungraded assertions.

15. The January 5, 2026 publication of a revised childhood vaccination schedule by the CDC ("Schedule Change") neither included reference to the EtR framework nor GRADE. As compared to the typical evidence evaluated by ACIP and published upon recommendation, the Schedule Change cited minimal to no scientific evidence.

16. I, along with my fellow infectious disease physicians, depend heavily on ACIP and the CDC to conduct the deep, time-intensive review of scientific evidence regarding vaccines. Throughout my entire practice of medicine, I have relied on ACIP recommendations, which I previously knew were supported by a team of experts at the CDC. My role as a physician is to take the carefully developed, evidence-based recommendations from ACIP and the CDC and implement them in the real world by counseling patients and advising primary care physicians who turn to me for guidance. Over many years, there has been a harmonious relationship between ACIP and infectious disease physicians like me.

17. I understand that at the September 2025 ACIP meeting, the new ACIP (appointed by the Secretary) changed the Covid-19 vaccine recommendation for essentially all adults under age 65 to shared clinical decision-making instead of the prior straightforward routine recommendation. CDC adopted this change. I am also aware that this change by the ACIP and the CDC was made without the usual transparent presentation of GRADE tables or EtR framework for evaluating the quality of evidence, or a clear, contemporaneous explanation in the MMWR.

18. I further understand that the January 5, 2026 Schedule Change operated outside of the normal process for recommendations and adopted recommendations made by the leaders of the CMS, FDA, and NIH, via the Presidential Memorandum. The revised childhood schedule includes downgrades from routine to SCDM for the rotavirus, influenza, HepA, and MenACWY vaccines.

19. ACIP is responsible for evaluating vaccinations and publishing recommendations based on this evaluation. When ACIP adopts SCDM for any vaccine recommendation, CDC normally publishes explanatory guidance in the Morbidity and Mortality Weekly Report (MMWR) to assist clinicians in interpreting the change. No such guidance was published for Covid-19 vaccination after the September 2025 vote. Further absent a formal evaluation by ACIP, no explanatory guidance was published for those vaccines downgraded in the Schedule Change. Absence of this guidance is unprecedented and has direct, widespread consequences for physician practice. In my practice, this change to the CDC immunization schedule for Covid-19 vaccines for adults to SCDM and Schedule Change has significantly disrupted the prior harmonious system and created multiple layers of confusion and harm to me and my practice. By continuing to meet under its current composition ACIP threatens further upend my practice and inject further confusion into vaccine administration.

20. When the CDC classifies a vaccine as routine, that means that the patient should be offered the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient. A routine recommendation also indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive it. I consider the CDC immunization schedule change from "routine" to "SCDM" to be a downgrading of the CDC's recommendation and sending a message to patients discouraging uptake of vaccines with this label.

21. Changing a vaccine recommendation from "routine" to "SCDM" causes significant confusion for providers, patients, and the public. From a behavioral standpoint, SCDM signals that CDC is no longer strongly recommending vaccination. Physicians become hesitant to raise the subject and patients enter the conversation with distrust.

22. SCDM is analogous to adding a ten-page consent form to a ferris wheel ride that has always been safe, creating doubt and uncertainty where none previously existed, which adds time to the physician-patient counseling discussions to overcome the new mistrust. Before the ACIP recommendation on Covid-19 was issued, when the Covid-19 vaccine was a routine recommendation for adults under 65, I spent very little time counseling my patients on the Covid-19 vaccine because there was very little to debate about the safety and effectiveness of the Covid-19 vaccine. However, the new ACIP recommendation and CDC adoption related to the Covid-19 vaccination has contributed significantly to the confusion and distrust about the Covid-19 vaccine. The Schedule Change has further sown doubt into vaccinations, in turn requiring me to spend even more time explaining risk and benefits to patients of multiple vaccines, and addressing safety concerns, whether real or theoretical. Further, in counseling patients, I often field questions arising from or relating to misinformation or falsehoods stated by members of ACIP or leaders within

HHS. Together, these actions and corresponding statements have led to increased distrust and general hesitancy, which requires me to spend more time building trust with my patients and telling them the truth about the safety and effectiveness vaccines.

23. As an infectious disease physician, I bill for my professional services that I provide to my patients by using Current Procedural Terminology ("CPT") codes. Each code is tied to a patient care service and is used to document and receive reimbursement for medical encounters.

24. Vaccine administration has its own family of CPT codes, with the codes tying compensation of doctors to actual administration of the vaccine during a patient visit. Following the ACIP's recommendation, and CDC's adoption, for Covid-19 vaccines to SCDM for adults under the age of 65 I received increase patient inquiries regarding the safety and efficacy of the Covid-19 vaccine, causing me to spend additional time with patients. The January 5 Schedule Change has injected uncertainty, not only into those vaccines that have been downgraded, but into all vaccines on the Childhood Immunization Schedule. This has caused me to spend increase time, addressing concerns about a multitude of vaccines, including those whose recommendations have gone unchanged. Considering this trend, should ACIP be permitted to meet in February they will inject further hesitancy and distrust into administration of all vaccines. This is likely to result in increased visit times. There is no billable code that I can use to compensate me for the additional time now spent counseling patients who are resistant to vaccination. Due to this new uncertainty or confusion, on average, I spend about five minutes counseling each patient who is reluctant to receive a vaccine and I may see up to six such patients in a day, so this adds up to 30 minutes per day spent on non-reimbursable vaccine counseling that was unnecessary previously. This is a significant opportunity cost because I could use this time to see an additional patient and get reimbursed for that time.

25. Unlike other vaccines subject to SCDM, the change to SCDM for the Covid-19 vaccine for adults under the age of 65, and shifts to SCDM for rotavirus, influenza, HepA, and MenACWY vaccines as it relates to the childhood schedule was done without publication of supporting data in the CDC's MMWR. Normally, the MMWR provides clinicians with the evidence base to guide patient counseling and serves as the trigger for payer coverage. No such data or guidance accompanied this change, leaving me without a clear basis to counsel patients, which also contributes to the increased amount of time spent on unbillable counseling time on these vaccines.

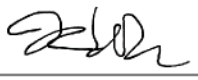
26. The resulting downgrade to SCDM for Covid-19, rotavirus, influenza, HepB, HepA, and MenACWY vaccination has left me and my fellow infectious disease physicians having to use our own time and resources to navigate the gap created by the absence of the MMWR guidance, abandonment of the GRADE and EtR methodology, and unscientific nature of the September 2025 ACIP vote on Covid-19 vaccines and the Schedule Change. The current ACIP did not do the work to analyze and interpret the data to support the change to SCDM for Covid-19 vaccines for adults under the age of 65, or the rotavirus, influenza, HepA, and MenACWY vaccines and the current ACIP did not provide me with the guidance I need to understand the change and apply it. This has further complicated my counseling process with patients and other providers who ask me for guidance on vaccines in my community. This complication has been further exacerbated by the rhetoric of ACIP, which has endorsed unscientific theories and false narratives. These meetings have caused increase anxiety amongst both the provider and patient community I counsel, leading to an increase in time spent counseling concerns and providing evidence-based counterarguments. These effects have been amplified by the newly reconstituted ACIP's use of an established and trusted body to promulgate false rhetoric. In totality, the actions

of ACIP and HHS have disrupted my practice and ability to provide clear guidance to my community of patients and providers, as it is often clouded by misinformation amplified by members of ACIP.

27. Since the ACIP's and CDC's change to SCDM for Covid-19 vaccines for adults under the age of 65 and HHS' revision to the childhood immunization schedule, I have spent, and continue to spend, additional and unreimbursed time counseling physicians and patients, addressing increased confusion, and interpreting the changed recommendations myself. These harms are related directly to ACIP's September 2025 recommendation for Covid-19 vaccines and Schedule Change. If the decision were vacated or corrected, these harms would be reduced or eliminated. Further, if the scheduled February ACIP meeting were not permitted to continue, these harms would not be further exacerbated.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Maryland, that the foregoing is true and correct.

Executed on January 21, 2026 in Baltimore, Maryland.

/s/ 

Dr. Wilbur Chen

EXHIBIT 42

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SECOND SUPPLEMENTAL DECLARATION OF BRENDA ANDERS PRING, MD

I, Brenda Anders Pring, MD, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over the age of 18 years old. All of the facts set forth in this supplemental declaration are based on my personal knowledge. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint filed in the above-captioned action.

2. I am the President of the Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP"). I have served in that role since July 1, 2024. I make this statement based on personal knowledge and if called as a witness could and would testify competently thereto.

3. I graduated from Harvard Medical School in 2010 and I completed my residency in pediatrics at the University of Colorado.

4. I am board-certified in pediatrics.

5. The MCAAP is a member organization of 1,600 Massachusetts-based primary care and specialty pediatricians across the Commonwealth. The MCAAP is committed to the attainment of

optimal physical, mental, and social health for all infants, children, adolescents, and their families, and to supporting the medical professionals who care for them.

6. MCAAP supports pediatric health professionals in the Commonwealth in maintaining high childhood immunization rates by providing state-specific logistical guidance and evidence-based educational resources, previously based on strong FDA and CDC vaccine review processes.

7. Due to the steadfast work of dedicated pediatricians, public health teams, and engaged parents, Massachusetts consistently leads the nation in routine childhood immunization. According to the 2024 National Immunization Survey, Massachusetts ranked first nationally in vaccination rates for children aged 19 to 35 months receiving the full series of seven recommended vaccines. Massachusetts parents and pediatricians have reached these historically high immunization rates relying on high quality guidance from the American Academy of Pediatrics as well as the previously standardized, science-based vaccine recommendations from the CDC. Vaccine confidence among Massachusetts parents and pediatricians is strengthened by knowing that members of the Advisory Committee on Immunization Practices ("ACIP") are thoroughly vetted and serve staggered terms, ensuring both expertise and continuity in the committee's work.

8. In Massachusetts, the Department of Public Health ("DPH") has offered educational and implementation support for evidence-based immunization practices for child health, including our Vaccines for Children and Universal Vaccine Purchase programs.

9. The Massachusetts Universal Purchase Program is a statewide initiative designed to ensure equitable access to all routinely recommended childhood vaccines, regardless of a child's insurance status or ability to pay. Administered through the Massachusetts Department of Public Health, the program uses state funds to purchase vaccines in bulk and distribute them to providers at no cost. As a result, healthcare providers throughout the Commonwealth, whether they serve patients in

private practice, public clinics, or community health centers—can offer all recommended immunizations without financial barriers.

10. Notwithstanding these initiatives, Massachusetts' childhood vaccination rates have begun to decline, in line with national trends, despite the vast majority of Massachusetts parents choosing to fully vaccinate their children as recommended by their pediatricians and the current CDC immunization schedule.

11. The May 27, 2025, video on X, posted by Secretary Kennedy featuring Robert F. Kennedy Jr., FDA Commissioner Dr. Marty Makary, and NIH Director Dr. Jay Bhattacharya, and the subsequent directive and change in the CDC schedule, are a troubling departure from the federal government's established approach to vaccine policy. This decision to curtail COVID vaccine access for children and pregnant persons ignores expert advisory committee recommendations, and even more concerning, ignores the historically standardized vaccine review and recommendation process. These decisions have profoundly endangered the health and safety of Massachusetts children while also acutely increasing emotional and professional burdens on Massachusetts pediatricians.

12. The Secretary's directive has sown confusion and created an environment of uncertainty for Massachusetts families and the pediatricians who care for them. Even for families that want to vaccinate their children, there is a lot of fear about which vaccines may be available to them now, or in the future.

13. I am aware that on June 9, 2025, all of the sitting ACIP members' appointments were terminated and replaced slowly with non-experts who did not meet the criteria for membership. I am aware that this newly constituted ACIP met on June 25-26, 2025 and included COVID-19 vaccination in their discussions. Although the ACIP did not vote on a new COVID-19 vaccine

recommendation, after this meeting, I became concerned that they would remove the recommendation entirely for some, if not all populations, in the near future. This is a concern that my patients also share. Some of them have expressed to me that they think ACIP is going to "take all the shots away."

14. In August 2025, the FDA limited the indication for the 2025-2026 strain of the COVID-19 vaccine to individuals aged 65 and older and those under 65 with underlying health conditions. At the same time, Secretary Kennedy withdrew all Emergency Use Authorizations for COVID-19 vaccines. This, coupled with the Directive, created widespread uncertainty in Massachusetts about where people of different ages could get vaccinated against COVID-19. Families were especially confused about whether pharmacists could still vaccinate children 5 and older.

15. To reduce scope of practice problems these actions created, the DPH revised its vaccine administration rules so the DPH Commissioner could decide which vaccines pharmacists were allowed to provide. The DPH Commissioner then issued a standing order to keep COVID-19 vaccines available at pharmacies. This resolved access issues for patients 5 and older with private insurance. Children under 5, who rely on pediatricians for routine shots, still faced obstacles.

16. . In my role as President of MCAAP, I had several meetings to discuss the consequences of leaving Massachusetts vaccination policies unchanged. I reached out to the DPH Commissioner with our concerns. I had to take substantial time out of my workday to arrange and attend these meetings which would not have been necessary if the Directive had not been issued.

17. Children covered by the Vaccines for Children ("VFC") program experienced a significant delay because vaccines administered as part of the VFC program rely on ACIP guidance for shipping. ACIP did not issue a recommendation for the 2025-2026 COVID-19 vaccine in during its June 2025 meeting, which meant that in August 2025 when the 2025-2026

COVID-19 vaccine was approved, Massachusetts providers could not purchase doses through the universal purchase program. As a result, children between 6 months and 5 years old were left without access at both pediatric offices and pharmacies. Some providers, including Minute Clinics that rely on nurse practitioners, were also unsure how to handle the situation, and though they stocked the vaccine, they refused to give it to some children.

18. I am aware that this newly reconstituted ACIP met from September 18 and 19 and that at this meeting the Committee discussed recommending the COVID-19 vaccine through Shared Clinical Decision Making ("SCDM") for essentially all patients. This approach was not supported by solid data or evidence. ACIP has also provided no guidance on how SCDM is supposed to work in a pediatric practice. Many pediatricians, including me, do not agree with this recommendation.

19. The direct result of the SCDM recommendation is that vaccine counseling has become more awkward and time consuming for me and for many other pediatricians. It has also created confusion for families, who often assume that an SCDM approach means the vaccine is "not important." I am seeing more patients who do not want to talk about the COVID-19 vaccine at all, and if I raise this issue, some will even forgo receiving other vaccines like influenza. Because of this, some pediatricians have stopped having these discussions altogether. On the other hand, some patients worry that the vaccine access they have now could disappear overnight, and they want to talk about getting vaccinated earlier than the guidelines allow. I understand why they feel this way, especially after the Directive abruptly took away vaccine access for pregnant women without a sound scientific basis or meaningful consideration of the consequences.

20. Even families who were comfortable getting the COVID-19 vaccine last year are now hesitant. The vaccine itself has not changed; the only thing that has changed is the rhetoric and recommendation from ACIP.

21. ACIP has not provided any supporting materials for its SCDM recommendation for the COVID-19 vaccine, and it has offered neither guidelines published in the CDC's Morbidity and Mortality Weekly Report ("MMWR") nor any guidance describing a standard SCDM process for COVID-19 vaccination. Without these, pediatricians must look to other sources to assist with the SCDM conversation.

22. The AAP has issued recommendations that differ slightly from those of the Massachusetts DPH, and both differ substantially from ACIP's SCDM approach. The AAP guidance works well for children under 2, but because I also care for older patients, I rely on the Massachusetts recommendations that advise vaccination for everyone over 6 months of age. Until June 2025, ACIP's recommendations were the standard language I used when counseling families, and they provided a consistent baseline for other clinicians as well. Since ACIP issued its baseless SCDM recommendation for COVID-19 vaccination without any additional supporting guidance, I no longer feel comfortable using their recommendation in practice and have instead chosen to follow the Massachusetts DPH guidance. Other pediatricians I have spoken with are now forced to choose which framework to adopt. This has led to noticeable differences in how providers across the state counsel their patients.

23. As a chapter, MCAAP has had to expend substantial resources to update its website to reflect the AAP guidelines, and we are considering additional materials and possible webinars to support physicians who administer the COVID-19 vaccine. In order to do so, MCAAP will have to divert resources away from other activities that are part of our mission.

24. As president of MCAAP, I also serve as the main contact for media inquiries and appearances, such as speaking publicly on TV or on the radio. The confusion created by the SCDM recommendation has led to a sharp increase in these inquiries. Because inaccurate information about vaccines can cause real harm, I feel obligated to respond quickly to every request in order to counter misinformation and support both pediatricians and families.

25. Due to the lack of supporting materials from ACIP, several MCAAP members feel uncomfortable stocking and administering COVID-19 vaccines because some pediatrician office policies require pediatricians to give out a Vaccine Information Sheet, published by CDC, with each vaccination. I am aware that the reconstituted ACIP voted to have the CDC consider publishing a new COVID-19 Vaccine Information Sheet that includes misleading claims about the vaccine, which would cause further disruption and frustrate the ability of MCAAP members to provide care to their patients.

26. In his October 6 endorsement of ACIP's SCDM recommendation, the Deputy Secretary of Health and Human Services, who is also the acting director of the CDC, said that "Informed consent is back." I disagree with this statement and do not think that he understood the implications of that statement. It suggested that pediatricians had not been obtaining informed consent, which is simply not true and is contrary to well-accepted medical practice. It also implied that SCDM and informed consent are the same, when they are completely different processes. Pediatricians have always obtained informed consent for every medical intervention, including vaccines. In contrast, we do not use SCDM for most pediatric vaccinations. Unlike informed consent, SCDM is a more drawn-out conversation that requires explaining why a vaccine might be recommended for one child but not for all children, the way routine vaccines are. Only people

who work closely in this area understand the distinction between an SCDM recommendation and a routine recommendation.

27. Taken together, the events since May 2025 have contributed to an unstable vaccine regulatory environment that harms Massachusetts pediatricians, their patients, and their families. With the erosion of these formerly rigorous processes, Massachusetts pediatricians are spending much more time in and out of the exam room in discussions with parents on what the Covid and other vaccine risks and benefits are and why the federal recommendations have changed so suddenly, with no supporting data.

28. In addition to the changes made in the Directive, on January 5, 2026, Jim O'Neill, Acting Director of CDC, adopted a completely revised CDC Childhood Immunization Schedule (the "Schedule Change"). Several routinely recommended vaccines were changed to recommended via SCDM or recommended only for high-risk or certain populations. The changes were not reviewed or recommended by the ACIP. Instead, they were implemented unilaterally by agency leadership. The change to the immunization schedule is not grounded in a transparent or scientifically rigorous process. Despite this, the change was described as effective immediately, without any implementation guidance.

29. These changes were not triggered by any new professional medical consensus or changes to any practice guidelines published by AAP. There have been no new peer-reviewed studies that call into question the safety and efficacy of vaccines as administered currently. There was no opportunity for public notice and input from professional organizations such as AAP. I am not aware of any alerts from the Food and Drug Administration that have changed the safety and efficacy profiles of vaccines administered currently.

30. Within 24 hours of the Schedule Change, I experienced disruption to my professional duties. I have had to take time away from clinical and practice-launch activities to respond to reporter inquiries, and to attempt to communicate with colleagues attempting to understand what the change means and how to respond to it.

31. The change is very large and very new. It has been difficult for clinicians to wrap their heads around what has happened, and there has been immediate confusion among pediatricians about which schedule they are supposed to follow. In Massachusetts, the Commissioner of Public Health previously issued a vaccine schedule that closely mirrors the American Academy of Pediatrics schedule. As a result, pediatricians were uncertain whether they should follow the new CDC schedule, the AAP schedule, or the Massachusetts schedule, which all differed.

32. One of the most troubling aspects of the Schedule Change is that it does not appear to have been preceded by basic due diligence. There was no transparent effort to ask fundamental questions such as whether the pediatric healthcare infrastructure can safely absorb the predictable changes that will follow from reduced vaccination. There was no publicly shared modeling evaluating how many additional cases of diseases like rotavirus or measles we should expect if vaccination rates drop, over what time period, and in which communities. There was no analysis of whether pediatric hospitals have the beds, staffing, and resources to handle the anticipated increases in the incidence of these diseases. In many communities, the answer to that question is plainly no. Pediatric units have closed or downsized because the success of widespread vaccination has reduced hospitalizations. That capacity does not magically reappear overnight. When pediatric beds are unavailable locally, children are transported hours away from their families to receive care. That separates children from parents and places families in impossible positions, especially families with multiple children or limited resources. For those children of school age, this also means

missing vital educational opportunities. These are not hypothetical concerns. We have already seen how fragile pediatric capacity can be during seasonal surges, such as the ongoing severe influenza season. Nor has CDC presented any proof that a reduced vaccine schedule will cause the overall pediatric vaccination rate to increase.

33. I have been asked directly which schedule doctors are following, and at present, my understanding is that most clinicians are still following the old schedule because the new schedule is unclear and operationally difficult to implement.

34. The divergence between the CDC schedule and the AAP schedule will make it more confusing for pediatricians to explain vaccine recommendations to families. This confusion will be particularly harmful when working with vaccine-hesitant families, who may point to the federal schedule as justification for delaying or declining vaccines that were previously routine. In my experience, progress that has been made with vaccine-hesitant families is likely to backtrack.

35. The Hepatitis B ("HepB") vaccination changes are especially harmful. HepB is an uncurable viral infection of the liver that can lead to liver failure and liver cancer. HepB is highly transmissible and can be spread not just from mother to baby, but in other ways; for example, it can be spread through shared water and towels or even bites from other infected children on the playground.

36. The new schedule removes the routine birth dose and instructs that infants born to HepB negative mothers should not receive the first dose of the HepB vaccine before two months of age, and even then, this is not a routine recommendation but SCDM. This fundamentally changes how HepB prevention has worked in pediatric practice. The HepB birth dose previously prevented infections acquired from caregivers other than the mother, including fathers, grandparents, and

daycare providers. This is not contemplated in the Schedule Change. By eliminating the birth dose, infants are left unprotected during a vulnerable window when HepB is highly transmissible.

37. This change also alters the nature of conversations with families. There is a significant difference between continuing a vaccine series that was started in the hospital and initiating a discussion at two months about whether a child should be vaccinated against HepB at all. This creates confusion for families who may want to complete a vaccine series they have already started but are now being told by the government that the vaccine is no longer routine. This will require more time, more counseling, and more explanation.

38. The change also disrupts the use of combination vaccines such as Pediarix and Vaxelis which include HepB as a component along with diphtheria, tetanus, acellular pertussis (DTaP), inactivated poliovirus (IPV), and hemophilus influenza B (Hib). Combination vaccines have been used safely for decades and lessen the number of injections given to a child, decreasing pain and infection risk. If HepB is declined while other components remain routine, practices must either stop using combination vaccines or give additional injections using single-antigen vaccines, which creates substantial operational burdens.

39. In my prior practice, single-antigen vaccines such as Hib were not routinely stocked in the pediatric vaccine area. Obtaining them required staff to leave the vaccine workspace, coordinate with pharmacy staff, physically retrieve the vaccine from another location, and return it for administration. This process is significantly more time-consuming than using routine combination vaccines. This workflow increases the risk of errors, including ordering errors, administration errors, documentation errors, and missed doses at future visits. Tracking exceptions to the routine schedule requires additional attention from multiple staff members and increases the likelihood that doses will be delayed or omitted. These issues will be compounded across multiple visits.

Separating HepB from combination vaccines requires repeating this complex workflow multiple times across a three- or four-dose series.

40. In order to accommodate the Schedule Change, practices will need to stock more individual vaccines, requiring more refrigerator and freezer space, more ordering, and more complex inventory management. Many pediatric practices use small, dedicated vaccine refrigerators with limited capacity. Vaccine refrigerators and freezers are medical-grade equipment sold through medical vendors with specific features for maintaining accurate temperatures. The cost for a combination freezer/fridge is over $3500 and require specific type of electrical outlet.

41. There is also a risk of supply shortages. Manufacturers no longer routinely produce large quantities of single-antigen vaccines, and widespread demand for separated vaccines could result in shortages. Practices may not be able to obtain the vaccines even if they attempt to do so. Vaccine storage limitations are a serious concern. Practices already struggle to maintain adequate space for existing vaccine supplies. I personally experienced difficulty identifying a backup storage site for vaccines in the event of a power outage because other practices lacked refrigerator capacity to store additional doses.

42. The changes to meningococcal ACWY vaccination are internally inconsistent and dangerous. Neisseria meningitis, the bacteria targeted by meningococcal vaccines, is highly transmissible among close contacts who may breathe the same air, share food, etc. Meningococcal disease carries high morbidity and mortality. Ten percent of infections result in death, often very quickly. About 20% of those infected become deaf or suffer hearing loss, develop brain injuries, or require limb amputations. Routine vaccination at ages 11 and 16 has been a cornerstone of prevention, including protection for college students, summer camp attendees, and others in

congregate settings. Moving this vaccine to SCDM undermines population-level protection. These changes will also conflict with school, college, and summer camp requirements.

43. The expansion of SCDM from one vaccine to seven vaccines at once will significantly increase complexity. It requires separate counseling conversations for each vaccine, potentially during the same visit. This is not a single discussion but multiple, overlapping discussions that must be individualized. For example, at a two-month or six-month well-child visit, pediatricians will now need to separate routine vaccines from those moved to SCDM, even though they are typically administered together.

44. Conducting SCDM separately for rotavirus, hepatitis B, and meningococcal disease within a single visit will significantly lengthen appointments. Even a conservative estimate adds at least five additional minutes to well-child visits, which already include essential discussions about growth, development, feeding, sleep, and safety. As a result, important developmental and preventive counseling may be shortened or omitted due to time constraints. This harms overall pediatric care, not just vaccination delivery.

45. The removal of explanatory footnotes and detailed guidance from the schedule further exacerbates confusion. Clinicians historically relied on these notes to interpret and implement the schedule safely. Their absence leaves critical questions unanswered. Pediatricians and professional organizations will now need to develop additional educational materials, train clinicians and staff, hold emergency meetings, and communicate with public health authorities, all of which require time and resources and divert attention from patient care.

46. My concerns regarding the February ACIP meeting are based on my experience with the June, September, and December 2025 ACIP meetings. For example, the fallout from the December ACIP meeting has already affected HepB vaccination practices, and the September meeting

created confusion around SCDM for COVID-19 vaccines. Those meetings included presentations that were framed as scientific or evidence-based but relied on data that was outdated, inaccurate, or inconsistent with established immunization science. Several presenters lacked relevant expertise in immunization or public health. Following each of the prior ACIP meetings, I spent significant time taking immediate remedial actions on behalf of MCAAP. These included contacting the Commissioner of Public Health and communicating with state officials to clarify vaccine guidance and address misinformation arising from ACIP proceedings. Given that these ACIP meetings provided no guidance or evidence to accompany their changes, I also had to issue communications to our membership to explain how to interpret ACIP actions and to provide recommendations for vaccine schedules that align with evidence-based pediatric care. If the February ACIP meeting is allowed to continue, I will need to repeat these efforts again, all of which required significant time and resources and diverted attention from patient care and other organizational priorities for MCAAP. As of the time of this Declaration, there is no publicly available agenda for the February ACIP meeting. No meeting announcement has been posted in the Federal Register and no meeting materials have been compiled despite the meeting being imminent. Prior to June 2025, the content covered during the next ACIP meeting could be determined from Work Group presentations made during prior ACIP meetings. The agenda was almost never a surprise. However, based on ACIP's practices since June 2025, I cannot anticipate what topics will be discussed at the February ACIP meeting. This lack of transparency continues to raise serious concerns about whether the February meeting will follow established scientific and deliberative processes. Based on prior meetings, I am concerned that the February ACIP meeting may again include presentations that appear scientific but lack current, accurate evidence, or that are delivered by individuals without appropriate expertise in immunization or public health. If the February ACIP meeting proceeds

similarly to the June, September, and December 2025 meetings, it will likely generate additional misinformation or ambiguous guidance. This will create further confusion for clinicians and patients regarding appropriate vaccination practices.

47. Each new instance of inconsistent or misleading federal guidance requires pediatricians to spend additional time counseling families, correcting misconceptions, and rebuilding trust. These conversations lengthen visits, strain already limited clinical capacity, and reduce access to care for other patients. Repeated contradictions or departures from evidence-based immunization recommendations risk eroding patient trust not only in federal health authorities but also in pediatric providers and the medical system as a whole. Once trust is lost, it is difficult to restore. For MCAAP, another poorly conducted ACIP meeting would impose additional administrative, educational, and advocacy burdens. These harms are ongoing and cumulative and cannot be fully remedied after the fact.

48. A related concern is that if community or state-wide vaccination rates drop, the entire population may lose the protection known as herd immunity for individual diseases, which occurs when enough people in a group or area have immunity to a germ such as a virus that it no longer spreads easily. Herd immunity benefits people who cannot get a vaccine, for example because they are too young to receive the vaccine, and those who are immunocompromised or immunosuppressed, like children undergoing chemotherapy for cancer or using biologic drugs to treat autoimmune diseases.

49. As a result of these genuine and combined changes, Massachusetts pediatricians bear both fiscal and moral loads from the additional work brought on by changes in federal health recommendations that are no longer supported by either evidence or rigorous process. They are

less able to focus on routine care, urgent visits, behavioral health needs, or chronic disease management across the pediatric population.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Massachusetts, that the foregoing is true and correct.

Executed on January 18, 2026 in Newton, Massachusetts.

/s/ Brenda Anders Pring

Brenda Anders Pring, MD

EXHIBIT 43

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916

SECOND SUPPLEMENTAL DECLARATION OF DR. AARON BORNSTEIN

I, Dr. Aaron Bornstein, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old. All the facts set forth in this declaration are based on my personal knowledge and are true and correct. I submit this supplemental declaration in further support of Plaintiffs' Fourth Amended Complaint in the above-captioned action.

2. I reside in Massachusetts.

3. I completed medical school at the University of Pittsburgh School of Medicine in 1999 and I completed my residency at Children's Memorial Hospital in 2002.

4. I am a member of the American Academy of Pediatrics ("AAP"). I am also a member of the Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP").

5. I am a board-certified pediatrician currently practicing at Middleboro Pediatrics, a private pediatric medical practice located in Lakeville, Massachusetts. We serve about 4,800 patients and their families. My practice cares for many families over multiple generations. I provide

preventive care, diagnose and treat acute and chronic illnesses, and counsel my patients and families about vaccines, including the Covid-19 vaccine.

6. Our practice serves the greater Middleboro region of Massachusetts and consists of four pediatricians and three nurse practitioners. Middleboro Pediatrics participates in the Vaccines for Children ("VFC") program and is subject to the Massachusetts Universal Purchasing Program.

7. We are one of few pediatric practices that has chosen not to dismiss patients solely for being unvaccinated. That said, we require families who choose not to vaccinate their children to sign an acknowledgment form documenting that we reviewed the risks and benefits and that they declined against medical advice. This is both to protect the child's continuity of care and to protect our practice from legal liability.

8. Our practice provides and administers childhood vaccinations to our patients, including the Covid-19 vaccine.

9. The actions of the Department of Health and Human Services that include (i) the Directive issued by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") on May 27, 2025 designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and removing the recommendation for the Covid-19 for pregnant individuals, and (ii) the Advisory Committee on Immunization Practices ("ACIP") new recommendation in September of this year to change the Covid-19 vaccine recommendation for individuals under age 65 from routine to SCDM, which the Centers for Disease Control and Prevention ("CDC") later improperly conflated with informed consent, has injected confusion and disruption into my practice and care that I am delivering to my patients and their families. These actions have materially increased the time I must spend counseling families about the Covid-19 vaccine (which I am not

reimbursed for); undermined parents' trust in me as their pediatrician; and impaired my ability to provide efficient, evidence-based care to my patients.

10. Throughout my career, I have relied on the CDC immunization schedule and ACIP recommendations as the backbone of evidence-based pediatric vaccination practice. As a practicing pediatrician, I do not have the capacity to independently review every study on every vaccine. Instead, I have relied on ACIP and the CDC to review the scientific evidence in a methodologically sound, transparent way and to translate that evidence into clear, stable recommendations that I can interpret and apply in my practice for my pediatric patients and their families. Prior to the Secretary's Directive and the recent ACIP recommendations on Covid-19 vaccines, my experience with ACIP recommendations and changes to the CDC immunization schedule was that they were supported by transparent presentations of the evidence, including GRADE tables and Evidence-to-Recommendation ("EtR") frameworks to evaluate the quality of the evidence, and accompanied by contemporaneous Morbidity and Mortality Weekly Report ("MMWR") publications to provide guidance. I understood ACIP to be, in essence, the general of the national immunization system, with community pediatricians like me serving as the foot soldiers that implement ACIP's evidence-based recommendations in real-world clinical practice.

11. Before the Directive and the new ACIP recommendation for Covid-19 vaccines, I could confidently tell families that Covid-19 vaccination for children was a routine recommendation endorsed by national experts after careful review of the evidence. Although I routinely discussed vaccines with parents, there was a clear baseline: a routine recommendation on the CDC immunization schedule meant that vaccination was standard of care, and that I was not acting alone when I recommended it.

12. The Secretary's Directive in May 2025 and ACIP's September 2025 recommendation, which CDC adopted in October, downgraded the Covid-19 vaccine for children from a straightforward routine recommendation to SCDM. In my experience, and in the experience of my colleagues, this has not functioned as a neutral or minor change in wording. Instead, it has signaled to many families in my practice that the Covid-19 vaccine is no longer truly recommended for children, and has fueled uncertainty and mistrust in me, which directly impacts my physician-patient relationship and results in extended and uncompensated discussions with my patients and their parents around the conflicting Covid-19 vaccine recommendations.

13. As a result of the Directive and the ACIP recommendation to change Covid-19 vaccination to SCDM for children, my conversations about Covid-19 vaccines with families have become significantly longer and more contentious. A question about Covid-19 vaccines that might once have taken a few minutes now routinely expands up to a 10-minute discussion dominated by the conflict that now exists between my recommendation for Covid-19 vaccination and the Directive and ACIP recommendation to downgrade Covid-19 vaccines to SCDM. These extended counseling sessions are not compensated when my practice seeks reimbursement for my services. In our pediatric office, well-child visits are typically scheduled for about 20 minutes of physician time. When a Covid-19 vaccine SCDM discussion consumes up to 10 minutes, it displaces other important topics that I should cover during the visit and reduces the number of children I can see. Over time, this represents a substantial opportunity cost and a concrete burden on my practice.

14. For example, in July 2025, a parent brought in two adolescent children for a routine well visit. I recommended that both children receive the COVID-19 vaccine. The parent responded by saying that the CDC no longer recommends it, referencing recent changes to the official guidance. I explained that our practice is not following the updated CDC recommendation, as it did not

go through the usual thorough evaluation process involving the ACIP. This created more confusion for the parent, and I spent a significant portion of the visit explaining the difference between standard recommendation procedures and what occurred in this case. The conversation took about 20 minutes of a 30-minute visit. The parent ultimately agreed to have both children vaccinated. However, the extended discussion put me 20 minutes behind schedule, which delayed other patients and disrupted the normal flow of care for the rest of the day.

15. I have also witnessed the level of vaccine hesitancy among parents increase not only in relation to the Covid vaccine, but also increasingly toward other routine immunizations as well. I and my partners are spending significantly more time during wellness visits discussing vaccinations with families who are reluctant to vaccinate their children with one or more of the vaccines that we recommend. For example, I have spent at least an hour on two separate occasions with different sets of parents in counseling on vaccines. I do not recall ever before having to spend that much time counseling on vaccines. In one of these hour-long counseling sessions, parents refused to sign a standard AAP vaccine refusal form, which is our office policy for families who decline immunization. In that case, I informed the parents that refusal to sign the form would result in discharge from our practice due to failure to comply with office policy and related liability concerns. They eventually complied. The second hour-long visit involved a parent who, following media reports of outbreaks, wanted to discuss measles vaccination despite previous hesitancy. I billed insurance for that visit, which the family's commercial insurance reimbursed.

16. This level of counseling is not financially sustainable at scale. While we might be reimbursed for such visits occasionally, we cannot afford to allocate an hour for every hesitant family. Our practice serves nearly 4,800 patients, and extended counseling adds significant strain to our already full schedules. In some cases, particularly for patients on MassHealth, the combined

Medicaid and the Children's Health Insurance Program, who account for approximately 40% of our patient population, providers receive no reimbursement for the additional time spent and the provider absorbs the cost of that time entirely.

17. Since the Directive, my practice has also absorbed a disproportionate share of vaccine-hesitant families dismissed from other practices for refusing vaccinations, which has required substantial unbillable time in meet-and-greet visits occurring after regular clinic hours. For vaccine-hesitant families, meet-and-greet visits allow us to understand which of the family's beliefs may differ from standard pediatric medical care, to clarify our office's vaccination policies, and answer any specific questions a family may have prior to transferring to our office. These visits are important for engaging and developing trust with families and also play a role in risk management for our practice. We generally do not have to conduct meet-and-greet visits with families who support vaccination, because it is more likely that they believe and trust in standard pediatric care and are aligned with our approach to medical care of children. In those circumstances, there is also less risk management concern.

18. Because these are meet-and-greet visits for patients who are not yet members of the practice, we cannot bill for them. We can bill for established patients, but we cannot bill for a patient who is not yet an established member of our practice. Even when we do bill for an established patient, it is a question of whether or not we will be reimbursed, and for MassHealth patients we will not be reimbursed. Since the Directive, our practice conducts approximately 10–15 meet-and-greet visits per month, amounting to 8-12 hours of uncompensated time per month.

19. Growing public skepticism and confusion caused by mixed messages coming from the current Secretary of Health and Human Services have contributed to a significant increase in the counseling burden at my practice and has increased uncertainty as to both insurance coverage

and potential legal liability to my practice. This burden is not just clinical but also financial and operational.

20. I have cared for newborns who were hospitalized with Covid, and in at least one case, the mother had contracted Covid during labor and delivery. These situations are stressful, often result in separation of mother and infant, which disrupts bonding and poses added risks to newborns, who are especially vulnerable. Limiting maternal access to the Covid vaccine through policy changes that disincentivize or restrict coverage has had a deleterious effect on pediatric care, particularly in the first six months of life when infants depend on maternal antibodies for protection.

21. I reviewed digested summaries of the September 2025 ACIP meeting and its SCDM recommendation for Covid-19 vaccines for essentially all individuals under age 65. I was struck by the absence of a transparent, detailed presentation of the underlying evidence. There were no GRADE tables, EtR framework, or contemporaneous publication in the MMWR that thoroughly explained or justified the change for children. As a result, I am left without the kind of clear, data-driven rationale that I have historically relied on from ACIP and the CDC to implement a vaccination recommendation in my practice.

22. Parents now ask me very specific questions about why ACIP and CDC made this change, whether new data emerged, and whether the change means that the Covid-19 vaccine is no longer necessary or beneficial for children. I cannot answer these questions with the level of certainty and transparency I previously could, because ACIP has not provided the evidence summary and published guidance for physicians on how to apply the SCDM recommendation in the MMWR. This forces me to guess based on instinct and scattered individual studies, rather than to rely on a coherent, expert-reviewed synthesis for Covid-19 vaccines for my population of patients.

In effect, I am being compelled to do, in my limited personal time, the work that ACIP and CDC used to do for the entire pediatric community. This is not feasible and significantly complicates my counseling and increases the time I must spend on each encounter, which I am not reimbursed for.

23. In July 2025, I treated a healthy teenage patient whose parent is currently undergoing active chemotherapy. Before the CDC change to SCDM for Covid-19 vaccination, I relied heavily on ACIP's clear, evidence-based recommendation and corresponding MMWR guidance to support my conversations with my patients and provide my patients with straightforward, trusted public-health direction on Covid-19 vaccination. Now, because ACIP has not followed the EtR framework and the CDC has not issued any rationale or updated MMWR guidance on the SCDM recommendation for Covid-19 vaccination, I was forced to navigate the conversation without evidence-based materials from ACIP and the CDC. I went back and forth with the teenager for an extended period of time (at least an additional 10 minutes) on why I strongly recommend Covid-19 vaccination in his specific circumstances, and how vaccination is a critical layer of protection for vulnerable family members like his immunocompromised parent because I had no authoritative federal guidance to anchor the discussion or to reassure him that vaccination remains recommended in cases like his. I am not reimbursed or paid for the extended time I spent with the teenage patient engaging in this discussion on Covid-19 vaccination. This confusion, hesitancy, and the uncompensated prolonged visit are direct harms resulting from the Directive and ACIP recommendation (adopted by the CDC) changing the Covid-19 vaccination recommendation for children to SCDM and failing to provide clear guidelines on how to implement SCDM. Encounters like this are now routine in my practice, and they impair my ability to deliver efficient, evidence-grounded pediatric care.

24. Since the Directive and ACIP's change to SCDM for Covid-19 vaccines for my patients, and in light of the Secretary's public statements on Covid-19 vaccines, I have experienced a dramatic increase in mistrust from families. Parents who have known me and my practice for years (some over two generations) now question whether they can trust me when I recommend the Covid-19 vaccine. They ask why they should believe me instead of what they hear online from the Secretary and the CDC's new recommendations. Trust is the foundation of pediatric care and my physician-patient relationship. The erosion of trust caused by the SCDM downgrade and the Secretary's public statements on Covid-19 vaccines is a real, ongoing injury to both my practice and to the health of my patients.

25. As a pediatrician, I receive only a small administration fee to provide vaccines. Those fees are necessary to cover the cost of equipment, supplies, and staffing for proper vaccine storage and safe vaccine administration. I do not receive any payments from vaccine manufacturers and I am not reimbursed for extended counseling on Covid-19 vaccinations. Yet I must now spend precious time rebutting the Secretary's public statement that physicians are paid agents of pharmaceutical companies and that further defending my recommendations for Covid-19 vaccination (that is supported by my professional guidelines) that now conflicts with the Secretary's Directive and ACIP recommendation for SCDM for Covid-19 vaccinations. This is time I previously used to discuss my patients' health, not to defend my integrity and explain a conflict that the Secretary and ACIP has not even explained to me and my fellow pediatricians in the field.

26. As a direct result of the Secretary's Directive and ACIP's and CDC's decision to change the Covid-19 vaccine recommendation from routine to SCDM for children I spend significantly more time in each visit addressing misinformation, and confusion about Covid-19 vaccines for children, none of which is compensated. In addition, I must devote additional time to

compensating for the Secretary's and ACIP's failure to provide transparent, data-driven guidance for the pediatric SCDM change for Covid-19 vaccination. Overall, the efficiency and capacity of my practice have been reduced to the detriment of my patients and the broader community. These harms are specific, ongoing, and directly traceable to the Secretary's Directive and ACIP's and CDC's subsequent SCDM recommendation for Covid-19 vaccines for children. If those actions were vacated, the confusion and mistrust would be reduced, my uncompensated counseling burden would ease, and the harms to my practice and my patients would be diminished.

27. On January 5, 2026, Jim O'Neill, Acting Director of CDC, adopted a completely revised CDC Childhood Immunization Schedule (the "Schedule Change"). Several routinely recommended vaccines were changed to recommended via SCDM or for high-risk or certain populations only. The Schedule Change was not reviewed or recommended by the ACIP. Instead, it was implemented unilaterally by agency leadership.

28. Since I was seeing patients all day, I only became aware of the Schedule Change after it was announced as effective immediately. There was no meaningful advance notice to practicing clinicians, and there has been no transition period.

29. The materials released with the new schedule did not include any cost-benefit analysis or any analysis of the projected impact of these changes on the burdens placed on the U.S. health care system. In my professional opinion, the documents do not reflect a rigorous review of evidence and read more like policy statements than scientific assessments. Making this many changes all at once makes it very difficult to digest what has changed in a way that allows us to implement the Schedule Change and explain them to our patients. The absence of transparent scientific reasoning undermines clinicians' ability to counsel patients, erodes trust, and creates confusion in clinical decision making.

30. Since December 18, 2025, after reports began to circulate about the Schedule Change and Dr. Robert Malone, vice chair of ACIP, published an article anticipating the Schedule Change, my colleagues and I have observed a noticeable increase in parent concerns regarding vaccination. These questions have arisen even during visits unrelated to vaccination, such as behavioral health visits. Even among parents who support vaccinating their children, many parents have expressed anxiety about potential loss of access to vaccines and concern that their children may no longer be recommended for or able to receive routine immunizations due to the Schedule Change. We have also seen many parents who were on the fence about vaccinating their children and are now choosing not to vaccinate; this is related directly to the Schedule Change and public messaging from HHS, CDC, and ACIP. When these questions and concerns arise, my colleagues and I must spend time to address them, often without compensation.

31. One recent example from our practice involved one of my partners who met with a family with three children who were visiting our clinic for an initial, unpaid meet-and-greet consultation. The two older children were fully immunized, but the parents were now considering delaying or declining vaccines for their youngest child. During that visit, the father explicitly stated that he was a "Republican and Trump supporter," cited CDC language suggesting that there are "too many vaccines," and asserted that the CDC no longer recommends certain immunizations. Although my partner attempted to redirect the conversation away from politics and toward established medical recommendations, the father was unwilling to continue any conversation on the matter. The encounter ended without resolution, and it remains unclear whether the family will ultimately transfer care to our practice. Because this was an initial meet-and-greet visit, we were uncompensated for the extra time required to engage with and counsel the parents about the

misinformation being spread by CDC and the data, epidemiology, and our experience supporting the importance of vaccination.

32. In another instance, a parent of a nine-month-old child declined the influenza vaccine, simply stating that the CDC was no longer recommending it. The Schedule Change downgraded the influenza recommendation from routine to SCDM. However, this parent interpreted the change to mean that the influenza vaccine was no longer recommended. Regardless of whether the parent was already hesitant, recent public messaging was used as justification to categorically reject the influenza vaccine, and the family indicated they were not open to further discussion.

33. These conversations can sometimes be adversarial and make me concerned for the safety of my staff. At the end of December 2025, after the Schedule Change had been reported in the press but before it went into effect, our practice experienced a concerning incident involving a teenage patient who was accompanied by their father and was being seen by a young, female nurse practitioner. The patient was due for a second dose of a meningococcal vaccine, which was still routinely recommended at that time. However, when this was discussed, the father became agitated and confrontational, accusing the clinician of recommending vaccines for financial reasons and refusing to allow the vaccine to be given. The father became sufficiently aggressive that the nurse practitioner focused on de-escalation rather than clinical counseling and the father ultimately left the room. After the father left the room for the exam portion of the visit, the patient apologized profusely to the nurse practitioner about their father's behavior and expressed their embarrassment at the situation. This added significant additional, uncompensated time for the visit as a result. The patient left without receiving the routinely recommended vaccine. Later that day, the patient's mother called the practice to apologize and stated that the father would no longer accompany the

children to visits. She subsequently scheduled a follow-up appointment, and the patient returned to receive the vaccine.

34. This incident resulted in substantial additional, uncompensated staff time. The initial visit required additional staff time because of the father's political rhetoric. The subsequent phone call from the mother took up an additional 15-20 minutes of the nurse practitioner's time at the end of the day; as there is no billing code for these types of conversations, this time was uncompensated by insurance. Since nurse practitioners are paid on an hourly basis, this additional time also increased the practice's labor expenses. Additional staff time was also required to reschedule the patient for a separate vaccination appointment. Lastly, and most concerningly, It also created an uncomfortable, inappropriate, and potentially dangerous situation for the nurse practitioner.

35. This incident occurred before the Schedule Change was implemented, based solely on media coverage and public speculation. In my experience, innuendo and rhetoric, such as the language in Dr. Malone's article from December 18, 2025, can be as disruptive as official action, as negative or misleading information spreads rapidly and influences behavior before accurate guidance can be clarified. The father mentioned above specifically mentioned the "Danish Schedule" when he was becoming aggressive towards our nurse practitioner. Similar incidents have occurred in the past and disproportionately involve male parents directing aggressive behavior toward female staff and clinicians. I am concerned that HHS, CDC, and ACIP's growing anti-vaccine rhetoric will continue to embolden such behavior and escalate hostility towards pediatricians and staff. Secretary Kennedy stated that the Schedule Change "protects children, respects families, and rebuilds trust in public health" but from my experience, the Schedule Change is doing the exact opposite.

36. Vaccination is inherently preventive. The harm caused by failure to vaccinate is not typically immediate in the way a physical injury is immediate. Instead, vaccination prevents severe disease, disability, and death that occur once exposure happens. Once exposure occurs, the opportunity for prevention is lost. For example, without the protection of vaccination, exposure to the bacteria which causes meningococcal disease poses an immediate and acute risk of severe harm or death.

37. Several immunizations affected by the schedule changes, including rotavirus, influenza, respiratory syncytial virus monoclonal antibody (RSV-mab) products, and meningococcal vaccines, prevent highly contagious diseases that historically caused significant pediatric hospitalizations. Prior to widespread vaccination, rotavirus was a leading cause of hospitalization for dehydration in infants and young children. RSV and influenza continue to strain pediatric inpatient capacity. In my own state, children have previously been transferred out of state due to lack of available pediatric hospital beds during RSV surges. Reclassifying these vaccine recommendations away from routine recommendations will predictably reduce uptake, increase disease incidence, and place immediate strains on hospitals, clinics, and families. These changes run counter to basic public health principles of prevention, and will likely increase both human and financial costs.

38. Pediatric practices, including my own, rely heavily on combination vaccines that include Hepatitis B (HepB) vaccine as a component in addition to diptheria, tetanus, and acellular pertussis (DTaP), inactivated poliovirus (IPV), and hemophilus influenzae B (Hib). Pediatricians, including myself, prefer combination vaccines to reduce the number of injections given to infants, minimize pain, reduce administration errors, and manage vaccine storage limitations.

39. The new schedule completely overlooks the widespread use of these combination vaccines by changing HepB to SCDM while maintaining a routine recommendation for the other components. As a result, parents may decline the HepB component of a combination vaccine while still expecting the remaining components, which is not operationally feasible without entirely re-structuring vaccine inventory, storage, ordering, staff training, and administration protocols. It is my understanding that if manufacturers have to switch from combination vaccines to single component vaccines, there may be widespread shortages during the time that manufacturers need to alter their production.

40. Changing vaccine inventory would impose significant administrative burden, financial cost, and staff retraining, and I am unwilling to assume those burdens without clear scientific justification for the Schedule Change. I will continue using combination vaccines in my practice, but I am concerned that that parents will forgo vaccination altogether, leaving their children vulnerable to diseases previously prevented by DTaP, IPV, and Hib vaccines. Since my practice has chosen not to dismiss patients solely for being unvaccinated, this also increases the risk that other children visiting my practice and my colleagues will be exposed to these vaccine-preventable illnesses.

41. Pediatric practices already engage in informed consent and vaccine counseling as part of routine care, including provision of Vaccine Information Statements and documentation required by insurers. The new designation of routine vaccines, including influenza and rotavirus, as subject to SCDM introduces substantial ambiguity. If SCDM is interpreted to require a direct physician or nurse practitioner consultation at the time of vaccination, it would severely restrict access to vaccines. This problem is magnified by the fact that patients receive many vaccines from clinics located in pharmacies that are not staffed by physicians or nurse practitioners.

42. My practice, like many others, operates nurse-run influenza clinics that allow families to self-schedule brief vaccination visits. These clinics are essential to achieving adequate immunization coverage and meeting the needs of our patients. When a parent or guardian chooses to self-schedule their child for a flu vaccine clinic, it is reasonable to assume they have already weighed the expected benefits and risks and decided vaccination is appropriate for their child. In many cases, these discussions happen earlier, well before flu season. We also make vaccine education materials available on our website, which families can review before booking an appointment. Adding a required in-person counseling step and separate SCDM documentation during the clinic visit would primarily add 15 to 20 minutes of administrative work per visit, with little to no practical benefit for the patient in this scenario. It also implicitly suggests that families who self-schedule are neither educated nor informed about the flu vaccine, which is not a fair assumption. Families who still have questions typically contact us in advance, or they choose not to self-schedule until those questions are addressed.

43. ACIP has not provided specific guidance on when SCDM must occur relative to vaccine administration. Requiring individualized provider consultations for each vaccination on the same date of vaccination would make such clinics infeasible, reduce vaccination capacity, and divert physician time away from other patient care. It would be impossible for me to personally conduct SCDM for every patient receiving a seasonal influenza vaccine without canceling other clinical services. Similarly, requiring a physician to conduct and separately document SCDM for each vaccine administered during what is usually a nurse-led visit would create a substantial uncompensated burden, both in the additional time required and in the opportunity cost of being unable to see other patients.

44. The Massachusetts Department of Public Health has issued guidance to physicians in the state that Massachusetts will continue to follow the recommendations of the American Academy of Pediatrics and the American Academy of Family Physicians, regardless of the Schedule Change. The Department has also confirmed that school vaccination requirements in Massachusetts remain unchanged. While this clarity at the state level has been helpful in reassuring families, I am concerned that the conflict between the schedules will cause more confusion, especially if insurers choose not to cover SCDM-recommended vaccines without cost-sharing or if the federal government refuses to provide SCDM-recommended vaccines to states.

45. To help combat the spread of misinformation about vaccines, my practice is collaborating with a network of pediatric practices to develop and disseminate patient facing materials on vaccine-preventable illnesses. Our network includes a small administrative team and a volunteer committee made up of clinicians from multiple practices who are helping to spearhead this work. For example, influenza rates are currently elevated in Massachusetts, and additional, region-specific messaging is needed. This effort requires additional commitment of both time and financial resources.

46. If the February ACIP meeting proceeds and follows the same pattern observed in recent meetings, including the use of presenters who promote misinformation and the absence of a robust, evidence-based review process, I am deeply concerned about the resulting harm to my patients, my practice, and the physician-patient relationship more broadly.

47. Based on my understanding, the usual process by which ACIP conducts a thorough review of evidence and then forwards recommendations to agency leadership was not followed in connection with the recent Schedule Change. Instead, the Schedule Change was made without any formal ACIP recommendation, undermining the advisory role ACIP is intended to serve.

48. To my knowledge, there has been no public announcement of a detailed agenda for the February meeting as of the date of this Declaration, which itself raises serious concerns about transparency. Additionally, recent appointments to the committee further erode confidence in the integrity of the process. For example, one new appointment to ACIP is an OB/GYN who has publicly declared herself to be "anti-vax." The limited time between appointment and the meeting would not allow for a comprehensive and independent review of the extensive vaccine-related changes under consideration as a result of the Schedule Change. This creates the appearance of a predetermined outcome rather than a meaningful scientific deliberation.

49. The scope of the Schedule Change makes it implausible that it could be responsibly evaluated in a single meeting. The changes at issue are not limited to minor adjustments but include downgrading recommendations for multiple vaccines, each of which would ordinarily require its own careful review of evidence, risk-benefit analysis, population-level considerations, and public input. Meaningful scientific discussion, opportunity for public comment, and engagement with medical and public health experts cannot realistically occur under these constraints.

50. If the February ACIP meeting were to proceed under these circumstances and ultimately endorse the Schedule Change, this will have immediate and lasting effects on my clinical practice. While parents who are firmly committed to vaccination are unlikely to change their views, parents who are hesitant or undecided would likely view an ACIP endorsement of the Schedule Change as validation of their concerns and decline recommended vaccines. This group is particularly difficult to reach and often requires years of repeated, trust-based conversations before accepting vaccination. An ACIP action perceived as politically driven would completely undo those efforts.

51. Equally problematic is that, for families who follow accepted medical guidance by adhering to the vaccine schedule endorsed by the AAP and the state of Massachusetts, an abrupt ACIP endorsement of the contradictory Schedule Change will only add to confusion and distrust. Allowing the February ACIP meeting to proceed would also strain physician-patient trust, which takes years to build and cannot be quickly restored once damaged. In my experience, even small setbacks in trust can delay appropriate care for years. When patients are encouraged to distrust medical institutions or are told that physicians' recommendations conflict with federal guidance, it creates confusion and suspicion that extend beyond vaccines and into other areas of medical care. This erosion of trust interferes with the advisory role physicians are meant to play and encourages patients to substitute online information or self-diagnosis for professional medical judgment. As vaccine preventable diseases reemerge, pediatric practices must devote substantial additional time to infection control, contact tracing, reporting to public health authorities, and staff protection. Suspected cases of measles, for example, require isolation protocols, room closures, specimen coordination with state laboratories, extensive documentation, and family quarantine counseling. These activities consume limited clinical resources and disrupt care for other patients. Staff immunity verification, serologic testing, and revaccination impose further costs and administrative burdens on medical practices.

52. Parents are already asking more questions and requiring longer counseling visits. This change will further increase counseling demands, reduce my practice's capacity to see patients, and spread further confusion. Presenting abrupt schedule changes without evidence reinforces the false narrative that pediatricians vaccinate without consent or discussion, which is untrue and harmful to the physician patient relationship.

53. Once confidence in vaccination is undermined, it is extraordinarily difficult to restore. Vaccine hesitancy, once introduced, spreads rapidly and persists even when corrected with evidence. Research demonstrates that adherence to early childhood vaccine schedules strongly predicts completion of later vaccines, including the measles, mumps, and rubella (MMR) vaccine by age two. Disruptions to early schedules reduces overall vaccination completion and increases outbreak risk. This erosion of routine vaccination practice is not reversible once established. It leads to a population that is variably protected, partially protected, or unprotected in ways that are difficult to track and impossible to manage epidemiologically.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Massachusetts, that the foregoing is true and correct.

Executed on January 18, 2026 in Lakeville, Massachusetts.

/s/ Aaron Bornstein

Dr. Aaron Bornstein

EXHIBIT 44

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SECOND SUPPLEMENTAL DECLARATION OF CARLENE PAVLOS

I, Carlene Pavlos, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs in this matter and in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction. I am over the age of 18 and make this declaration based on my personal knowledge.

2. I am the Executive Director of the Massachusetts Public Health Association d/b/a Massachusetts Public Health Alliance ("MPHA"), a nonprofit organization created by charter in the Commonwealth of Massachusetts in 1879. MPHA exists to promote and improve the health of all residents of the Commonwealth, which obligates us to foster conditions for people to achieve their full health potential. MPHA carries out this mission through public education, advocacy, and coalition-building to strengthen our state's public health.

3. I have served as the Executive Director of MPHA since 2018. As the Executive Director of MPHA, I lead and manage MPHA's priorities, positions, and engagement with our allies and members. I submit this declaration in support of MPHA's participation as a plaintiff in this matter. I am over the age of 18 years old and I make this declaration based on my personal knowledge and in my official capacity as Executive Director.

4. MPHA is headquartered in Massachusetts and is a statewide advocacy organization which includes both individual and organizational members who share a commitment to achieving our mission to promote and improve public health in Massachusetts. Our membership includes physicians, nurses, and other healthcare workers, academic public health professionals, public health advocates, the leadership of local boards and health departments, and community health centers.

5. MPHA's main purpose is to protect and strengthen the public health in Massachusetts and support the population of Massachusetts by assuring access to public health services and advancing racial, geographic, and economic health equity in Massachusetts. MPHA's mission also includes educating Massachusetts residents on public health and promoting public health policies that protect the health and wellbeing of residents.

6. Vaccines are a significant health and health equity issue, and vaccine policy has therefore been a priority issue for MPHA and our members for years. The Centers for Disease Control and Prevention ("CDC") immunization framework is incorporated into public health systems at every level, and national consistency is essential in immunization practice. Preventing vaccine-preventable diseases requires population-level coordination. Because viruses and other infectious diseases spread across state borders, a uniform national benchmark is crucial for ensuring that individuals receive vaccinations at evidence-based ages and intervals regardless of

where they live. This consistency is critical for protecting Massachusetts residents from preventable outbreaks and is engrained in the policies for which MPHA advocates and the public health services our members provide to their communities.

7. Maintaining nationally consistent vaccination benchmarks is also essential for protecting vulnerable populations. Infants, immunocompromised individuals, older adults, and those who cannot be vaccinated rely on broad community immunity. The CDC immunization schedules ensure that providers across the country—including MPHA members—administer vaccines in a manner that achieves predictable and optimal protection levels, thereby reducing the risk of outbreaks.

8. With respect to COVID-19 vaccines, MPHA has invested time and resources to keep the population of Massachusetts and our members informed on these issues since the COVID-19 vaccines were first developed. Our members, especially those working in local health departments and community health centers, are on the front lines of Massachusetts's public health infrastructure. For decades they have relied on clear, trustworthy, science-based guidance from federal public health authorities, including the CDC immunization schedules and recommendations, to inform their work.

9. I am aware of the May 27, 2025 announcement by Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") that he was rescinding the prior recommendations of the Advisory Committee on Immunization Practices ("ACIP") that pregnant women and healthy children ages six months to 17 years old be routinely immunized against COVID-19 (the "Directive"). Following the Directive, the CDC Immunization Schedule was updated to show that the COVID-19 vaccine was no longer recommended for pregnant people and that it was recommended on the basis of shared clinical decision making ("SCDM") for children.

10. I am aware that on June 9, 2025, the Secretary terminated the appointments of all voting ACIP members. I am also aware that on June 11, 2025, the Secretary appointed eight new voting members to the ACIP, most of whom are not experts in infectious disease or immunizations.

11. I am aware that this new ACIP met on June 25–26, 2025 during which the COVID-19 vaccine was discussed but no recommendations were voted on. ACIP did not discuss several of the vaccines that were initially published in the Federal Register notice for the June ACIP meeting.

12. I am aware that in August 2025, the FDA limited the indication for the 2025–2026 strain of the COVID-19 vaccine to individuals aged 65 and older and those under 65 with underlying health conditions. At the same time, the Secretary withdrew all Emergency Use Authorizations for COVID-19 vaccines. This, coupled with the Directive, created widespread uncertainty in Massachusetts about who could administer COVID-19 vaccines and where people of different ages could get vaccinated against COVID-19. Families were especially confused about whether pharmacists could still vaccinate children 5 and older.

13. I am aware that the new ACIP met again on September 18–19, 2025, during which they voted to recommend the COVID-19 for all individuals using SCDM. I am also aware that the CDC subsequently adopted this recommendation, which changed the COVID-19 vaccine recommendation for all individuals under the age of 65 from routine to SCDM.

14. MPHA believes that the Directive and the CDC's change in the COVID-19 vaccine recommendation from "routine" to "SCDM" are life-threatening recommendations that immediately exposed all individuals to an increased risk of severe illness and death, undermining the public's trust in vaccines, and irreparably harming the public health in Massachusetts that MPHA and our members work so hard to protect and improve.

15. MPHA has members across the Commonwealth of Massachusetts, including individual members and organizational members whose work directly involves the health of children and adults, including pregnant individuals; vaccination delivery; and pandemic response. Our members have been irreparably injured by the effects of the change of the COVID-19 vaccine recommendation from "routine" to "SCDM" and the CDC's and the Secretary's associated messaging.

16. The reliability, transparency, and scientific rigor of the ACIP process are essential to the integrity of the entire federal immunization framework. Healthcare providers and public health practitioners depend on the ACIP to apply consistent, evidence-based methodologies when issuing national recommendations. However, the ACIP's recent COVID-19 SCDM recommendation represents a substantial departure from the scientific rigor that providers historically expect. The COVID-19 SCDM recommendation was issued without a coherent scientific basis and did not reflect a meaningful or well-established scientific consensus, and it reflects a troubling decline in the quality and transparency of the ACIP's decision-making. The CDC's SCDM recommendation for the COVID-19 vaccine therefore sows distrust, making it substantially harder for MPHA and our members to promote not only COVID-19 vaccination but also other critical immunization and health programs. This immediate erosion of trust threatens to undermine overall public health efforts and cannot be easily or quickly repaired.

17. There was no reliable scientific justification for changing the COVID-19 vaccination designation to SCDM. The change of the COVID-19 vaccine recommendation for all individuals from "routine" to "SCDM" was made without the usual transparent presentation of GRADE tables or Evidence to Recommendation (EtR) framework for evaluating the quality of evidence, nor was this change accompanied by a clear, contemporaneous explanation in the CDC's

Morbidity and Mortality Weekly Report ("MMWR"). As an organization based in Massachusetts—a state with a historic leadership role in advancing public health and a deeply committed public health workforce—we are particularly concerned that the new SCDM recommendation diminishes the influence of evidence-based medicine and risks further eroding public trust. Accurate, trustworthy information is at the heart of public health, which depends upon the public's confidence in science and in our recommendations in order to change behaviors. The SCDM recommendation for the COVID-19 vaccine is not based in science and, by suggesting that there are equally valid competing views on the value of vaccination (which is demonstrably false), it threatens to reverse years of public health progress in Massachusetts on vaccine safety and equity that MPHA and its members are working every day to protect.

18. MPHA advances the public health in Massachusetts by actively promoting science-based policies and practices that foster confidence in the safety and efficacy of vaccines and assure vaccine accessibility for those who need them. Public health is rooted in science, and the science is clear: COVID-19 vaccines are safe and effective in preventing severe illness and death, including among children and pregnant women. The CDC immunization schedule change for the COVID-19 vaccine from "routine" to "SCDM" is a downgrading of the CDC's recommendation and sends a message to patients discouraging COVID-19 vaccine, without any explanation or scientific reasoning to support this messaging. MPHA has thus had to divert staff time and organizational resources away from other strategic priorities in order to respond to the confusion and misinformation created by change in the COVID-19 vaccine recommendations and the CDC's and the Secretary's associated messaging. MPHA has issued public statements, letters to the editor, and informational materials in an effort to restore public confidence in the COVID-19 vaccine and prevent further erosion of trust in public health institutions.

19. By issuing a recommendation untethered from robust scientific evidence, the ACIP and the CDC have placed MPHA and its members in an untenable position. The CDC has effectively instructed public health practitioners to implement guidance that lacks analytical integrity and does not meet the evidentiary standards that normally govern national immunization recommendations. This has forced providers to choose between following a federal recommendation they believed was scientifically unsound or deviating from it and risking accusations of failing to follow the standard of care.

20. The CDC's COVID-19 SCDM recommendation has also created confusion in the public's understanding of vaccine safety and effectiveness. The change to a SCDM recommendation for the COVID-19 vaccine and the associated messaging from the CDC and the Secretary has led to disruptions in MPHA's work. The messaging from the CDC and HHS has resulted in undermining the public's trust in vaccines, and an erosion of the physician-patient relationship; this has resulted in MPHA's work being seen as less credible. The outcome is that community members across the state now doubt the safety and efficacy of all vaccinations in general. At the same time, the absence of meaningful scientific data supporting the COVID-19 SCDM recommendation has also left providers without any coherent way to explain to patients why this change was made. The ACIP offered no clear evidentiary basis, clinical rationale, or population-level justification for shifting COVID-19 vaccination into an SCDM framework. As a result, clinicians have been forced to counsel patients on a recommendation that cannot be meaningfully explained because no underlying data have been provided to support it. Many members of the public now view vaccines as a "political" issue rather than a mechanism for protecting their health and the health of their families and communities. This has undermined patient trust, weakened the therapeutic relationship, and placed providers in a position where they

cannot deliver informed, evidence-based counseling consistent with the expectations of the national standard of care.

21. No mechanism exists for MPHA and its members to recover the substantial financial costs and expenses they are incurring right now as result of the change in the COVID-19 vaccine recommendation from "routine" to "SCDM."

22. The downgrading of the CDC immunization schedule for COVID-19 vaccines from "routine" to "SCDM" is forcing the MPHA to spend funds, time, and resources to rebuild trust in science and public health and combat the spread of misinformation about the safety and effectiveness of COVID-19 vaccinations.

23. MPHA estimates that it spends at least 3 hours each week responding to inquiries from or developing fact-based information for its members and allies regarding the change in the vaccination schedule recommendations to SCDM where vaccines are available, or whether local health departments will be able to offer vaccination clinics this year. For example, before the issuance of the Directive and the change in the COVID-19 vaccination recommendation to SCDM, my day-to-day job rarely involved discussions regarding the safety and effectiveness of vaccines. Now, my day-to-day work and interactions with members and allies frequently concerns the SCDM COVID-19 recommendation, other more recent vaccine changes made by the CDC, and/or combatting the distrust, confusion, and misinformation circulating as a result of the CDC's and the Secretary's actions and messaging.

24. MPHA has also had to divert at least 8 hours of its time each week to communicating with state and local health officials regarding concerns about insurance coverage for the COVID-19 vaccine as well as the ability for pharmacists to deliver COVID-19 vaccinations, and the impact of the opaque and non-evidence-based federal policy on COVID-19 vaccines and

preparing and giving presentations regarding these topics to students or members of the public. As a result, MPHA has been forced to sideline its other initiatives in order to focus its time, money, and resources to helping its members and allies understand and navigate the changes to the CDC's SCDM recommendation for the COVID-19 vaccine. For example, MPHA has had to focus portions of its conferences and presentations—that would otherwise be dedicated to other public health initiatives—to combat misinformation about the safety and effectiveness of the COVID-19 vaccine.

25. On January 5, 2026, Jim O'Neill, Acting Director of CDC, adopted a completely revised CDC Childhood Immunization Schedule. Several routinely recommended vaccines were changed to recommended via SCDM or for high-risk or certain populations only. The changes were not reviewed or recommended by the ACIP nor was there a period of public comment. Instead, they were implemented unilaterally by agency leadership. The change to the immunization schedule is not grounded in a transparent or scientifically rigorous process. Despite this, the change was described as effective immediately, without any implementation guidance.

26. The Scientific Assessment that was published in the press release is filled with claims that are based on single studies taken out of context, non-comparable populations, or sources that do not meet basic standards of transparency, peer review, or reproducibility.

27. There is a fundamental mismatch between the Danish population being cited to justify policy changes and the realities of population health status as well as health care delivery in the United States. Denmark has universal health care, consistent prenatal screening, paid parental leave, and uniform access to services do not translate to the United States. In the United States, screening is inconsistent, access to care varies widely by income, immigration status, and geography. Structural inequities shape who receives timely and effective care. As a result, reliance

on such comparisons, when presented as authoritative, creates a false sense of security and further confuses the public about actual risk.

28. One of the changes to the schedule was the removal of the routine recommendation for influenza, which was changed to SCDM. This comes at a time when there is a higher than normal prevalence in influenza. In fact, as of this declaration which comes early in the season, the Department of Public Health has reported the deaths of four children in Massachusetts as a result of influenza disease.

29. As recently as January 16th, 2026, the CDC website continued to display the prior immunization schedule. The supporting scientific assessment referenced in public statements was not available on the CDC website and was instead located on the Department of Health and Human Services website. This location was not communicated clearly, and even senior state public health officials I spoke to were unaware of where to find it. As a result, our organization lacked the basic information needed to respond to press inquiries, advise our members, or explain the change to the public. If we had not been closely monitoring the issue, we would have had no way to understand what had occurred by consulting the CDC website, which is the standard source for immunization schedules. The abrupt change to the CDC Childhood Immunization Schedule has imposed an extraordinary and unplanned work burden on MPHA. We are being forced to divert staff time, expertise, and resources away from our planned public health work to address confusion created by the federal government's actions and to respond to questions from the public and the press. This diversion disrupts our annual work plan and undermines our ability to carry out our core activities. Since the announcement on January 5, 2026, I have spent more than three hours each day studying the announcement, reviewing the so-called "scientific assessment", discussing the changes with

experts in pediatrics and immunology, and preparing communication for our members and the press.

30. Our members include local public health departments, physicians, and community health centers that operate vaccination clinics and counsel patients and the public on the importance of vaccination. At the time the change took effect, many of these members were entirely unaware that any change had occurred. We were unable to notify or guide our members because we also did not have sufficient or reliable information to share.

31. We did not have information about the scientific analysis that formed the basis of the new schedule, how the change applied to patients born immediately before or after the announcement, how providers would receive information about the changes and if the changes would apply in Massachusetts, or how recommendations were to be communicated by the federal government to clinical and public health settings. This created confusion for our members who are responsible for advising patients, administering vaccines, and answering questions about coverage and recommendations.

32. This confusion causes direct harm to MPHA by undermining our credibility and the confidence our members place in us as a source of trustworthy, evidence-based public health guidance. When we cannot explain why a major federal policy change was made, our members reasonably question our reliability, even though the lack of information is not of our making.

33. The manner of the rollout also harms our organization by reinforcing public confusion and skepticism about vaccines generally. Mixed messages, inaccessible information, and unexplained reversals create the impression that vaccine recommendations are arbitrary or dependent on who is asked, rather than grounded in consistent scientific evidence. This perception directly increases the workload of our organization and our members, who must spend additional

time responding to confusion, mistrust, and misinformation generated by the federal government's actions.

34. The wholesale change to the CDC Childhood Immunization Schedule appears to be an intentional decision by the government to promote chaos. That's a harm to anybody who cares about public health. And it's definitely a harm to our members who then have the burden of trying to explain this to the public and patients.

35. If the February ACIP meeting proceeds, it will cause harm to myself, my organization, and the communities we serve. First, the meeting will include misleading and false statements presented as fact by senior federal officials, including the Secretary of Health and Human Services, who is a defendant in this action. Those statements will predictably generate significant national media coverage. It will reach the public in Massachusetts, creating confusion about vaccine safety, vaccine policy, and the state of scientific consensus. That confusion directly harms MPHA and MPHA members. We are already experiencing, and would again experience, a surge of inquiries from our members, from partner organizations, from the press, and from the public. Each inquiry requires careful, individualized response. We cannot ignore misinformation when it is attributed to federal authorities or framed as the product of a legitimate scientific process. As a result, we are compelled to devote even more staff time and organizational resources to correcting falsehoods, explaining the limits of what has been claimed, and re-establishing what the credible science actually shows.

36. This diversion of resources is substantial and ongoing. Addressing misinformation related to ACIP and federal vaccine policy is not incidental to our work. It consumes almost three to four hours of my time each day and requires sustained attention from other staff and leadership. This time is taken away from our core mission and from other responsibilities I am expected to

fulfill as an executive director, including program development, member services, fundraising, and strategic planning. Critical organizational work has gone unfinished because of the demands imposed by responding to this situation, which will only worsen if ACIP meets again in February.

37. Historically, CDC and ACIP provided trustworthy information on which state and local public health organizations could rely. We did not have to independently verify basic scientific claims, dissect methodological choices, or counter narratives that reject the existence of objective scientific standards. That has changed as this ACIP frames scientific questions as matters of political perspective instead of evidence-based science. This work takes significant additional time. To responsibly speak to the media or our members, I must consult multiple experts, review primary literature, and interpret these findings in the context of the populations we serve. This is labor-intensive work that should not be required of state public health associations like MPHA and would not be required if federal processes functioned as they historically have.

38. The harms described above are not confined to past events and are ongoing with respect to the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women and children. Since the changes to the CDC immunization schedule recommendations for Covid-19 vaccination, I continue to have to respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance. I must repeatedly spend time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption undermines confidence in vaccination recommendations that I rely on daily. The Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women and children is undermining my role at MPHA and causing needless negative health outcomes to the community we serve. The harms to me set forth above are ongoing and will continue unless the Directive and

the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children are immediately enjoined and the ACIP and CDC return the evidence-based, transparent process for making vaccine recommendations for children.

39. The harms identified above are compounding rather than isolated. The harms identified above associated with the Directive, CDC's changes to the CDC immunization schedule for Covid-19 vaccination for children, the January 5, 2026 changes to the childhood immunization schedule — as well as the anticipated harms that will result from any additional changes that may result from the upcoming February 26, 2026 ACIP meeting—are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as a public health professional. I do not regain lost time, trust, or clarity between policy shifts. Instead, each new change increases the burden on MPHA, amplifies patient skepticism with our recommendations, and diminishes the effectiveness of MPHA's messaging. There is a practical limit to how much uncertainty we can absorb while still providing effective guidance, and in my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the imminent February 26, 2026 ACIP meeting has pushed MPHA toward or beyond that limit absent immediate injunctive relief.

40. The harms described above are also compounded by the failure to follow established the GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. MPHA relied on those frameworks to understand what the recommendations actually meant and ensure that vaccination recommendations are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without

adherence to those frameworks, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does not replace prior work, it is added on top of my existing responsibilities and diverts MPHA's other priorities. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the anticipated February 2026 ACIP actions, the harm compounds. I do not have the time or practical ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that MPHA has relied on throughout for years. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in MPHA's ability to answer questions and provide recommendations on these vaccinations, pushing MPHA toward a breaking point absent immediate injunctive relief.

41. For all these reasons, I ask the Court to prevent the serious, irreparable harm the CDC's SCDM recommendation for the COVID-19 vaccine and the changes to the overall childhood immunization schedule is immediately and presently inflicting on MPHA, its members, and to the health of Massachusetts residents.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Massachusetts, that the foregoing is true and correct.

Executed on January 23, 2026.

Carlene Pavlos

Carlene Pavlos, Executive Director
Massachusetts Public Health Alliance

EXHIBIT 45

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF JENIFER LEAF JAEGER, MD, MPH, FAAP

I, Jenifer Leaf Jaeger, MD, MPH, FAAP, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs in this matter and in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction. I am over the age of 18 and make this declaration based on my personal knowledge.

2. The May 19, 2025 Directive issued by the U.S. Department of Health and Human Services ("HHS") under Secretary Robert F. Kennedy Jr., designating the Covid-19 vaccine for children as Shared Clinical Decision Making ("SCDM") and recent unexplained changes by the Advisory Committee on Immunization Practices ("ACIP") and Centers for Disease Control and

Prevention ("CDC") for multiple vaccinations harms my patients and is interfering with my ability to practice pediatric medicine in accordance with the accepted standard of care.

3. I am a graduate of the Washington University School of Medicine. I completed a residency in pediatrics at Tufts Medical Center ~~Tufts University~~ and a fellowship in pediatric infectious diseases at Hasbro Children's Hospital/Brown University. I served as an Epidemic Intelligence Service Officer for Centers for Disease Control and Prevention ("CDC") and received a Master of Public Health Degree from the Harvard T. H. Chan School of Public Health. I am board-certified in pediatrics.

4. I was the pediatric medical director of the New Bedford Community Health Center in New Bedford, Massachusetts ("NBCHC"), which is a Federally Qualified Health Center. I will formally resign my position at NBCHC on December 16, 2025 to join Partners in Health, a social justice organization providing high-quality health care globally to those who need it most. Prior to joining NBCHC, I was a physician with Doctors Without Borders in Bangladesh. I have practiced pediatrics for over 30 years. I care for children from birth through 21 years of age.

5. Beginning February 9, 2026, I will be starting as a Pediatrician at the Lynn Community Health Center in Lynn MA which is part of Massachusetts' Refugee Health Program. In that position, I anticipate teaching Refugee/Immigrant Health at Harvard Medical School and Boston University School of Medicine.

6. I am a member of the Massachusetts Public Health Alliance ("MPHA"). MPHA is a statewide advocacy organization that includes both individual and organizational members who are dedicated to promoting and improving public health in Massachusetts. MPHA's membership includes physicians, nurses, and other healthcare workers, academic public health professionals,

public health advocates, the leadership of local boards and health departments, and community health centers.

7. MPHA's main purpose is to protect and strengthen the public health in Massachusetts and support the population of Massachusetts with increasing access to health care and advancing racial, geographic, and economic health equity in Massachusetts. MPHA's mission also includes educating Massachusetts residents on public health and promoting public health policies that protect the health and wellbeing of residents.

8. The HHS Secretary issued the "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "May 19 Secretarial Directive"). The Secretary stated, "I have determined that the known risks associated with the use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine." The May 19 Directive directed the CDC to "remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy." Recent actions taken by CDC, following the Directive, removing the "routine" recommendation for Covid-19 vaccination for children is contrary to evidence-based, accepted pediatrics standards of care for vaccinations supported by rigorous, evidence-based research and clinical follow-up. I am forced to either violate my oath to "do no harm" to my patients or risk professional consequences, including medical malpractice liability and potential disciplinary action by the state medical board. Not recommending the Covid-19 vaccine to my patients is bad patient care and places not only the patient but their family, household contacts, and the community at large at potential risk of severe morbidity and mortality.

9. The May 19 Directive, and HHS's subsequent guidance requiring SCDM for pediatric Covid-19 vaccination, has introduced confusion, fear, and hesitation among health center

patients 'families. It has cast unwarranted doubt on a vaccine that is proven safe and effective, and is essential for protecting our most vulnerable patients, specifically infants and children with underlying health conditions. Pediatricians are the primary trusted source for health information for families. The spurious and abrupt change in Covid-19 vaccination recommendations undermines the patient-provider relationship.

10. As a result of the downgrade to SCDM, I am required to spend additional time counseling patients and their parents as they weigh the risks and benefits of vaccination against COVID-19. By changing the CDC immunization schedule recommendation from "routine" to SCDM the Secretary, ACIP, and CDC has shifted responsibility onto parents for understanding the relative risks and benefits of the COVID vaccine vis-a-vis the potential vulnerabilities of their child, and placed families in an impossible position of making the best medical decision, particularly those with lower health literacy or fewer educational resources. Most parents do not have the medical background or foundational understanding of vaccines (their purpose, development, risks, and benefits) to independently weigh complex scientific information, recognize inaccurate information presented in the media, and make a truly informed decision. These inequities mean that the level of understanding required for an informed decision varies dramatically across my patient population. Further, the time necessary to adequately prepare a parent to make a medically sound decision far exceeds what is feasible in a typical 20-minute well-child visit. As a result, I am forced to spend significantly more unreimbursed time counseling parents, correcting misconceptions, and attempting to bridge health literacy gaps—all of which materially detract from my ability to provide comprehensive pediatric care and directly harm my clinical practice. Despite specific and extensive counseling regarding the Covid-19 vaccine, patients and their parents have expressed less trust in

the COVID-19 vaccine as a result of the SCDM designation, which is often mistaken to signal that the vaccine is no longer important.

11. The additional time spent counseling patients, as a result of the shift to SCDM, has created a substantial burden on my practice. While various billing codes for vaccine counseling exist for COVID-19, it is unclear whether these codes can be used in all settings, for all insurances, and in all states. But the core problem for me is not billing, it is time. A typical pediatric well visit in the United States is allotted 15–20 minutes (15–30 minutes in Massachusetts, with 20 minutes most common), during which providers must complete a full review of systems, perform a physical exam, provide anticipatory guidance, vaccines, and—at federally qualified health centers like mine—review multiple required screenings (SBIRT, PISQ, PHQ-2/9, GAD-7, SDOH, and others). This already allows for little room for comprehensive counseling. The SCDM requirement now demands lengthy, individualized discussions to help parents evaluate complex clinical and epidemiological Covid-19 vaccine data that most are not equipped to interpret on their own. Adding this counseling to an already overloaded visit is nearly impossible and forces me to choose between cutting essential components of care or extending visits far beyond what is feasible. This increased time burden directly harms my ability to provide complete, evidence-based pediatric care.

12. The patient populations at NBCHC and LCHC include a large number of individuals with limited English proficiency (~80% do not speak English) and health literacy. The majority present to the FQHC as uninsured or underinsured.

13. Following the May 19 Secretarial Directive, I have seen a decline in my patients ' willingness to be vaccinated or even to seek care. For example, NBCHC administered 104 doses of COVID-19 vaccines between April 1, 2024 and August 1, 2024 for all age groups between 6 months and 18 years; by comparison, fewer than 50 doses were administered between May 1, 2025 and

July 1, 2025. Parents are now questioning whether they should vaccinate their children against COVID-19. With limited health literacy regarding the processes for vaccine development and production, as well as a near complete lack of knowledge regarding the difference in mode of transmission and prognosis for the various respiratory illnesses, families are also declining other respiratory virus vaccines (e.g., influenza) which will likely result in increased hospitalizations and ICU admissions, increasing medical costs and placing an increased burden on limited healthcare resources, with the downstream potential of other critically ill persons not being able to receive the care they need for other conditions.

14. The downgrade to SCDM for pediatric Covid-19 vaccination also has broader implications and compounding harms beyond the clinical visit. When children become ill, parents must remain home to care for them, leading to lost wages and reduced productivity that disproportionately affect families with fewer resources. Unvaccinated children can transmit infection to their parents, who may themselves become ill and miss additional work. As seen early in the pandemic, rising infection rates among families strain the workforce (including first responders and essential personnel) placing entire communities at heightened risk. Increased infections in the community burden EMS, emergency departments and ICUs, limiting capacity, staff, and resources required to manage other critical needs such as heart attacks and trauma care.

15. I am especially concerned about infants under 6 months of age for whom the vaccine is not available. During pregnancy, the immune system is suppressed to protect the developing fetus. This places pregnant women at higher risk for severe Covid-19 among other infections. As infants under 6 months of age cannot receive the Covid-19 vaccine, their only protection resides in the presence of maternal antibodies. The absence of these antibodies places the infant not only at increased risk of acquiring Covid-19 infection, but of developing severe or

fatal infection. Further, an unimmunized mother is more likely to experience premature birth. Prematurity is an independent risk factor of long-term complications and possibly death. And premature infants who become infected are more likely to experience complications or death from Covid-19. Deterring patients from accessing the Covid-19 vaccine in this population is medically dangerous and ethically indefensible. This is exactly why the May 19 Directive and recent actions by ACIP, and the CDC, unnecessarily increase risk of infection among child who are then able to spread infection through the schools (to other students and teachers) and communities, thereby placing all vulnerable persons, not only children, at potential risk for severe infection including chronic disability from complication of long-Covid.

16. The Directive and recent actions by the ACIP and CDC are interfering with my ability to provide the standard of care I have learned from my professional training and from national professional organizations that have published practice guidelines based on experience and peer-reviewed research. These guidelines include practice guidelines from the American Academy of Pediatrics, the Pediatric Infectious Disease Society, the Infectious Disease Society of America, the Advisory Committee on Immunization Practices prior to June 2025, and UpToDate, which is an online database that is a compendium of clinical decision support tools, published clinical trial data, and detailed information on drugs that is widely used by practicing physicians. These resources all recommend the Covid-19 vaccine to all pediatric patients, including the primary series for infants. Nevertheless, by following these professional guidelines I know that I am now potentially placing myself at odds with the federal directive. I am exposing myself to malpractice liability, jeopardizing my medical license, and facing disciplinary action from the Board of Registration in Medicine, which includes having to bear the cost of defending my professional reputation—all for recommending and administering a vaccine that is FDA-approved and fully

supported by pediatric standards of care. My medical judgment is now being overridden by a HHS directive that is not based in science or evidence, and the result is measurable harm: my patients delaying or foregoing Covid-19 vaccination, confusion and fear of unknown costs among my patients 'parents, operational strain in my practice, and a growing sense of mistrust in the Covid-19 vaccine that is deeply damaging to the physician-patient relationship.

17. Because of vaccine hesitancy and loss of trust caused by the Directive, physicians such as myself are required to spend more time correcting misinformation with individuals and families regarding the effectiveness of the Covid-19 vaccines, which diverts time and resources away from other important health care or public health duties. If there is another severe Covid-19 outbreak, unvaccinated individuals create a risk to themselves as well as the rest of the community because they can spread infection and thereby consume limited resources; all of which is preventable. Covid-19 is still a public health threat in our communities, especially because a new variant of the virus known as NB.1.8.1 or "Nimbus" is now becoming prevalent in the United States, so being up to date on one's vaccination status is still a sound public health recommendation.

18. In short, the Secretary's May 19, 2025 Directive and recent actions by ACIP and the CDC downgrading the recommendation for Covid-19 vaccination to SCDM completely contradict the evidence of the safety and effectiveness of the Covid-19 vaccines and likely will result in otherwise preventable illness, hospitalizations, and death.

19. On January 5, 2026, Jim O'Neill, Acting Director of CDC, adopted a completely revised CDC Childhood Immunization Schedule (the "Schedule Change"). Several routinely recommended vaccines were changed to recommended via SCDM or recommended for high-risk or certain populations only. These changes by-passed the standard review process and were neither evaluated nor recommended by the ACIP. Instead, they were implemented unilaterally by agency

leadership. The changes to the immunization schedule were not grounded in a transparent or scientifically rigorous process. Referencing other developed nations, specifically Denmark in this decision to change healthcare policy, it is important to recognize that the population of Denmark in 2025 was ~6 million compared with 342 million in the U.S. in 2025, and further that Denmarks's healthcare system provides for universal, tax-funded, largely free primary, specialty and hospital-based care for all residents and thus drastically different from the U.S. healthcare system.

20. I learned of the Schedule Change through multiple professional alerts and communications, including notices distributed by CDC, the American Academy of Pediatrics, and the American Medical Association. The Schedule Change was announced without prior engagement with frontline clinicians or public health practitioners, and without any transition period. The changes were effective immediately. There was no phased implementation, no provider education period, and no opportunity for clinicians or health systems to prepare patients or staff for the shift.

21. Vaccination is by design preventive. The harm caused by failure to vaccinate is not typically immediate in the way a physical injury is immediate. Instead, vaccination prevents severe disease, disability, and death that occur following exposure. Once exposure occurs, the opportunity for prevention is lost. Regarding meningococcal disease, however, the risk associated with failure to vaccinate can be immediate and catastrophic. The mechanism of transmission for meningococcal disease is via respiratory droplets through coughing, sneezing, or sharing eating utensils and cups making exposure likely among close contacts. The incubation period, defined as the period of time between exposure and symptom onset, is short, and the disease can be deadly within hours. Persons who survive infection may be permanently disfigured with 20% of survivors suffering amputation

due to blood clotting, seizures, or brain damage, etc. In the absence of immunization, prevention of death or disability requires immediate action with appropriate antibiotics within 24 hours.

22. During my service as an Epidemic Intelligence Service officer assigned to the New York State Department of Health, I was involved in responding to a meningococcal outbreak among unvaccinated college students. The outbreak began with a single case just prior to the students leaving for winter break. The source individual died. Numerous other students became critically ill and were hospitalized. Enormous efforts in resources, time, and manpower were spent to identify all potentially exposed persons throughout the United States all of whom had returned home or traveled elsewhere, and provide antibiotic prophylaxis. Meningococcal disease can progress with extreme rapidity. I have personally treated children who appeared mildly ill with low-grade fever and nonspecific symptoms, were put to bed by their parents, and were dead within 24 hours. I have also treated children who survived meningococcal infection but suffered catastrophic and permanent injuries. While antibiotic prophylaxis can sometimes be administered after exposure, it is not a substitute for vaccination. It requires rapid identification of exposed individuals, immediate access to care, and timely response. Even then, some individuals will already be ill or will not respond in time. The only effective and reliable method of preventing meningococcal disease is routine vaccination before exposure.

23. College students are a particularly high-risk population due to close living quarters and common behaviors that facilitate transmission through saliva, including sharing drinks at social gatherings, fraternity and sorority events, athletic activities, and communal living environments. College terms are beginning imminently. Delaying meningococcal vaccination even briefly, including by requiring a SCDM conversation rather than recommending routine administration,

materially increases the risk of exposure during a period of intense social contact. That delay can be the difference between life and death.

24. I have seen meningococcal illness spread not only among college students, but across all age groups, from elementary school children through young adults, often through close-contact activities such as sports. During a documented outbreak in Rhode Island, public health authorities, in coordination with the CDC, vaccinated nearly the entire population between the ages of two and twenty-two in order to control the spread. Without rapid emergency treatment, meningococcal disease carries a mortality rate up to fifteen ~~fifty~~ percent, and as many as 20% of survivors will suffer permanent, irreversible harm including deafness, brain damage, seizures, kidney failure or limb loss, even with treatment.

25. Influenza poses a similarly imminent risk. In my role as Director of Infectious Diseases for a large municipal public health department, every pediatric death due to influenza during my tenure occurred in an unvaccinated child. Not a single vaccinated child died. This was a consistent and absolute pattern.

26. Although existing herd immunity may temporarily mask the consequences of the Schedule Change, this should not be interpreted as an absence of immediate harm. As vaccination rates begin to decline, herd immunity will erode, at which point outbreaks will occur more rapidly. When this happens, there will be an urgent need for large-scale catch-up vaccination efforts, which are more costly, more disruptive, and generate significantly more fear and panic than maintaining consistent preventive care.

27. Based on my clinical experience, vaccinated children almost never require hospitalization or admission to an intensive care unit for these illnesses, while unvaccinated children are at significantly higher risk of severe disease and death.

28. Pregnant individuals are at particular risk in this environment. All pregnant women are inherently relatively immunosuppressed, which places them at higher risk for severe outcomes from vaccine-preventable illnesses, even if they themselves are vaccinated. The Schedule Change increases risk not only for children, but also for pregnant patients and their unborn children.

29. The Schedule Change is causing profound and potentially irreversible damage to public trust in public health institutions, pediatricians, and established vaccine recommendations. For decades, ACIP recommendations adopted by the CDC have formed the foundation of routine pediatric care. Pediatricians rely on the thoroughness, stability, and credibility of these recommendations to present vaccination as a standard, expected component of care. The abrupt change has created confusion among patients and families, who now ask why vaccines that were previously recommended are suddenly described as SCDM, which parents interpret as optional.

30. Once confidence in vaccination is undermined, it is extraordinarily difficult to restore. Vaccine hesitancy, once introduced, spreads rapidly and persists even when corrected with evidence. Research demonstrates that adherence to early childhood vaccine schedules strongly predicts completion of later vaccines, including the measles, mumps, and rubella (MMR) vaccine by age two. Disruptions to early schedules reduces overall vaccination completion and increases outbreak risk. This erosion of routine vaccination practice is not easily or quickly reversible once established. It leads to a population that is variably protected, partially protected, or unprotected in ways that are difficult to track and impossible to manage epidemiologically.

31. Even before the formal Schedule Change, public discussion and threats of altering the schedule increased hesitancy among parents, including those who had never previously expressed concerns. As Medical Director of a pediatric department, I had to hold additional meetings with pediatricians and nursing staff to address confusion, reinforce vaccine risks and

benefits, and retrain staff on how vaccines are introduced in clinical encounters. When vaccines are presented as SCDM rather than routine, parents are more likely to delay or decline. Delays increase the likelihood that future vaccines will also be delayed or missed entirely, including meningococcal, measles, influenza, and varicella vaccines. Clinicians must now spend substantially more time addressing misinformation and irrational fears. This time is often not reimbursed. Separate nurse-only vaccination visits increase staffing needs and healthcare costs.

32. The vaccines included in the recently changed schedule include respiratory and gastrointestinal diseases which can have profound impact on the health and well-being of children and in the worst cases can result in respiratory distress, electrolyte imbalance, dehydration, and ultimately potentially cardiac arrest and death. The risks associated with vaccines are negligible compared with risks associated with infection.

33. Further, the ability to treat the various infections associated with those vaccines impacted with the schedule change requires access to high quality health care. Removing these vaccines requires the ability to effectively recognize and treat these infections early in order to prevent more severe (and expensive) disease. Health and well-being are also impacted by the social determinants of health, e.g., housing, transportation, safety, food, environment, etc. found to be responsible for 80% of a person's overall health. Particularly in the setting of poverty, vulnerability, minority status, housing and food instability, etc. the ability to treat even minor conditions becomes more difficult, making vaccines an ever more important component of the country's medical care and public health strategies.

34. Beginning on February 9, I am preparing to begin clinical practice at a federally qualified health center serving a predominantly immigrant, refugee, and non-English-speaking population with limited prior access to healthcare. These patients are at higher risk of severe

outcomes from vaccine-preventable diseases. Due to the Schedule Change, I expect increased vaccine hesitancy immediately upon starting, requiring more extensive counseling and increasing the likelihood of delayed or declined vaccination during periods of high transmission risk, including influenza and meningococcal disease. In my past experience practicing in these settings, these conversations frequently are not resolved in a single visit. Parents often leave to discuss the issue with other family members, such as a spouse, and then return for additional appointments in which the same concerns must be addressed again. These discussions are often emotionally charged, and patients can become defensive, particularly when trust has already been undermined by conflicting public messaging.

35. Should the February ACIP meeting proceed as scheduled, parents will hear more fragmented and inaccurate information that they do not fully understand, which will necessitate lengthy discussions to explain not only specific vaccines, but the broader implications of these policy changes.

36. Under normal circumstances, I am ethically obligated to explain the risks and benefits of vaccination. However, as a result of the Schedule Change and the anticipated impact of the February ACIP meeting, these conversations will extend far beyond the standard risk–benefit analysis. I will be required to address widespread confusion, misinformation, and distrust generated by shifting federal guidance before meaningful medical counseling can even begin. Each visit therefore becomes progressively longer, not shorter, as families return with additional questions or seek repeated reassurance. This directly reduces the number of patients I am able to see in a day, lengthens wait times, increases strain on clinic staff, and limits access to care for a population that already faces significant barriers to timely medical services. As a provider in a federally qualified health center, I am not reimbursed the additional time required for these expanded discussions.

37. I took an oath as a physician to do no harm. Today, because of the May 19 Secretarial Directive and recent actions by ACIP, CDC, and HHS, I am being placed in an impossible situation that may result in actions that conflict with my best medical judgment and against the science that I know saves lives. These actions by the Department of Health and Human Services puts an unfounded personal agenda of the HHS Secretary over patients.

38. The harms described above are not confined to past events and are ongoing with respect to the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children. Since the changes to the CDC immunization schedule recommendations for Covid-19 vaccination, I continue to have to respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance. I have to address Covid-19 vaccinations now with my patients throughout my day, and I must repeatedly spend time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption directly interferes with my routine care, diverts my clinical time, and undermines confidence in vaccination recommendations that I rely on daily. The Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children is undermining my physician-patient relationship and causing needless negative health outcomes to my patients. The harms to me set forth above are ongoing and will continue unless the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children are immediately enjoined and the ACIP and CDC return the evidence-based, transparent process for making vaccine recommendations for children.

39. The harms identified above are compounding rather than isolated. The harms identified above associated with the Directive, CDC's changes to the CDC immunization schedule for Covid-19 vaccination for children, the January 5, 2026 changes to the childhood immunization

schedule—as well as the anticipated harms that will result from any additional changes that may result from the upcoming February 26, 2026 ACIP meeting—are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as their physician. As a physician, I do not regain lost time, trust, or clarity between policy shifts. Instead, each new change increases the burden on my practice, amplifies patient skepticism with my recommendations during my consultation, increases the time I am spending during each visit, and diminishes the effectiveness of my clinical counseling. There is a practical limit to how much uncertainty I can absorb while still providing effective care, and in my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the imminent February 26, 2026 ACIP meeting has pushed my clinical practice toward or beyond that limit absent immediate injunctive relief.

40. The harms described above are also compounded by the failure to follow the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach formally adopted by ACIP for developing evidence-based recommendations as well as disregarding the Evidence-to-Recommendations (EtR) framework in communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does

not replace prior work, it is added on top of my existing clinical responsibilities and diverts from patient care. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the anticipated February 2026 ACIP actions, the harm compounds. I do not have the time or practical ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that I have relied on throughout my entire career as a practicing physician. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in my ability to answer questions and provide recommendations to my patients on these vaccinations, pushing my clinical practice toward a breaking point absent immediate injunctive relief.

41. For all these reasons, I ask the Court to prevent the harm that I believe the HHS's May 19 Directive and recent actions by ACIP and the CDC downgrading the recommendation for Covid-19 vaccinations and changing the childhood vaccination schedule will inflict on me as a physician and the patients who I presently treat.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Massachusetts, that the foregoing is true and correct.

Executed on January 22, 2026 in Boston, Massachusetts.

Jenifer Leaf Jaeger, M.D., M.P

Jenifer Leaf Jaeger, M.D., M.P.H., FAAP

EXHIBIT 46

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF SINDHU K. SRINIVAS, MD, MSCE
(As President of the Society for Maternal Fetal Medicine)

I, Sindhu K. Srinivas, MD, MSCE, hereby declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge:

1. I am the President of the Society for Maternal-Fetal Medicine ("SMFM") and am board certified in Obstetrics and Gynecology and Maternal Fetal Medicine. In this role, I lead SMFM's relationships with its more than 7,000 physician members and oversee the publication of standards that SMFM's members consult to provide the highest level of care to their patients. As such, I have in-depth knowledge of the operations of SMFM, its members, the standard of care SMFM's physician members follow, and the facts and circumstances set forth herein.

2. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction. I am over the age of 18 and make this declaration based on my personal knowledge and in my official capacity as President of SMFM.

3. I received my Doctor of Medicine degree from the University of Medicine and Dentistry of New Jersey, and completed a residency and fellowship at the Hospital of the University of Pennsylvania. I am currently a professor of obstetrics and gynecology and treat high-risk pregnant patients at a hospital in Pennsylvania.

4. SMFM is a professional organization dedicated to advancing the practice of maternal-fetal medicine, which involves the care of people with high-risk pregnancies. The organization focuses on education, research, and advocacy to improve outcomes for both the pregnant person and the fetus. SMFM exists to ensure that high-risk pregnant patients receive consistent, evidence-based care across the United States and provide physicians the resources to deliver this care to their patients.

5. SMFM's membership includes over 7,000 physicians nationwide who specialize in maternal-fetal medicine and provide direct care to high-risk pregnant patients in both hospital and outpatient settings across the United States. Our mission is to advance evidence-based care provide and ensure high-risk pregnant patients receive accurate, scientifically grounded medical care and guidance.

6. SMFM is dedicated to advancing optimal and equitable perinatal outcomes for all people who desire or experience pregnancy and leads the evidence-based practice of high-risk pregnancy care by providing education, promoting research, and engaging in advocacy. To accomplish these goals, SMFM offers a range of educational resources for clinicians specializing in high-risk pregnancies, including the provision of accredited medical education and clinical guidelines. SMFM also supports numerous research initiatives aimed at improving outcomes for high-risk pregnancies and has an official society journal, PREGNANCY, which is an open-access

journal that publishes innovative research, ensuring that the latest scientific advancements are freely available to the global maternal-fetal medicine community.

7. SMFM members provide direct patient care in every state across the United States, including in large health systems, rural hospitals, community practices, and academic centers. Because maternal-fetal medicine involves management of complex and high-risk pregnancies, SMFM members rely on CDC and ACIP recommendations and the CDC immunization schedule to guide patient counseling and clinical decision-making on vaccination.

8. Before the Secretary's Directive and ACIP's September 2025 vote, SMFM members uniformly relied on the CDC's "routine" recommendation for Covid-19 vaccination in pregnancy. The CDC immunization schedule recommendations were not advisory background noise; they were central tools SMFM physician members used in the exam room to ensure patient safety and meet the standard of care. Maternal-fetal medicine depends on clear, evidence-based standards, including those issued by the ACIP and CDC on vaccinations, because high-risk pregnancies require tightly calibrated risk-benefit assessments grounded in authoritative guidance.

9. SMFM has physician members throughout the United States who have been (and continue to be) directly and immediately harmed by the May 27, 2025 Directive (the "Directive") issued by United States Secretary of Health and Human Services Robert F. Kennedy Jr. (the "Secretary") rescinding "the CDC recommendation that pregnant women receive the COVID-19 vaccine" and ordering the CDC to remove Covid-19 immunizations from the CDC's recommended vaccines during pregnancy. SMFM physician members have also been directly and immediately harmed by the reconstituted Advisory Committee on Immunization Practices ("ACIP") and their September 2025 shift of Covid-19 vaccination recommendation for adults under the age of 65 to

shared clinical decision-making ("SCDM"), which the CDC subsequently mischaracterized as "informed consent."

10. These actions by the Secretary, ACIP, and the CDC have overturned the reliance framework for vaccinations under which maternal-fetal medicine specialists practice. They eliminated the uniform baseline that clinicians had used to counsel patients (i.e. the CDC immunization schedule) and have thrust our physician members into an unprecedented conflict between medical evidence and federal directives. These actions by the Secretary, ACIP, and the CDC have further caused disruption to SMFM as we have had to use SMFM resources to address the mass confusion caused by these actions.

11. SMFM's members and the patients they care for have been impacted and will continue to be impacted at the hands of the Secretary's, ACIP's, and CDC's recent changes to the CDC immunization schedule recommendation for Covid-19 vaccination for pregnant women. Members of SMFM have reported that the Secretary's Directive and recent actions by ACIP and the CDC have frustrated their ability to effectively counsel patients regarding the effectiveness of the Covid-19 vaccine at preventing illness and that the Directive and recent ACIP recommendation is compromising the standard of care by inciting patient delays or refusals to receive the Covid-19 vaccination.

12. The Directive has directly impacted SMFM physician members' ability to provide the optimal standard of care that they have been following since the Covid-19 vaccines were approved and has placed SMFM's members in a difficult situation. SMFM members have reported that their clinical judgment, which is rooted in years of medical training, board certification in maternal-fetal medicine, and reliance on data from peer-reviewed literature and prior CDC/ACIP recommendations, is now being overridden by the Directive. In addition, the recent ACIP

recommendation to change Covid-19 vaccination to SCDM for essentially all adults is essentially no recommendation at all for pregnant women and it did not address the conflict with the Directive, did not follow the transparent presentation of GRADE systematic review tables or EtR (evidence to recommendation framework for evaluating the quality of evidence, and did not have a contemporaneous explanation in the CDC's Morbidity and Mortality Weekly Report ("MMWR"). As a result, SMFM Members are being forced to justify scientifically sound recommendations for the Covid-19 vaccination during pregnancy against a federal Directive and ACIP recommendation that has no evidentiary basis in obstetrics or infectious disease. Peer-reviewed studies have demonstrated that administration of the Covid-19 vaccine during any trimester of pregnancy lowers hospitalization rates, serious illness, and adverse outcomes in pregnant people and infants. With the efforts and advocacy of SMFM, peer-reviewed studies investigating and analyzing the safety and effectiveness of administration of the Covid-19 vaccine during pregnancy have been conducted. These studies show no signal of harm to the pregnant patient, the pregnancy, or the newborn resulting from the administration of the Covid-19 vaccine during pregnancy.

13. Based on a recent survey conducted among a subset of the SMFM membership, SMFM members report that counseling patients about Covid-19 vaccination now requires an additional 10-20 minutes per patient, because patients arrive with confusion created by the Directive and ACIP's recent change to the CDC immunization schedule for Covid-19 vaccines to SCDM. This increased consultation time is financially and logistically harmful to SMFM members and their practices. These are quantifiable harms that did not exist prior to the Secretary's Directive, the recommendations approved by the reconstituted ACIP, and the CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women.

14. Further, SMFM members are reporting a rapid erosion of trust and vaccine confidence among their pregnant patients as a result of the Directive and recent action by ACIP changing the recommendation for Covid-19 vaccination for essentially all adults to SCDM. SMFM members have also reported that the Secretary's sudden and unilateral Directive removing the Covid-19 vaccine from the routine vaccination recommendations for pregnant people has undermined some patients' faith and trust in all recommended vaccinations during pregnancy, causing them to refuse other routine vaccinations and creating even more risk of serious illness and hospitalization.

15. In maternal-fetal medicine, the CDC immunization schedule has been an authoritative, central tool physicians used in exam rooms to consult with patients on vaccinations, ensure patient safety, and meet the standard of care. The Secretary, ACIP, and CDC unexplained changes to the CDC immunization schedule for Covid-19 vaccination for pregnant individual (that essentially is no recommendation for Covid-19 vaccination) has shifted the burden entirely to individual physicians to defend their medical advice on vaccination without the authoritative evidentiary framework that accompanies a change to the CDC immunization schedule that physicians and patients have long relied upon. The deterioration of trust that SMFM physician members are experiencing right now in their exam rooms with their patients is a direct result of these recent actions by the Secretary, ACIP and CDC.

16. Preserving trust is essential in high-risk pregnancy care where delayed decisions can be life threating. In the wake of the issuance of the Directive, SMFM members' patients are questioning not only the Covid-19 vaccine but also the safety and necessity of longstanding vaccinations, such as the influenza and Tdap vaccines, during pregnancy. Some SMFM physician members are now fielding questions like "Why should I trust any of these vaccines if the

government suddenly pulled the Covid vaccine for pregnancy?"—questions that were not previously part of the physician-patient dialogue. SMFM physician members report spending time and resources on counseling patients about the safety and effectiveness of the Covid-19 vaccine to rebut the mistrust and confusion that has resulted from the Directive and recent ACIP recommendation to change Covid-19 vaccination to SCDM. This growing mistrust is undermining SMFM members' physician-patient relationship and jeopardizing maternal and neonatal health.

17. Since the issuance of May 19 Directive, September Schedule Change, and January 5 Childhood Schedule Change, SMFM has been forced to divert time, personnel, and resources away from its regular educational and policy initiatives in order to respond to the confusion caused by these abrupt federal policy shifts on routine vaccine recommendations embedded in SMFM guidance and SMFM members' practices and patient care. These efforts have included SMFM staff developing public communications, answering questions from members, correcting misinformation, and coordinating with other national medical associations to reaffirm the evidence-based guidance on vaccination, including Covid-19 vaccination, during pregnancy. These efforts are essential to mitigate ongoing harm, and they represent a significant and unplanned burden for SMFM.

18. The Directive and the ACIP and CDC's recent change to the CDC immunization schedule for Covid-19 vaccination to SCDM is forcing SMFM to divert additional time, personnel, and resources away from its regular educational and initiatives in order to address the confusion caused by the conflicting recommendations for Covid-19 vaccines for pregnant women. These efforts include SMFM staff shifting their time away from other SMFM priorities to draft

emergency statements to members,[1] respond to member emails seeking clarification, and coordinating with other professional associations on how to interpret these actions by the Secretary, ACIP, and CDC. This time would otherwise have been spent on SMFM's core mission: evidence-based guideline development, research support, and education for the evidence-based practice of high-risk pregnancy care.

19. The shift by the Secretary, ACIP, and CDC from the CDC immunization schedule routine recommendation for Covid-19 vaccination for pregnant women to essentially no recommendation for pregnant women has real world implications for SMFM physician members and directly burdened SMFM members' medical practices. For example, since the Directive and these recent actions by ACIP and CDC, SMFM members have reported: (i) escalating vaccine hesitancy among pregnant patients who had accepted vaccination before the Directive; (ii) longer, more complex counseling sessions devoted to addressing confusion created by the government's abrupt change to the CDC immunization schedule for pregnant women; and, (iii) legal and professional risk, as the shifts to essentially no recommendation for Covid-19 vaccination for pregnant women conflicts with the medical standard of care for high-risk pregnant patients who face severe adverse health outcomes from Covid-19 infection. These are not policy disagreements; they are real-world, predictable consequences of the Secretary, ACIP, and CDC actions that have changed the rules under which SMFM physician members are practicing right now.

20. Since the Directive and these recent actions by ACIP and the CDC changing the CDC immunization schedule recommendation for Covid-19 vaccination for pregnant women, multiple SMFM members have also been forced to contact insurers to determine coverage and

[1] For example, as a result of the Directive, SMFM had to spend time, resources, and money to immediately issue a statement to SMFM members addressing the Directive and reaffirming Covid-19 vaccination recommendations during pregnancy.

coding for counseling or vaccine administration; redirect staff time to address the confusion on Covid-19 vaccination for pregnant patients caused by these conflicting actions taken by the Secretary, reconstituted ACIP, and the CDC; and, increase documentation for Covid-19 vaccination consultation and decision-making due to the liability risk created by these actions.

21. SMFM member physicians are not passive observers of federal vaccine policy. Their clinical obligations, malpractice exposure, reimbursement, and daily operations are directly impacted by these changes to the CDC immunization schedule by the Secretary, ACIP, and CDC. Many SMFM members also report experiencing increased liability risk because removing the "routine" recommendation for Covid-19 vaccination deviates from the standard of care they are expected to provide. This forces SMFM physician members into an untenable conflict: follow the new federal directives on Covid-19 vaccination for pregnant women and risk patient harm or malpractice claims should a patient or child contract Covid-19; or follow the medical evidence and recommend Covid-19 vaccination, which risks accusations of deviating from CDC standards and insurer confusions.

22. SMFM members have informed SMFM staff that Secretary, ACIP, and CDC changes to the CDC immunization schedule recommendation for Covid-19 vaccination for pregnant women from "routine" to essentially no recommendation has forced SMFM physician members to spend significantly more unreimbursed time counseling patients on Covid-19 vaccination, correcting misconceptions, and attempting to bridge health literacy gaps, all of which materially detract from their ability to provide comprehensive care to their patients. We have received questions from our members regarding the Secretary, ACIP, and CDC's changes to the CDC immunization schedule for Covid-19 vaccination for pregnant individuals, including how to understand and apply ACIP and the CDC's recent recommendation for Covid-19 vaccination for

pregnant individuals that did not follow the EtR framework and has no guidance published in the MMWR. We expect to continue to have to divert SMFM resources and staff member time to answer SMFM questions related to the Secretary, ACIP, and CDC changes to Covid-19 vaccination for pregnant individuals. Without these additional obligations, SMFM staff would be devoting their time and resources to supporting members' efforts to advance the care provided to their patients.

23. The Secretary, ACIP, and the CDC changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women imposes a significant burden and expense on SMFM members who provide direct care to high-risk pregnant women, which includes care related to Covid-19 vaccination. I am aware of SMFM members who provide care to high-risk pregnant patients, which includes Covid-19 vaccination. SMFM physician members have informed me that they are concerned about the immediate harms caused by the actions of the Secretary, ACIP, and CDC, including the cost to their medical practices, conflict with the standard of care, documentation, and liability. Both before and after the actions by the Secretary, ACIP, and the CDC, SMFM staff members have spent considerable time addressing member concerns specifically related to the changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women, instead of discussing other member business or initiatives, particularly important during the respiratory virus season.

24. Without prompt and immediate intervention, the Directive and the ACIP and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women will continue to interfere directly with the SMFM physician's medical practices, undermine the physician-patient relationship, and cause needless negative maternal and neonatal health outcomes. These harms to SMFM and SMFM members are ongoing and will continue

unless the Directive and the ACIP and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women are vacated and the ACIP and CDC return the evidence-based, transparent process for making vaccine recommendations for pregnant individuals.

25. The May 19 Directive, September Schedule Change, and January 5 Childhood Schedule Change are immediately harming SMFM itself by compelling SMFM to abandon planned mission-critical work and operate in a urgent response mode. Several members of SMFM leadership, staff, and committees now spending at least one hour each day responding to misinformation, correcting federal pronouncements, and briefing members on the internally inconsistent CDC materials. These compelled diversions of resources are concrete, ongoing, and unrecoverable.

26. If the February 25–26, 2026 ACIP meeting proceeds as scheduled, it will immediately compound the harms already inflicted on SMFM and SMFM members by the May 19 Directive, September Schedule Change and January 5 Childhood Schedule Change. This ACIP, constituted and operating outside the qualified-expert, evidence-based framework that historically anchors vaccine policy, will serve as a national megaphone for misinformation, confusion, and instability. SMFM members are frontline physicians who will be forced, yet again, to divert substantial time, expertise, and organizational resources away from their high-risk patient care to address confusion and erosion of trust generated by illegitimate federal guidance. Each additional ACIP meeting and each vote taken by this body inflicts new and compounding injury. SMFM members must spend extra unreimbursed time counseling high-risk pregnant patients on vaccinations amid uncertainty created by unstable and unexplained federal vaccine recommendations for pregnant women and children. They must devote increasing amounts of

unreimbursed time explaining changes to the CDC immunization schedule that were not produced through the established GRADE and Evidence-to-Recommendations framework. SMFM itself must continue redirecting staff, expertise, committee members' time from its core mission to respond to these federal abrupt, unexplained, vaccine policy changes. These harms occur the moment ACIP votes to endorse or ratify changes to the CDC immunization schedule, because such votes are immediately treated nationwide as authoritative federal guidance and enter SMFM physician's exam rooms across the country. The moment a new CDC immunization schedule recommendation change is issued by ACIP, the damage to the SMFM physician-patient relationship and vaccine confidence is immediate and cannot be fully reversed through later litigation, post-hoc agency explanations, or retrospective reconsideration. Absent immediate injunctive relief, SMFM and SMFM physician members will sustain these ongoing and irreparable injuries to their missions, their professional integrity, and the health of the high-risk pregnant women they treat.

I, Sindhu K. Srinivas, MD, MSCE, declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, that the foregoing is true and correct.

Executed on January 23, 2026 in Philadelphia, Pennsylvania.

Sindhu Srinivas

Sindhu K. Srinivas, MD, MSCE
On behalf of the Society for Maternal-Fetal Medicine

EXHIBIT 47

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916 (BEM) District Judge: Hon. Brian E. Murphy Magistrate Judge: Hon. M. Page Kelley

SECOND SUPPLEMENTAL DECLARATION OF JAMIE LOEHR, MD, FAAFP

I, Jamie Loehr, MD, FAAFP, declare pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs in this matter and in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction. I am over the age of 18 and make this declaration based on my personal knowledge.

2. I am a board-certified family physician. I have been a physician for 35 years. I am the founder and owner of Cayuga Family Medicine, located in Ithaca, NY, where I have practiced family medicine since 2000.

3. I graduated from Cornell University in 1985 and then Baylor College of Medicine in 1990. I completed my residency in family medicine at the University of Rochester, Highland Hospital, in Rochester, NY in 1993.

4. I began my service on the Advisory Committee on Immunization Practices ("ACIP") in July 2011 as an American Academy of Family Physicians ("AAFP") liaison member.

5. In addition to voting and ex-officio members, ACIP is also comprised of 31 liaison members, primarily from professional organizations. Appointments of liaison members are based on written requests from the professional organizations. Liaison members represent organizations that have broad immunization interests and represent large constituencies. I served as the AAFP liaison member for four years and also on the Influenza Vaccines Work Group. After four years as a liaison member, I continued my service to the ACIP as a subject matter expert on the Influenza Vaccines Work Group. I then became a voting member of the ACIP in September 2021, until my termination from ACIP on June 9, 2025.

6. I applied to be a voting member of ACIP in 2015. The application process required me to submit a current curriculum vitae, two letters of recommendation, and a cover letter. I applied to be a voting member of the ACIP several times over the next few years.

7. In 2020, I was nominated to be a voting member of ACIP. Generally, ACIP submits the names of their nominated members to the Department of Health and Human Services (HHS) for approval. Nominations are not always approved, but once they are approved, nominations have always been confirmed. My nomination was confirmed, and I was supposed to begin my term as a voting member of ACIP on July 1, 2020. However, I was subsequently told that the White House rejected my nomination. I was also told that had never happened before and no reason was given to me for this rejection. As a result, I did not start as a voting member on ACIP in 2020.

8. Later in 2020, I put my name forward again. My nomination was accepted in late July 2021 and I began as a voting member with ACIP in September 2021. My initial term was

supposed to run from July 1, 2021 until June 30, 2025, in accordance with the four-year term of ACIP voting members.

9. I was appointed to be Chair of ACIP starting July 1, 2025 until June 30, 2028, in accordance with the three-year term for the Chair of ACIP.

10. I saw the May 27, 2025 announcement on the X social media platform by Secretary of Health and Human Services Robert F. Kennedy, Jr. that he was rescinding prior ACIP recommendations that pregnant women and healthy children ages six months to 17 years old be routinely immunized against COVID-19. I was shocked by his announcement, especially because the Secretary changed the recommendations without consulting with the ACIP or without the ACIP voting to take this action. This decision was contrary to the longstanding practice and policy of vaccines being put on or taken off of the CDC's immunization schedules only after thorough review and a vote by the ACIP. This announcement came to the entire ACIP totally without warning. COVID-19 vaccines were not up for a vote at the prior ACIP meeting on April 15-16, 2025, and no data was presented at the April 15-16 meeting suggesting that COVID-19 vaccines should not be recommended for pregnant persons or children. In fact, there was discussion at the April 15-16, 2025 meeting that pregnancy was a risk factor for severe illness from COVID-19.

11. On June 9, 2025, at around 4 p.m., the Wall Street Journal published an opinion commentary ("June 9 Op-Ed") authored by Secretary Kennedy entitled "HHS Moves to Restore Public Trust in Vaccines."[1] The article read:

> Today, we are taking a bold step in restoring public trust by totally reconstituting the Advisory Committee for Immunization Practices (ACIP). We are retiring the 17 current members of the committee, some of whom were last-minute appointees of the Biden administration. Without removing the current members, the current Trump administration would not have been able to appoint a majority of new members until 2028.

[1] A true and correct copy of the June 9 Op-Ed is attached hereto as **Exhibit A.**

12. Later that day, on June 9, 2025, at 6:06 p.m., I received formal communication of my removal from CDC.[2] The email read:

> Per the June 9, 2025, directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).
>
> We appreciate your prior service and commitment.

13. After receiving this email, I later learned that all seventeen (17) voting members of ACIP ("Former ACIP") were informed of their terminations in this manner.

14. I have not been told any other reason for termination of the entire Former ACIP other than the statements included in the June 9 Op-Ed.

15. Secretary Kennedy stated in the June 9 Op-Ed that the necessity for reconstituting ACIP arose from a need to "avoid conflicts of interest." Secretary Kennedy also asserted that the Former ACIP "has been plagued with persistent conflicts and has become little more than a rubber stamp for any vaccine." The June 9 Op-Ed cited conflicts of interests from an investigation into the Vaccines and Related Biological Products Advisory Committee in 2000; potential conflict of interests with the Rotashield vaccine in 1997; and an HHS inspector general report from 2009.

16. I was not on the Committee in 1997, 2000, or 2009. To the best of my knowledge, no one of the 17 terminated Former ACIP members were on the ACIP in 1997, 2000, or 2009.

17. ACIP members are required to disclose any conflicts of interest. Generally, this means that the member must disclose if they have any financial interactions or ongoing contact with a pharma company. Conflict is generally defined as participating in a study, on the public safety data review committee, or being on the speaking committee for a pharma company.

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[2] A true and correct copy of the June 9, 2025 email is attached hereto as **Exhibit B.**

18. As part of the application process, I was required to complete and file several forms including OGE Form 450 (Confidential Financial Disclosure Report), Foreign Activities Questionnaire, Special Government Employee Annual Certifications, and Special Government Employee Supplemental Report: Research Support/Project Funding. On these forms I was required to disclose, for example, how my salary was paid, whether I participated on any boards, all my assets (including stocks and bonds), and several other activities. I know that ACIP members were required to disclose whether they were working on a study or safety monitoring board

19. As part of the application process, I disclosed that my wife owned stock in Johnson & Johnson ("J&J"). She was required to divest from these stocks before I was allowed to participate in ACIP meetings. As a result, I missed the August 2021 ACIP meetings and did not attend my first meeting until September 22, 2021.

20. As part of the application process, I was required to review Ethics Training materials provided to me and also available at https://cdc.gov/faca/ethics/index.html.

21. Former ACIP members erred on the side of being overly transparent when disclosing conflicts of interest. Members would recuse themselves from votes if they previously worked at a company whose vaccine is up for a vote or if they worked on that vaccine previously. I did not need to disclose my wife's prior ownership of J&J stock because she divested her ownership of J&J stock before I began service on the Former ACIP as a voting member.

22. Whenever there was a question about what qualified as a conflict, I went to ACIP leadership, primarily Melinda Wharton, M.D., M.P.H. for clarity. For example, when I realized that I, as an owner of a physician practice that purchases vaccines, may have a transactional relationship with vaccine manufacturers, I disclosed my concerns to Melinda Wharton directly

who assured me that this was an "arm's length" transaction that did not qualify as a conflict for purposes of ACIP.

23. I have found my fellow Former ACIP members to be of the highest integrity and character. I have never witnessed or believed that any of my fellow Former ACIP voting members acted or voted unethically or without the best interests of the public health of Americans in mind. We have performed our duties on the ACIP with diligence, with integrity, and ethically. The accusations in the Secretary's Op-Ed against me and my fellow Former ACIP members are simply untrue.

24. Two days after my termination from the ACIP, on June 11, 2025, Secretary Kennedy appointed eight (8) new voting members to the ACIP ("Current ACIP"). Given that there were only two days between my termination and the announcement of the new members, I find it very hard to believe that these new ACIP members went through the rigorous, lengthy application process that I went through, and I know that other ACIP members went through, to become voting members of the ACIP. I also find it hard to believe that every Current ACIP member managed to finish all the required forms, go through the conflict checks, and review the ethics training materials in such a short time.

25. Prior to June 11, 2025 Former ACIP members were experts in their fields. For example, the Former ACIP included people who have done research into vaccine preventable diseases, run large public health departments, are knowledgeable about statistics, or knowledgeable about public health. It is my opinion that the vast majority of the Current ACIP members are not experts in any of these areas and lack credibility because they do not have these important experiences. The vast majority of the Current ACIP members do not have a depth of experience in vaccines, the ACIP process, public policy, nor how their decisions affect the world.

26. I have observed during meetings held by the Current ACIP that they were not familiar with the Vaccines for Children ("VFC") Program or the way the Affordable Care Act affect vaccine reimbursement. In fact, during an ACIP meeting, one Current ACIP member stated "I don't know what we just voted on," after the vote was completed.

27. In my view, the Current ACIP is not fulfilling the responsibility laid out in its charter, which calls for giving the CDC Director advice on how vaccines should be used to control vaccine-preventable diseases across the civilian population and to conduct a thorough, evidence-based review of the data to support an ACIP recommendation on COVID-19 vaccines. It seems to me that the committee is approaching vaccines as if the focus were individual patient care rather than public health. This comes through when members rely on personal stories about adverse events to argue that vaccines are causing broad harm during ACIP meetings. This was made clear to me when, during the public ACIP meeting, Current ACIP members used anecdotal evidence about adverse events to support claims of widespread harm being caused by vaccines.

28. Since the changes to the CDC immunization schedule recommendations for Covid-19 vaccination and now the January 5, 2026 changes to the childhood immunization schedule that again abandoned the GRADE and EtR framework, the confusion, hesitancy, and mistrust continue to arise and compound from this inconsistent federal guidance. Misconceptions created and exacerbated by federal statements and abrupt policy shifts undermine confidence in vaccination recommendations. The Directive, the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children, and the January 5, 2026 changes to the childhood immunization schedule undermine the physician-patient relationship and cause needless negative health outcomes to patients. These harms are serious, ongoing, and will continue unless the Directive, the ACIP's and CDC's changes to the CDC immunization schedule for Covid-19

vaccination for children, and the January 6, 2025 changes to the CDC childhood immunization schedule are immediately enjoined and the ACIP and CDC return the evidence-based, transparent process for making vaccine recommendations that I have relied on.

29. The harms identified above associated with the Directive, CDC's changes to the CDC immunization schedule for Covid-19 vaccination for children, and the January 5, 2026 changes to the childhood immunization schedule—as well as the anticipated harms that will result from any additional changes that may result from the upcoming February 26, 2026 ACIP meeting—are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence their physician. Each new change amplifies patient skepticism and diminishes the effectiveness of clinical counseling. In my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the imminent February 26, 2026 ACIP meeting has pushed clinical practice toward or beyond that limit absent immediate injunctive relief.

30. The harms described above are also compounded by the failure to follow established the GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. Practicing physicians rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations they discuss with their patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, physicians are forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure

from established methodology. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the anticipated February 2026 ACIP actions, the harm compounds. Physicians do not have the time or practical ability to reconstruct population-level evidence analyses that the ACIP processes are designed to perform and that they have relied on throughout their entire career. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in vaccinations, pushing clinical practice toward a breaking point absent immediate injunctive relief.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of New York, that the foregoing is true and correct.

Executed on January 21, 2026 in Ithaca, NY.

Jamie Loehr

Dr. Jamie Loehr, MD, FAAFP

EXHIBIT A

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https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112

OPINION COMMENTARY Follow

RFK Jr.: HHS Moves to Restore Public Trust in Vaccines

We're reconstituting an advisory committee to avoid conflicts of interest.

By Robert F. Kennedy Jr.

June 9, 2025 4:00 pm ET



A nurse holds a Pfizer-BioNTech Covid-19 vaccine in Miami, May 29. PHOTO: JOE RAEDLE/GETTY IMAGES

Vaccines have become a divisive issue in American politics, but there is one thing all parties can agree on: The U.S. faces a crisis of public trust. Whether toward health agencies, pharmaceutical companies or vaccines themselves, public confidence is waning.

Some would try to explain this away by blaming misinformation or antiscience attitudes. To do so, however, ignores a history of conflicts of interest, persecution of dissidents, a lack of curiosity, and skewed science that has plagued the vaccine regulatory apparatus for decades.

That is why, under my direction, the U.S. Department of Health and Human Services is putting the restoration of public trust above any pro- or antivaccine agenda. The public must know that unbiased science guides the recommendations from our health agencies. This will ensure the American people receive the safest vaccines possible.

Today, we are taking a bold step in restoring public trust by totally reconstituting the Advisory Committee for Immunization Practices (ACIP). We are retiring the 17 current members of the committee, some of whom were last-minute appointees of the Biden administration. Without removing the current members, the current Trump administration would not have been able to appoint a majority of new members until 2028.

ACIP evaluates the safety, efficacy and clinical need of the nation's vaccines and passes its findings on to the Centers for Disease Control and Prevention. The committee has been plagued with persistent conflicts of interest and has become little more than a rubber stamp for any vaccine. It has never recommended against a vaccine—even those later withdrawn for safety reasons. It has failed to scrutinize vaccine products given to babies and pregnant women. To make matters worse, the groups that inform ACIP meet behind closed doors, violating the legal and ethical principle of transparency crucial to maintaining public trust.

In 2000 the House issued the results of an investigation of ACIP and another vaccine advisory committee under the U.S. Food and Drug Administration—the Vaccines and Related Biological Products Advisory Committee. It found that enforcement of its conflict-of-interest rules was weak to nonexistent. Committee members regularly participated in deliberations and advocated products in which they had a financial stake. The CDC issued conflict-of-interest waivers to every committee member. Four out of eight ACIP members who voted in 1997 on guidelines for the Rotashield vaccine, subsequently withdrawn because of severe adverse events, had financial ties to pharmaceutical companies developing other rotavirus vaccines. A 2009 HHS inspector-general report echoed these findings. Few committee members completed full conflict-of-interest forms—97% of them had omissions. The CDC took no significant action to remedy the omissions.

These conflicts of interest persist. Most of ACIP's members have received substantial funding from pharmaceutical companies, including those marketing vaccines. The problem isn't necessarily that ACIP members are corrupt. Most likely aim to serve the public interest as they understand it. The problem is their immersion in a system of industry-aligned incentives and paradigms that enforce a narrow pro-industry orthodoxy. The new members won't directly work for the vaccine industry. They will

exercise independent judgment, refuse to serve as a rubber stamp, and foster a culture of critical inquiry—unafraid to ask hard questions.

A clean sweep is needed to re-establish public confidence in vaccine science. In the 1960s, the world sought guidance from America's health regulators, who had a reputation for integrity, scientific impartiality and zealous defense of patient welfare. Public trust has since collapsed, but we will earn it back.

Mr. Kennedy is secretary of health and human services.

Further Reading

HHS to Stop Recommending Routine Covid Shots for Children, Pregnant Women

How RFK Jr. Is Boosting 'Food Babe' and Other MAHA Acolytes

Trump's FDA Sends a Bullish Signal to Biotech

OPINION **RFK Jr. Is Already Vindicating His Critics**

Videos

EXHIBIT B

From: **FACM Policy and Oversight Team (CDC)** <facmpo@cdc.gov>
Date: Mon, Jun 9, 2025 at 6:06 PM
Subject: Advisory Committee on Immunization Practices Notice
To: JamieACIP@Gmail.com <JamieACIP@gmail.com>, jamie@cayugafamilymedicine.com <jamie@cayugafamilymedicine.com>

To: Jamie Loehr

Per the June 9, 2025 directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).

We appreciate your prior service and commitment.

EXHIBIT 48

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916

SECOND SUPPLEMENTAL DECLARATION OF CHARLOTTE MOSER, M.S.

I, Charlotte Moser, M.S., declare pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs in this matter and in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction. I am over the age of 18 and make this declaration based on my personal knowledge.

2. I work at the Children's Hospital of Philadelphia ("CHOP"), which is a non-profit. At CHOP, I am the co-director at the Vaccine Education Center, an outreach program that provides accurate and up-to-date information on vaccinations. I helped establish and expand the Vaccine Education Center for two and a half decades.

3. At CHOP, I am also the co-creator of the Vaccine Update program, where I assist in the development of programming for healthcare providers involved with vaccinations; these

programs include a webinar series, a monthly e-newsletter, and resources for use at point of care and in professional development activities.

4. At CHOP, I am also the creator of the Parents PACK (Possessing, Accessing and Communicating Knowledge about vaccines), which is a program that helps develop a dialogue with families about vaccines, provides vaccine information more regularly than doctor visits, and establishes a place for parents to get up-to-date information and answers to vaccine questions.

5. I have a bachelor's degree in biology from Wilkes University and a master's degree in communication from Drexel University. I have done bench research studying the immunology of rotavirus.

6. I began service as a voting member of the Advisory Committee on Immunization Practices (ACIP) on July 1, 2024 as the consumer representative until I was summarily terminated on June 9, 2025.

7. The consumer representative position on the ACIP is a voting member position "held by a technically qualified person knowledgeable about consumer perspectives and/or social and community aspects of immunization programs."[1] My experience as co-director of the Vaccine Education Center at CHOP as well as with Parents PACK program at CHOP made me knowledgeable about consumer perspectives and social and community aspects of immunization programs. Just prior to my appointment to the ACIP, the consumer representative was a mother who lost their child to a vaccine-preventable illness.

8. I saw a call for applications to be an ACIP member and, based on my prior experience, thought I would like to do it. I spoke with Dr. Paul Offit, the Director of the Vaccine

[1] CDC, *Apply for ACIP Membership* (December 20, 2024), https://www.cdc.gov/acip/apply-for-membership/index.html, attached hereto as **Exhibit A.**

Education Center at CHOP, before applying and he said it was a great idea. I applied to be a voting member of ACIP on June 20, 2022. The application process required me to submit a current curriculum vitae, two letters of recommendation, and a cover letter. I submitted three letters of recommendation, including one from Dr. Paul Offit.

9. During the process, I was also required to complete an interview with the ACIP Secretariat and a CDC staff member. I received an invitation email for ACIP membership on May 14, 2024. The entire process took almost 2 years. Once invited, I submitted a signed letter accepting the invitation as well as completing onboarding paperwork and orientation before the start of my term.

10. My term on ACIP began on July 1, 2024. My initial term was supposed to run from July 1, 2024 until June 30, 2028, in accordance with the four-year term of ACIP voting members.

11. I saw Secretary of Health and Human Services Robert F. Kennedy, Jr.'s May 27, 2025 announcement on X that he was rescinding prior ACIP recommendations that pregnant women and healthy children ages six months to 17 years old be routinely immunized against COVID-19. I was surprised by his announcement because he did so without consulting with the ACIP or without the ACIP voting to take this action. This decision was contrary to the longstanding practice and policy of vaccines being put on or taken off of the CDC's immunization schedules only after thorough review and a vote by the ACIP. This announcement came without warning.

12. COVID-19 vaccines were on the agenda without a vote at the prior ACIP meeting on April 15-16, 2025, and no data presented at the April 15-16 meeting suggested that the COVID-19 vaccine recommendations for pregnant persons should be removed. In fact, a slide shown during the April meeting listed "pregnancy and recent pregnancy" as a condition that places one at higher risk for severe COVID-19. There was a discussion at the April 15-16, 2025 meeting that

we would be evaluating the recommendations for 2025-2026 COVID-19 vaccines during the June 2025 meeting.

13. On June 5, 2025, at 10:01 a.m., I received an email from CDC Office of Human Resources, Client Services Operations, with the subject line "[External]CDC-Termination SF50."[2] Generally, a Standard Form 50 (SF-50) documents a change in employment status at a federal agency. Attached was a SF-50 form which listed "EXP of APPT," which I interpreted to be an "expiration of appointment" and that I was terminated. However, a conversation with the ACIP Secretariat suggested that this may have been in error, and they were looking into it with Human Resources.

14. On June 9, 2025, at 11:41 a.m., I received an email from Isaac Anderson, Director, Client Services Operations at CDC which stated that my current term had "not yet been extended" and that "[r]enewal by Department of Health and Human Services (HHS) is pending."[3] That email also stated that that "the system automatically generated a termination notice. This was an internal HR administrative process unrelated to your standing in the Committee. We sincerely apologize for the oversight and thank you for your service." I interpreted this email to mean that I had not been terminated from the ACIP.

15. On June 9, 2025, at exactly 4 p.m., the Wall Street Journal published an opinion commentary ("June 9 Op-Ed") authored by Secretary Kennedy entitled "HHS Moves to Restore Public Trust in Vaccines."[4] The article read:

> Today, we are taking a bold step in restoring public trust by totally reconstituting the Advisory Committee for Immunization Practices (ACIP).

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[2] A true and correct copy of the June 5, 2025 10:01 a.m. email is attached hereto as **Exhibit B.**

[3] A true and correct copy of the June 9, 2025 11:41 a.m. email is attached hereto as **Exhibit C.**

[4] A true and correct copy of the June 9 Op-Ed is attached hereto as **Exhibit D.**

> We are retiring the 17 current members of the committee, some of whom were last-minute appointees of the Biden administration. Without removing the current members, the current Trump administration would not have been able to appoint a majority of new members until 2028.

16. Later that day, on June 9, 2025, at 5:51 p.m., I received formal communication of my removal from CDC.[5] The email read:

> Per the June 9, 2025, directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).
>
> We appreciate your prior service and commitment.

17. I learned that all seventeen (17) voting members of ACIP ("Former ACIP") were informed of their terminations in this manner.

18. I have not been told any other reason for termination of the entire Former ACIP other than the statements included in the June 9 Op-Ed.

19. Secretary Kennedy stated in the June 9 Op-Ed that the necessity for reconstituting ACIP arose from a need to "avoid conflicts of interest." Secretary Kennedy also asserted that the Former ACIP "has been plagued with persistent conflicts and has become little more than a rubber stamp for any vaccine." The June 9 Op-Ed cited conflicts of interest from an investigation into ACIP and the Vaccines and Related Biological Products Advisory Committee in 2000; potential conflict of interests with the Rotashield vaccine in 1997; and an HHS inspector general report from 2009.

20. I was not on the Committee in 1997, 2000, or 2009. To the best of my knowledge, none of the 17 terminated ACIP members were on the ACIP in 1997, 2000, or 2009.

[5] A true and correct copy of the June 9, 2025 5:51 p.m. email is attached hereto as **Exhibit E.**

21. I have no conflicts of interest and have never received money from pharmaceutical companies. Any such information about me would have been disclosed during the application process had it existed.

22. Two days after my termination from the ACIP, on June 11, 2025, Secretary Kennedy appointed eight (8) new voting members to the ACIP ("Current ACIP"). Given that there were only two days between my termination and the announcement of the new members, there is no way that these new ACIP members endured the same lengthy application process that I went through or that I understand other Former ACIP members went through to become members of the ACIP.

23. The current consumer representative, Vicky Pebsworth, has been part of an anti-vaccine group for many years.

24. I am aware that the Current ACIP met on June 25-26, 2025 and included COVID-19 vaccination in their discussions. I am also aware that the Current ACIP met September 18-19, 2025 and that at this meeting the Committee discussed recommending the COVID-19 vaccine through Shared Clinical Decision Making ("SCDM") for essentially all patients. During the September meeting, unvetted material and unsupported claims about the COVID-19 vaccine were presented. Some committee members relied on personal anecdotes or brought their own "studies" to the public discussion, expressed misunderstandings of basic biological concepts, and were at times confrontational toward CDC staff and vaccine manufacturers while discussing COVID-19 vaccines. I have also observed that during these meetings the Current ACIP members expressed a particular bias against COVID-19 vaccines.

25. I believe that the use of Current ACIP members' individual experiences in this setting is inconsistent with the ACIP's stated purpose to provide population-level guidance. The

purpose of public health is to provide a broad runway, so that when it comes down to individualized medicine, providers have a choice for their patients. In contrast, the Current ACIP tried to justify their limitation on COVID-19 vaccine access by framing it as "individual decision making" and treating that as the same as SCDM. To me, this illustrates a shift toward individualized medicine rather than the population-based work the ACIP is supposed to do. In my view, this was an attempt to use the committee to address individual medical concerns instead of public health concerns. When public health policy is used this way, it can undermine access to vaccines and weaken disease control.

26. Prior to September 2025, SCDM recommendations were used in situations where a general recommendation was not practical for the entire population, but from which some individuals could still benefit, as in the case where the vaccine was too costly for population-based administration to prevent a single case (cost per case) or offered limited protection, as with the meningococcal B vaccine. However, Former ACIP members believed that SCDM was not being well understood by providers and that it was creating substantial confusion and hindering vaccine use. It is my understanding that, prior to their termination, the Former ACIP had been deliberating doing away with the SCDM option. Therefore, the Current ACIP's decision to implement "individual decision making" and conflate it with the already-confusing SCDM recommendation is, in my experience, a step in the wrong direction.

27. I also believe the conflation of "informed consent" with SCDM is worsening the confusion that already surrounds the SCDM recommendation. In his October 6 endorsement of ACIP's SCDM recommendation, the Deputy Secretary of Health and Human Services, who is also the acting director of the CDC, said that "Informed consent is back." Informed consent is always part of medical care, but SCDM itself is not a mechanism to ensure that informed consent is

happening. This type of statement from CDC suggests that ACIP is focused on individual health care decision making rather than working within the scope of what they are charged with doing, which is to "provide advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States."

28. Decisions coming from ACIP, including the SCDM recommendation for the COVID-19 vaccine, are not improving clarity. As a result, our team at the CHOP Vaccine Education Center spent hours writing an article for our newsletter to help explain to providers what the recommendation actually means. Between September and November 2025, almost 25% of the inquiries sent to our website have been related to the COVID-19 vaccine. These questions come from both families and clinicians. We have also received inquiries about the Current ACIP's other talking points like use of placebo-controlled trials, the ability to sue manufacturers, changes to the CDC Immunization Schedule, autism, and even questions about germ theory. This has caused us to shift resources away from other educational initiatives intended to explain science and promote public health as described above.

29. Some patients who generally support vaccination now have concerns because they worry that ACIP is no longer relying on the strongest science. For example, they are uncertain whether the U.S. flu vaccine will be reliable because they believe the usual strain-selection process was not followed.

30. I have seen firsthand how the SCDM recommendation is hindering access to the COVID-19 vaccine. Because their children's own pediatricians are not offering the COVID-19 vaccine this year, parents have contacted the CHOP Vaccine Education Center looking for a place to have their infants vaccinated, even though we are not part of CHOP's clinical services. We often

have to explain that they need to reach out to CHOP primary care or other vaccination sources, such as local health departments or pharmacies, to check availability. Providers may not be willing to vaccinate patients who do not regularly see them because they have only ordered quantities they anticipate needing for their own patients. In addition, some pharmacies may not be willing to vaccinate children with the COVID-19 vaccine.

31. The changes to the CDC immunization schedule recommendations for Covid-19 vaccination and now the January 5, 2026, changes to the childhood immunization schedule that were made without use of the typical processes of GRADE and EtR framework, have contributed to confusion, hesitancy, and mistrust around vaccines. Misconceptions have been exacerbated by federal statements and abrupt policy shifts have undermined confidence in vaccination recommendations. The "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" issued on May 19, 2025, (the "Directive"), recent votes by ACIP, and recent federal changes to the childhood immunization schedule for Covid-19 vaccination for children, and the January 5, 2026 changes to the childhood immunization schedule were implemented without scientific evidence, complicating the physician-patient relationship and setting the stage for needless negative health outcomes for patients. The harms will be devastating and ongoing unless federal changes to the CDC's immunization schedule for Covid-19 vaccination for children, and the January 5, 2025 changes to the CDC's childhood immunization schedule are immediately enjoined and the ACIP and CDC return to the evidence-based, transparent process for making vaccine recommendations that was previously relied on.

32. The harms identified above associated with the Directive, CDC's changes to the CDC immunization schedule for Covid-19 vaccination for children, and the January 5, 2026 changes to the childhood immunization schedule—as well as the anticipated harms that will result

from any additional changes that may result from the upcoming February 26, 2026 ACIP meeting—are immediate, ongoing, and compounding. Each successive change to the CDC immunization schedule will build on unresolved confusion from prior changes and further erode patient confidence in vaccines. Each change stands to amplify patient skepticism and complicate clinical counseling. In my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the potential for additional changes during the February 26, 2026 ACIP meeting will lead some families to feel confident in decisions to forgo vaccinations that would prevent future suffering absent immediate injunctive relief.

33. The harms described above are also compounded by the failure to follow established GRADE and EtR frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. Practicing physicians rely on those frameworks to understand what evidence the recommendations were based on, ensuring that they can confidently recommend and discuss vaccination for their patients because those recommendations were developed and grounded in a transparent, systematic assessment of the evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to evidence-based frameworks, physicians are less confident in the recommendations. They also have less guidance to draw on when discussing individual patient needs and approaches to vaccination. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the anticipated February 2026 ACIP actions, the harm compounds. Each deviation from those frameworks increases uncertainty, complicates patient counseling, and further erodes confidence in vaccinations, further disadvantaging clinical practice and individualized patient care absent immediate injunctive relief.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 23, 2026, in Bensalem, PA

Charlotte Moser

/s/ Charlotte Moser, MS

EXHIBIT A

Docusign Envelope ID: B210EA24-EAAC-4903-9A60-5F9EC3669F13

Advisory Committee on Immunization Practices (ACIP)

Apply for ACIP Membership

For Everyone
DECEMBER 20, 2024

AT A GLANCE

- The Centers for Disease Control and Prevention (CDC) regularly solicits applications and nominations of candidates to fill upcoming vacancies on the Advisory Committee on Immunization Practices (ACIP).
- Seats become vacant as members rotate off the committee.
- This page provides information about member roles and responsibilities as well as instructions to apply for membership on the committee.

What to know

Collapse All

Categories of membership: medical professional members and consumer representative member

Medical Professional Members

ACIP includes up to 18 voting members representing clinical medical fields (e.g., physician, nurse, nurse practitioner) and/or public health professionals (e.g., state health department, epidemiologist). These positions are held by technically qualified people trained in a clinical medical field and possessing in-depth knowledge of vaccines and immunization.

Qualifications of the medical or public health professional include the following:

- Advanced medical degree (e.g., MD, RN)
- Board certification in area(s) of specialization
- Scientific knowledge of vaccines, immunization, and/or immunization programs
- Ability to interact actively and respectfully with other ACIP voting members, as well as ACIP *ex officio* members and liaison representatives, all of whom attend each ACIP meeting
- Willingness to take part in three regularly scheduled meetings per year, and any additional meetings that may be called
- Individuals must demonstrate expertise, comfort, and facility with active participation in deliberations of the ACIP during public meetings
- Willingness to participate actively in at least two ACIP work groups
- Willingness to review and give input on ACIP recommendation statements

Lay Member: Consumer Representative

ACIP must include a consumer representative as one of the voting members of the committee. This position is held by a technically qualified person knowledgeable about consumer perspectives and/or social and community aspects of immunization programs.

Qualifications of the consumer representative include the following:

- Lay knowledge of vaccines, immunizations, and/or immunization programs
- Ability to interact actively and respectfully with other ACIP voting members, as well as ACIP *ex officio* members and liaison representatives, all of whom attend each ACIP meeting

- Willingness to take part in three regularly scheduled meetings per year, and any additional meetings that may be called
- Individuals must demonstrate expertise, comfort, and facility with active participation in deliberations of the ACIP during public meetings
- Willingness to participate actively in at least two ACIP work groups
- Willingness to review and give input to ACIP recommendation statements

Membership qualifications

ACIP members are acknowledged experts with an outstanding record of achievement in their own field and an understanding of the immunization issues covered by ACIP. They have a responsibility to provide CDC with high quality, well-considered advice and recommendations on matters described in the ACIP Charter.

Qualities required for ACIP members

Below are the criteria that will be applied when assessing candidates. To be considered, you must be able to demonstrate that you have the qualities, skills and experience to meet all the criteria.

Candidates must have:

- An understanding of the vaccination and immunization issues covered by the ACIP;
- An understanding of immunization issues in the U.S., including the routine domestic immunization program and vaccines used for special circumstances, e.g. “travel” vaccines;
- An outstanding record of achievement and personal credibility within their own field;
- Experience of operating at a strategic level in the public or other sectors;
- Experience of working effectively in high level advisory committees;
- Excellent interpersonal and communication skills to support effective discussion with a range of stakeholders;
- Ability to evaluate complex issues and weigh conflicting opinions;
- Ability to influence at a senior level;
- A broad range of expertise and interest in vaccines and immunization.

Member roles and responsibilities

The Chair and members of the committee play a critical role in ensuring ACIP's continued standing as a nationally and internationally recognized leading body in the field of immunization and that it continues to observe the highest standards of impartiality, integrity and objectivity in its deliberations and that its recommendations are driven by available scientific evidence. Members of ACIP will:

- Be committed to continued development and improvement in this important area of public health;
- Bring relevant experience to the committee;
- Contribute to the provision of high quality and considered public health advice to the CDC and DHHS;
- Be expected to make a full and considered contribution to the work of the committee and to contribute fully to the debate and to the decision-making processes;
- Provide expert guidance when an issue that falls within your particular area of expertise is under discussion;
- Contribute to the debate in the capacity of a well-informed health professional when the issue does not fall within your expertise;
- Take into account the need for and impact of vaccines, the quality and safety of vaccines and strategies to ensure that the greatest benefit can be obtained from the most appropriate use of vaccines;
- Be prepared to respond quickly to interaction by e-mail;
- Be prepared, as requested by the Secretariat, to attend and contribute to the work of one or more of the ACIP work groups, which report to the ACIP;
- Be committed to declare all relevant interests. Any reported interest that could be perceived as a potential conflict of interest will be disclosed during public ACIP meetings and in written meeting minutes, which are posted on the ACIP website.

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All members serve in their personal capacity and should refrain from promoting the policies and views and products of the organization/institution for which they work.

Compensation

Appointments are not remunerated. However, members are compensated for expenses incurred by attendance at meetings. Such compensation, which includes the issuance of airline tickets, per diem to cover lodging, meals and incidental expenses will be in accordance with DHHS/CDC travel rules. An optional honorarium of $250/day for each day that a member attends an ACIP meeting is offered to voting members, who are designated as Special Government Employees during their tenure on the committee.

Location of meetings and time commitment

ACIP meets three times annually for a two- to three-day meeting at CDC in Atlanta, GA. The meetings take place usually during the third or fourth week in the months of February, June, and October, and meeting dates are posted on the ACIP website. Some preparation time for meetings will be required, which may involve weekends. In addition, members will be asked to participate in at least two ACIP work groups, which usually hold virtual one- to two-hour meetings, once or twice per month. Overall, including meeting and travel time, participation in virtual meetings, e-mail interaction, and participation in work groups, one can expect approximately a three-week commitment spread over the year.

Appointments and tenure

- Members will be appointed for a term of four years, which typically begins on July 1 in the year of appointment.
- In general, a member's term may not be extended beyond four years, and appointment to a second term is not allowed.
- The Chair shall be appointed for a term of up to three years. The Chair is selected and appointed by the HHS Secretary from among voting ACIP members with at least two years of experience serving on ACIP, that have demonstrated the ability both to lead the work of similar bodies and to work effectively with CDC.

Orientation and education

Orientation for new members is provided to enable members to fully understand the work and functioning of the ACIP, including participation in ACIP work groups. This is typically offered as a two-hour virtual meeting within one month of appointment of new members. The Secretariat will further arrange briefings and meetings with CDC staff and any other training in order to facilitate the full engagement of new members in the work of the ACIP.

The ACIP Secretariat also arranges educational sessions on topics such as the role of health economics in development of ACIP recommendations, immunization safety monitoring and procedures used in development of evidence-based recommendations. These sessions are sometimes held at the CDC on the day before an ACIP meeting.

Conflicts of interest

ACIP members are required to declare any potential conflicts of interest that arise in the course of ACIP tenure and any relevant business interests, positions of authority or other connections with organizations relevant to the work of the ACIP. Upon appointment, each voting member is required to file an Office of Government Ethics 450 form (OGE450), a Confidential Financial Disclosure Report, which is reviewed by the ACIP Secretariat, the Federal Advisory Committee Management Branch and the Office of General Counsel at CDC. Confidential Financial Disclosure must be updated annually during a member's term. At every ACIP meeting, the Chair calls for conflict of interest disclosure from each voting member at the opening of the meeting and prior to any vote taken by the ACIP.

Any actual or perceived conflict of interests will be explored fully by the Secretariat, CDC's Federal Advisory Committee Management Branch, and CDC legal counsel if necessary.

Members with declared interests will be asked to recuse themselves from participating in the discussion and decision-making of the issues relating to that interest. A member who has any doubt as to whether they have an interest that should be declared, or whether they should take part in the proceedings, should ask the Secretariat for guidance.

Application information

The ACIP Secretariat receives applications at any time of the year for candidates to fill upcoming vacancies on the ACIP. Selection of members is based on candidates' qualifications to contribute to the accomplishment of ACIP objectives.

The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of professional training and background, points of view represented, and the committee's function. Consideration is given to a broad representation of geographic areas within the U.S., with equitable representation of the sexes, ethnic and racial minorities, and the handicapped. Preference is given to candidates who are U.S. citizens.

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Candidates should submit the following items:

- Current ***curriculum vitae,***
- Two letters of recommendation from professional colleagues familiar with your work. A maximum of four letters of recommendation will be accepted.
  - Letters of recommendation should not come from current ACIP members.
  - At least one letter of recommendation must come from a professional colleague who is not employed by the U.S. Department of Health and Human Services (e.g., NIH, FDA, etc.). CDC employees should not provide letters of recommendation.
- A cover letter that includes a statement of interest in serving on the ACIP, qualifications and expertise, and written evidence to support all of the relevant criteria, which are identified in the "Membership Qualifications" section of this page.

The CV should include candidates' education, training, board certification and career history and list main areas of employment or other relevant activity and public appointments, if any. Include details of any relevant academic or professional qualifications.

A review of all applications will be conducted by the ACIP Steering Committee, with final selection of the candidates to be made by the Secretary, Department of Health and Human Services. Successful candidates will be notified of their appointment and those candidates not accepted will be informed in writing. Unsuccessful applicants are encouraged to re-apply in subsequent years. The need for various kinds of expertise varies from year to year and a candidate who is not selected in one year may be appointed in a subsequent year.

Complete online application

Access the online application. All candidates are required to submit their materials through the online application system. You must re-apply through the online application each year you would like to be considered for membership.

If you have previously submitted an application through our online system you may review and update your application. You must click the submit button to reapply every year, even if no new documents are submitted.

If you have any questions regarding these procedures, please email the ACIP Secretariat at ACIP@cdc.gov.

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases (NCIRD)

EXHIBIT B

From: Oden, DeChaka (CDC/OCOO/OHR)
To: Moser, Charlotte A
Subject: [External]CDC-Termination SF50
Date: Thursday, June 5, 2025 10:01:56 AM
Attachments: Moser, Charlotte SF50.pdf

You don't often get email from xvn4@cdc.gov. Learn why this is important

Greetings,

Please find your SF50 attached.

Thank you,
CDC, Office of Human Resources

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EXHIBIT C

From: OHRseparations (CDC)
To: Moser, Charlotte A
Subject: [External]Committee Member - Dr. Moser
Date: Monday, June 9, 2025 11:41:01 AM
Attachments: image001.png

You don't often get email from ohrseparations@cdc.gov. Learn why this is important

Distinguished Committee Member

Dear Dr. Moser,

We would like to add clarity to the email you received on June 5, 2025, from the CDC Office of Human Resources (OHR), Client Services Operations, team in reference to your Committee Member appointment. Your current term has not yet been extended. Renewal by Department of Health and Human Services (HHS) is pending.

Please note that our personnel data system only allows extensions in one-year increments and the system automatically generated a termination notice. This was an internal HR administrative process unrelated to your standing in the Committee. We sincerely apologize for the oversight and thank you for your service.

Isaac Anderson
Director, Client Services Operations
Office of the Chief Operating Officer (OCOO)
Office of Human Resources (OHR)
404-718-4073 (office); 210-863-9832 (cell)
fxd2@cdc.gov

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EXHIBIT D

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https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112

OPINION COMMENTARY Follow

RFK Jr.: HHS Moves to Restore Public Trust in Vaccines

We're reconstituting an advisory committee to avoid conflicts of interest.

By Robert F. Kennedy Jr.

June 9, 2025 4:00 pm ET



A nurse holds a Pfizer-BioNTech Covid-19 vaccine in Miami, May 29. PHOTO: JOE RAEDLE/GETTY IMAGES

Vaccines have become a divisive issue in American politics, but there is one thing all parties can agree on: The U.S. faces a crisis of public trust. Whether toward health agencies, pharmaceutical companies or vaccines themselves, public confidence is waning.

Some would try to explain this away by blaming misinformation or antiscience attitudes. To do so, however, ignores a history of conflicts of interest, persecution of dissidents, a lack of curiosity, and skewed science that has plagued the vaccine regulatory apparatus for decades.

That is why, under my direction, the U.S. Department of Health and Human Services is putting the restoration of public trust above any pro- or antivaccine agenda. The public must know that unbiased science guides the recommendations from our health agencies. This will ensure the American people receive the safest vaccines possible.

Today, we are taking a bold step in restoring public trust by totally reconstituting the Advisory Committee for Immunization Practices (ACIP). We are retiring the 17 current members of the committee, some of whom were last-minute appointees of the Biden administration. Without removing the current members, the current Trump administration would not have been able to appoint a majority of new members until 2028.

ACIP evaluates the safety, efficacy and clinical need of the nation's vaccines and passes its findings on to the Centers for Disease Control and Prevention. The committee has been plagued with persistent conflicts of interest and has become little more than a rubber stamp for any vaccine. It has never recommended against a vaccine—even those later withdrawn for safety reasons. It has failed to scrutinize vaccine products given to babies and pregnant women. To make matters worse, the groups that inform ACIP meet behind closed doors, violating the legal and ethical principle of transparency crucial to maintaining public trust.

In 2000 the House issued the results of an investigation of ACIP and another vaccine advisory committee under the U.S. Food and Drug Administration—the Vaccines and Related Biological Products Advisory Committee. It found that enforcement of its conflict-of-interest rules was weak to nonexistent. Committee members regularly participated in deliberations and advocated products in which they had a financial stake. The CDC issued conflict-of-interest waivers to every committee member. Four out of eight ACIP members who voted in 1997 on guidelines for the Rotashield vaccine, subsequently withdrawn because of severe adverse events, had financial ties to pharmaceutical companies developing other rotavirus vaccines. A 2009 HHS inspector-general report echoed these findings. Few committee members completed full conflict-of-interest forms—97% of them had omissions. The CDC took no significant action to remedy the omissions.

These conflicts of interest persist. Most of ACIP's members have received substantial funding from pharmaceutical companies, including those marketing vaccines. The problem isn't necessarily that ACIP members are corrupt. Most likely aim to serve the public interest as they understand it. The problem is their immersion in a system of industry-aligned incentives and paradigms that enforce a narrow pro-industry orthodoxy. The new members won't directly work for the vaccine industry. They will

exercise independent judgment, refuse to serve as a rubber stamp, and foster a culture of critical inquiry—unafraid to ask hard questions.

A clean sweep is needed to re-establish public confidence in vaccine science. In the 1960s, the world sought guidance from America's health regulators, who had a reputation for integrity, scientific impartiality and zealous defense of patient welfare. Public trust has since collapsed, but we will earn it back.

Mr. Kennedy is secretary of health and human services.

Further Reading

HHS to Stop Recommending Routine Covid Shots for Children, Pregnant Women

How RFK Jr. Is Boosting 'Food Babe' and Other MAHA Acolytes

Trump's FDA Sends a Bullish Signal to Biotech

OPINION **RFK Jr. Is Already Vindicating His Critics**

Videos

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EXHIBIT E

From: FACM Policy and Oversight Team (CDC)
To: Moser, Charlotte A
Subject: [External]Advisory Committee on Immunization Practices Notice
Date: Monday, June 9, 2025 5:51:07 PM

You don't often get email from facmpo@cdc.gov. Learn why this is important

To Charlotte Moser:

Per the June 9, 2025 directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).

We appreciate your prior service and commitment.

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EXHIBIT 49

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916 District Judge: William G. Young Magistrate Judge: M. Page Kelley

DECLARATION OF JANE DOE 3

I, Jane Doe 3, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old.

2. I reside in the state of Washington.

3. I am immunocompromised, which places me at a substantially increased risk of severe illness, hospitalization, or death if I contract Covid.

4. I am the mother of two minor children, sons ages 16 (Jimmy) and 14 (Timmy).

5. Both of my sons are neurodivergent.

6. Jimmy and Timmy both have anxiety disorders and attention deficit hyperactivity disorder ("ADHD") and Jimmy also has autism.

7. In addition to his underlying anxiety and ADHD, Timmy Doe has a severe needle phobia.

8. I hold a Master's degree in Public Health and Epidemiology and a Bachelor of Science (major in biology and minors in chemistry and mathematics).

9. My children and I have followed public health guidance throughout the Covid pandemic, including receiving recommended vaccinations. This year, both my sons again wanted to receive the Covid booster before school starts on August 27, 2025, so they would be fully protected at the start of the school year.

10. I saw the announcement that the Secretary of the Department of Health and Human Services ("Secretary") made on X on May 27, 2025, ordering the Centers for Disease Control and Prevention ("CDC") to remove from its immunization schedules the recommendation that healthy pregnant individuals and children ages 6 months–17 years get the Covid vaccine (the "Directive"). As an immunocompromised parent, this decision alarmed me and my children. They do not want to contract Covid or risk passing it to me, and they expressly wanted the vaccine before school began.

11. On August 8, 2025, I personally received a Covid vaccine from a national pharmacy chain. I scheduled that appointment online and was vaccinated without issue that day.

12. I used the same pharmacy's online scheduling system to book Covid vaccination appointments for both of my sons for August 14, 2025. The system accepted their birthdates and allowed me to select the Covid vaccine for each child.

13. On the night of August 13, 2025, anticipating his vaccine appointment, Timmy Doe suffered an anxiety attack.

14. Before entering the pharmacy on August 14, 2025, Timmy Doe had a panic attack including hyperventilating, crying, clenching his teeth, shaking, and other physical symptoms of his anxiety and needle phobia.

15. I drove my electric vehicle to the chain pharmacy on August 14, 2025 with my two sons at the time of their scheduled vaccine appointment. I checked in with pharmacy technician at the pharmacy counter, and my children sat in the seats behind me. After checking in with the pharmacy technician, she got the pharmacist (a female with short dark hair) who came to the counter to speak with me.

a. The pharmacist stated that the new vaccine is coming out in September and I said, we don't know that. The pharmacist then asked if my children previously received the vaccine, and I said yes. The pharmacist responded, "then why do you need it?" I explained to the pharmacist that "I wanted my children protected before school started, and as it takes up to two weeks to obtain the full effect of the Covid vaccine, I wanted them to receive the vaccine now."

b. The pharmacist then took out her phone and started scrolling through something on her screen. The pharmacist then looked up from her phone and told me, "I cannot give them the Covid vaccine because they are not in the eligible age group." When I asked, "what is the eligible age group?," the pharmacist replied, "either over 60 or 65 is the eligible age group." The pharmacist then ended the conversation by stating that she would not vaccinate my sons because they are not in the eligible age group.

16. As a result of being turned away by the pharmacist, my children remained unvaccinated until September 12, 2025. Until they could be vaccinated, both boys were deeply upset—they were fearful of catching what they call the new Covid strain's "razor-blade throat" and even more fearful of infecting me given my compromised immune system.

17. I have experienced firsthand the confusion, anxiety, and disruption caused by the Secretary's Directive. Before the Directive, my children were eligible for and received the Covid vaccine. I encountered absolutely no issues getting my children the Covid vaccine last year. After

the Directive, my children were refused vaccination at a national pharmacy chain, leaving them and me more vulnerable to the virus.

18. The denial of vaccination for my children is a direct consequence of the Directive. Vacating that Directive would immediately benefit me and my children by restoring their ability to receive the vaccine and reduce our risk of severe illness. I am joining this lawsuit because I and my children have suffered, and continue to suffer, personal harm as a result of the Directive. I therefore urgently seek relief that will protect my children and me from the ongoing threat of Covid.

19. I made a second appointment for Jimmy and Timmy to be vaccinated against covid-19 at a local national chain pharmacy for September 12, 2025. I told my sons about their appointment the night before on September 11, 2025.

20. On September 11, 2025, anticipating his vaccine appointment for the following day, Timmy Doe had another anxiety attack.

21. Routine is very important to Timmy as a neurodivergent individual and it is critical to the success of his coping mechanisms for his mental health struggles. When we were denied the covid-19 vaccine because of the Directive, his routine around vaccinations was disrupted, and now he cannot readily rely on clear expectations what a vaccine appointment will look like, which exacerbates his anxiety and phobia symptoms, and contributed to triggering and exacerbating the severity of his anxiety attack on September 11, 2025.

22. Timmy Doe's anxiety attack on September 11, 2025 was caused, at least in part, by the disruption of his expectations about what a vaccine appointment entails because we were denied the vaccine during the August 14, 2025 appointment.

23. School started for Timmy Doe on August 27, 2025. Because the pharmacist denied him the covid-19 vaccine on August 14, 2025 due to the Directive, he was not vaccinated when school started. One of his classes had a celebrating involving food, and Timmy, fearing contracting covid-19 and giving it to his immunocompromised mother, did not feel comfortable taking his mask off to enjoy the class treat. As a result, he was unable to participate fully in the celebration and suffered an element of social ostracism. Had he received the vaccine on August 14, 2025 as planned, he would have participated in the class event and avoided the social ostracism.

24. The recent changes to align the Child and Adolescent Immunization Schedule with the Denmark childhood schedule compounds the anxiety that I and my children feel about my immunocompromised-status. If other people choose not to get vaccinated or choose not to vaccinate their children because of the status changes, it puts me and my children at risk.

25. The recent changes to align the Child and Adolescent Immunization Schedule with the Denmark childhood schedule also have raised questions about my children's future vaccinations. For flu and Covid-19 vaccinations, they will have to go to the doctors' office to participate in shared clinical decision making. My children's doctors' office is 45 minutes further than our local pharmacy, where my children would normally receive these vaccinations. Needing to travel to the doctors' office to obtain these vaccinations will raise my electric bill because I will need to charge my electric vehicle to make this trip.

26. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath to the truth of these facts.

27. Prior to driving my electric vehicle to the pharmacy on August 14, 2025, I charged my electric vehicle at my home. My electric bill is higher than it would have been had I not driven

to the pharmacy and back on August 14, 2025 for my sons' vaccine appointment. The only reason I went to the pharmacy that day was to get my sons vaccinated against covid-19.

I declare under penalty of perjury under the laws of the United States of America and the State of Washington that the foregoing is true and correct.

Executed on January 25, 2026.

Jane Doe 3

/s/

Jane Doe 3

EXHIBIT 50

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; *et al.*, *Defendants.*	Case No. 1:25-cv-11916 (BEM) District Judge: Hon. Brian E. Murphy Magistrate Judge: Hon. M. Page Kelley

DECLARATION OF JANE DOE, MD

I, Jane Doe, MD, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. In October 2025, I gave birth to a full-term baby.

2. I talked with my obstetrician about my interest in receiving a Covid-19 vaccine during my pregnancy to protect me and Baby Doe. My obstetrician strongly endorsed my decision to get a Covid-19 vaccine and instructed me to wait until I was at least 34 weeks pregnant to ensure the best chance of maximally protecting Baby Doe from the upcoming respiratory season, especially because Baby Doe will be ineligible to get a Covid-19 vaccine for her first respiratory season.

3. My physician counseled me that, because of the Secretary's May 28, 2025 Directive rescinding the recommendation that healthy children and pregnant women receive routine Covid-19 vaccines, there has been such confusion in the medical community about who is eligible for the Covid-19 vaccine and, as a result, her patients have been having difficulty

getting the vaccine at the point in their pregnancies that afforded them maximal protection. In July 2025, my obstetrician told me that because of the uncertainty about whether I would be able to actually access the Covid-19 vaccine at the point in my pregnancy that would be maximally beneficial for my baby, she was deviating from her recommendation that I follow the standard of care and recommended, instead, that I consider trying to get a version of the Covid-19 vaccine that was developed for the 2024–2025 respiratory season earlier than she would normally recommend.

4. My obstetrician counseled me that even if I could access a 2024–2025 Covid-19 vaccine and my insurance agreed to cover me getting that Covid-19 vaccine before my pregnancy progressed to 34 weeks, if I wanted to get a 2025–2026 Covid-19 vaccine when it came out in the fall of 2025 when I would be at least 34 weeks pregnancy, my insurance carrier would likely deny my insurance claim for an updated 2025–2026 Covid-19 vaccine because I will have received some form of Covid-19 vaccine too recently.

5. My reasonable belief that I would encounter difficulty accessing a Covid-19 vaccine as a pregnant individual once I was 34 weeks pregnant was based on the information provided to me by my obstetrician. My obstetrician openly told me that the medical advice she gave me this summer is different advice than she would have given me without the Secretary's Directive.

6. Once the Directive rescinded the recommendation that healthy pregnancy women receive the Covid-19 vaccine, it forced me to gamble with my baby's life and my family's finances insofar as I was faced with the decision of whether to try to get a 2024–2025 vaccine and risk jeopardizing the protection to my baby girl or waiting with hope that we can get a 2025–2026 vaccine to better protect her with the knowledge that if we wait, we may not be able to get

any protection. I am not a betting person, and Mr. Kennedy demanded that I bet my firstborn child.

7. The magnitude of the dilemma the Secretary's Directive put me in was augmented by the fact that, under the Secretary's Directive, my daughter will not be able to receive a Covid-19 vaccine at all until she is at least six months old—after her first respiratory viral season—and she will be unable to receive a Covid-19 vaccine as a routine matter after she is born until she becomes an adult.

8. I needed to try to give Baby Doe the maximum protection possible while she was still in the safest place for her: my womb. The Secretary's Directive and outcome of the subsequent vote at the September ACIP meeting forced me to risk my baby's health and deprived me of my fundamental right as her mother to make the best decisions for my daughter, and my fundamental right to direct my personal medical decisions.

9. I have lost many hours of sleep worrying for my daughter's health and specifically about what decision I should have made once I was faced with the decision to either accept the sub-optimally timed old vaccine and paying out of pocket for a second updated vaccine, or waiting and risking my baby's best chance to be protected against this deadly virus.

10. My health suffered as a result of the stress of this decision; specifically, I lost sleep and suffered headaches and fatigue. I was fatigued and getting headaches at work because of the stress that the barriers to accessing the vaccine the Directive and outcome of the subsequent vote at the September ACIP meeting have caused, and my fatigue and headaches were negatively affecting my productivity at work.

11. Agonizing over the decision of whether to wait to get the 2025–2026 vaccine or accept the sup-optimally timed old vaccine, I actually contracted the Covid-19 virus on September 1, 2025.

12. Even though I actually contracted the Covid-19 virus during my pregnancy, my obstetrician counseled me that the Covid-19 vaccine was still the best way to protect my baby so I sought to be vaccinated.

13. I learned of pregnant women being denied the Covid-19 vaccine because of the Directive, and as a result of learning that, I called several pharmacies and my employer's employee health resources to try to figure out if I could get a Covid-19 vaccine during my pregnancy to protect myself and my baby. I spent significant time sorting out their various answers which ranged from being unable to tell me if I am eligible for the vaccine as a pregnant woman based on the Directive, and that I *should* be able to get it if I made an appointment, but the pharmacies I called could not make any guarantees that I would be able to get the vaccine there during my pregnancy. I reviewed news articles to try to get some insight where I might be successful in getting a Covid-19 vaccine, so I could best plan my attempt to get a vaccine for the highest chance of success. Today.com has reported that, even if pregnancy did not render me ineligible for the new 2025–2026 Covid-19 vaccine categorically, I wouldn't be able to get the new 2025–2026 Covid-19 vaccine in Massachusetts where I would, and I would need a prescription in Connecticut where I live. *Are the New COVID Vaccines Available, and Can You Get One? It Depends, Experts Say.* TODAY.COM (Sept. 10, 2025) https://www.today.com/health/coronavirus/covid-vaccine-2025-2026-rcna228529.

14. I mad calls to doctor's offices, pharmacies, and other individuals in my quest to get a Covid-19 vaccine in between patient appointments, at times when I would otherwise have been putting my efforts to profitable use.

15. I was far from sure that my insurance would pay for the Covid-19 vaccine. I had heard of insurance carriers rescinding coverage for the Covid-19 vaccine for pregnant women based on the Secretary's Directive. Because I am not privy to the internal workings of my insurer, I was not guaranteed advance notice of insurance changes regarding coverage for the Covid-19 vaccine.

16. My husband and I have significant educational debt, and on a medical trainee's salary with a baby on the way, I cannot afford to pay out of pocket for whatever the pharmacy wants to charge for a Covid-19 vaccine. Some pharmacies in my area are charging more than 200 dollars for a single Covid-19 vaccine out of pocket. *See Immunization*, CVS (last accessed Jan. 22, 2026) https://www.cvs.com/immunizations/covid-19-vaccine.

17. I ruminated over whether the Covid-19 vaccine will be actually or functionally available to me to protect myself and my baby and it caused significant stress to myself and my baby by proxy. As a result of the stress I felt about not being able to get a Covid-19 vaccine because of the barriers the Directive had caused, I lost sleep and suffered stress-induced headaches and fatigue. I am sure that these symptoms and the underlying stress induced by the Directive compromised my immune system and left me more susceptible to contracting Covid-19 when I did.

18. After much planning and preparation, I did receive a Covid-19 vaccine during my pregnancy; however, the physical symptoms of stress I was under leading up to the vaccine appointment were a burden on me and my baby and negatively affected my productivity at work,

which was already reduced by the burden of coordinating with pharmacies and doctor's offices. I would not have suffered of these symptoms if not for the Directive.

19. Now that I am a mother, I am responsible for making the best choices for my child. The CDC's actions to subject Covid-19 vaccination recommendations to shared clinical decision making ("SCDM") for pediatric patients will impose obstacles to my child being able to receive Covid-19 vaccines when she becomes eligible at 6 months of age. I will inevitably have to spend additional time and resources coordinating vaccinating Baby Doe when she becomes eligible to receive the vaccine. I will have to divert time away from productively working toward coordinating getting her a Covid-19 vaccine.

20. Likewise, the CDC's actions changing the Child and Adolescent Immunization Schedule to align with Denmark's childhood immunization schedule and downgraded other vaccines to SCDM for pediatric patients have caused stress and anxiety relating to Baby Doe receiving her vaccines. I am concerned as to whether Baby Doe's four-month vaccinations will proceed as scheduled, and this concern causes the same symptoms, including loss of sleep and anxiety, as produced by the changes implemented to the Covid-19 vaccine schedule. I will inevitable have to spend time and resources ensuring that Baby Doe receives her four-month vaccinations, and in doing so I will have to divert time that would otherwise be spent productively working.

21. The stress I feel knowing that I will have to fight for my child to access basic, scientifically-backed healthcare resources is causing me continued physical symptoms, including contributing to continued sleep loss, headaches, and fatigue.

22. Additionally, I am likely to become pregnant in the future and I reasonably expect that I will have to navigate similar obstacles to obtaining the Covid-19 vaccine to protect myself

and any future children I may have. The prospect of needing to navigate the hurdle of obtaining appropriate vaccinations, such as the Covid-19 vaccine in connection with a future pregnancy or vaccines for my newly born children, is exhausting and has contributed to my current fatigue, headaches, and sleep loss.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 25, 2026.

Jane Doe, MD

/s/
Jane Doe, MD

EXHIBIT 51

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916

DECLARATION OF ROBERT H. HOPKINS, JR., MD, MACP, FAAP

I, Robert H. Hopkins, Jr., MD, MACP, declare pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. Based on my over 30-year career as an Internal Medicine and Pediatrics physician, the recent arbitrary and unsupported decisions regarding COVID-19 vaccines by the Secretary of Health and Human Services Robert F. Kennedy, Jr., the Advisory Committee on Immunization Practices ("ACIP"), and the Centers for Disease Control and Prevention ("CDC") are harming me as a practicing physician and causing preventable suffering and death to Americans.

2. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath. I submit this supplemental declaration in support of Plaintiffs in this matter and in support of Plaintiffs' Fourth Amended Complaint and Motion for Preliminary Injunction. I am over the age of 18 and make this declaration based on my personal knowledge.

3. I am a board-certified Internal Medicine physician with an active clinical practice as Professor and immediate-past Chief of the Division of General Internal Medicine at the

University of Arkansas for Medical Sciences College of Medicine, which is our state medical school in Little Rock, Arkansas.

4. I conduct clinical care for both pediatric and adult patients, including pregnant persons.

5. From 2020–2022, I served as medical director for COVID testing and vaccination at the University of Arkansas for Medicinal Sciences.

6. I spend a significant part of my day counseling patients, trainees, and residents about vaccines, and I would consider myself the go-to person in my clinical setting for questions about vaccination.

7. I am an active member of the American College of Physicians ("ACP") and the current chair of the ACP Immunization Committee.

8. I am also actively involved with the Advisory Committee on Immunization Practices ("ACIP") of the Centers for Disease Control and Prevention ("CDC") as I served on several vaccine work groups, such as the COVID-19 Vaccines Work Group, Pneumococcal Vaccines Work Group, the Influenza Vaccines Work Group, and the Combined Schedule Work Group.

9. On May 19, 2025, the Secretary of Health and Human Services Robert F. Kennedy, Jr. (the "Secretary") issued a "Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less than 18 years of Age and Pregnant Women" (the "May 19 Secretarial Directive"). The Secretary stated, "I have determined that the known risks associated with the use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine." *See* Ex. A. The May 19 Secretarial Directive directed the CDC to "remove COVID-19 vaccines from the recommended Child and Adolescent Immunization

Schedule by Age and recommended vaccines during pregnancy." In September 2025, ACIP recommended the downgrade of the COVID-19 vaccine to shared clinical decision making ("SCDM") for essentially all children and adults and in October 2025 the CDC improperly conflated this recommendation with "informed consent".

10. The May 19 Secretarial Directive and recent actions by ACIP and the CDC were taken in contravention to the robust data compiled and presented by the COVID-19 Vaccines Work Group for years regarding the effectiveness of the COVID-19 vaccines, particularly for pregnant persons and children.

11. On June 9, 2025, the Secretary terminated all 17 voting members of ACIP. Because each work group must include at least two voting members of ACIP, all work groups were automatically terminated as a result.

12. The Secretary appointed new ACIP members ahead of the June 25–26, 2025 ACIP meeting, but only the COVID-19 Vaccines Work Group met before the September ACIP meeting. The Influenza Vaccine Work Group and the other work groups that I have participated in have not, to my knowledge, met since the Secretary's termination of the ACIP members on June 9, 2025, and therefore have not reviewed any new data or studies on COVID-19 vaccinations that would support the downgrade to SCDM. I understand from presentations at the December ACIP meeting that additional workgroups have been reconstituted focused on the childhood vaccination schedule and vaccine safety.

13. Non-governmental organizations, including the American Academy of Pediatrics and the American College of Obstetricians and Gynecologists, typically appoint liaison members to ACIP Work Groups, such as the COVID-19 Work Group and the Influenza Vaccine Work Group. These liaison members are experts in clinical medicine, vaccinology, pharmacy, and other

fields involved in vaccine research and delivery to patients. The role of the liaison is to represent their organization and advise ACIP on clinical and scientific issues relevant to vaccines and vaccinations. Many liaison members have served as external experts informing ACIP for a decade or more, and some are former ACIP voting members.

14. Typically, for prior ACIP meetings that I attended as a Liaison, I would receive an invitation to participate at the meeting along with documents and presentations that would be discussed at the ACIP meeting. This usual format was not followed prior to the June 25–26, 2025 ACIP meeting.

15. I received an invitation for the June 25, 2025 ACIP meeting the night before.

16. On the morning of June 25, 2025, after having issues with the Zoom link provided by the CDC, I was eventually able to join the call, but I was unable to access my video and microphone functions. As a result, I was unable to participate in the usual roll call of liaison members that takes place at the beginning of each ACIP meeting. The inability for liaison members to participate was blamed on "technical difficulties."

17. It took several hours for the "technical difficulties" to be resolved, so liaisons were unable to participate for most of the ACIP meeting on June 25, 2025. Generally, liaison members are able to speak at any point during an ACIP meeting as recognized by the Chair.

18. On the afternoon of June 25, 2025, I was able to access the audio function for the ACIP meeting, although I did not participate unless I was called upon by the ACIP Chair.

19. On June 26, 2025, there was a presentation at the ACIP meeting regarding thimerosal-containing influenza vaccines followed by three votes on the subject, which was a complete deviation from the normal practice that I have observed and participated in as an ACIP Liaison member.

20. Previously, in the Influenza Work Group, which I was a member of for 4 years and a Liaison for 1.5 years, we would have robust discussions and presentations regarding the epidemiology of the influenza disease. We would examine data regarding the effectiveness of the influenza vaccines during the current season and at the end of the season. We would also discuss vaccine safety and hear presentations from manufacturers about any changes in the vaccines. The Influenza Vaccines Work Group would then discuss implementation challenges, opportunities, and changes in vaccine strains for the upcoming flu season.

21. Whenever there is a change in recommendation for a vaccine, it goes through a certain process which is laid out in the Evidence to Recommendation ("EtR") framework that is published in the Mortality and Morbidity Weekly Report published by the CDC. The EtR framework is a structured, evidence-based process of review of vaccine evidence which is meant to allow the ACIP to consider vaccine safety, efficacy, access and availability, equity, and acceptability to the public. None of these processes were followed for the decision to remove thimerosal from seasonal influenza vaccines. Indeed, a retired nurse without a robust scientific background presented a non-peer-reviewed presentation with questionable assertions of data that contradicted standard practice, without quality evidence, without a work group-created evidence-recommended framework, and used junk data regarding thimerosal-containing vaccines that has been thoroughly studied and debunked. *See* Ex. B Thimerosal as a Vaccine Preservative, CDC ACIP Meeting (June 25, 2025) https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/05-influenza-redwood-508.pdf (presented by Lyn Redwood RN, MSN, FP (Retired)).

22. Following this presentation, there was a discussion during which Dr. Meissner and several liaison members raised valid concerns about the presentation. Several public commenters also raised concerns about the presentation and the upcoming vote. However, the ACIP voting

members then rushed into a series of votes and voted "yes" on removing thimerosal-containing influenza vaccines for children, pregnant women, and all adults, which was not supported by the evidence.

23. I did virtually attend the September 2025 ACIP meeting. There were no technology issues as in the June 2025 meeting, and all liaisons were able to sign on virtually and make comments for most of the meeting. The ACIP voting members, without presenting any robust analysis of evidence in support of their recommendation, including GRADE tables, and without following the EtR framework for evaluating the quality of evidence, voted against the advice of the liaisons and changed the COVID-19 immunization schedule to SCDM. This was only the second time in my years as serving as a Work Group Liaison that the EtR framework was not followed for a vaccine recommendation—the first being at the June 2025 ACIP meeting.

24. The Secretary's May 19, 2025 decision and recent actions by the ACIP and CDC to downgrade the CDC immunization schedule recommendation for COVID-19 vaccination to SCDM for essentially all adults and children has harmed and will continue to harm my patients.

25. Despite the Secretary's May 19, 2025 Directive and recent ACIP recommendation on COVID-19 vaccinations, I continue to counsel patients on the COVID-19 vaccination based on the evidence—that it is beneficial for pregnant women and children because it prevents severe illness and death.

26. The Secretary's May 19, 2025 Directive and recent ACIP vote on COVID-19 vaccinations now require that I spend more time counseling patients, specifically pregnant persons and parents of children, regarding the safety of the COVID-19 vaccine. Approximately half of the patients I see in a given day require counseling on COVID-19 vaccines. These meetings can be anywhere from 2–5 minutes long for patients who have previously gotten the COVID-19 vaccine

or a booster shot, and up to 10 minutes long for patients who have never had a COVID-19 vaccine or booster shot. The SCDM discussion is expected to be paid for by the vaccine administration fee, which is billed for vaccines which have been administered. There is no payment for vaccine counseling which does not result in a vaccine being administered, which accounts for approximately 20–25% of the SCDM conversations in my practice.

27. After these discussions, several patients, such as parents of young children, have refused to get the COVID-19 vaccine for their child due to vaccine skepticism that has increased since the Secretary's May 19, 2025 Directive.

28. Despite the Secretary's May 19, 2025 Directive, my practice is to provide the most optimal care possible for my patients, which includes giving the COVID-19 vaccine to pregnant persons and children in accordance with the science.

29. Indeed, at the April 15–16, 2025 ACIP meeting, which I attended in my capacity as a Liaison for the National Foundation for Infectious Diseases ("NFID"), the COVID-19 Vaccines Work Group presented five different presentations regarding the COVID-19 vaccines and ended with the Work Group's considerations for use of the 2025–2026 COVID-19 vaccines. *See* Ex. C, *ACIP COVID-19 Vaccines Work Group*, CDC ACIP Meeting (April 15, 2025) https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/01-Schechter-COVID-508.pdf (presented by Robert Schechter, MD, MSc); Ex. D *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, CDC ACIP Meeting (April 15, 2025) https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf (presented by Lakshmi Panagiotakopoulos, MD, MPH).

30. At the April 15–16, 2025 ACIP meeting, the COVID-19 Vaccines Work Group presented policy options for 2025–2026 COVID-19 vaccines based on the evidence gathered from

our meetings concerning a multi-dose initial series for persons ages 6 months to 4 years and those who are immunocompromised. *See* Ex. D at 8. The COVID-19 Vaccines Work Group also presented policy options regarding annual COVID-19 vaccine doses and semi-annual COVID-19 vaccine doses. *Id*. at 9–10. These "policy options" were a precursor to an anticipated vote at the June 2025 ACIP meeting, where the COVID-19 Vaccines Work Group would present more data and analyses before an anticipated vote on the 2025–2026 COVID-19 vaccines.

31. No data was presented by the COVID-19 Vaccines Work Group at the April 15–16, 2025 ACIP meeting to suggest that COVID-19 vaccines should not be recommended for pregnant persons or children. In fact, it was discussed that pregnancy and recent pregnancy were risk factors for severe illness of COVID-19.

32. There was no vote scheduled at the April 15–16, 2025 ACIP meeting regarding COVID-19 vaccine recommendations, meaning that ACIP committee members did not vote on changing the COVID-19 vaccine schedule for pregnant persons or children at that meeting. Indeed, the vote on the 2025–2026 COVID-19 vaccine recommendations was slated for the June 25–26, 2025 ACIP meeting. *See* Ex. E*, CDC ACIP Meeting Agenda*, April 15–16, 2025; Ex. D at 3.

33. I am currently unaware as of the date of this declaration whether a patient's insurance has denied COVID-19 vaccinations, but if it did, I would attempt to appeal it immediately because of this conflict between the Secretary's May 19 Directive and the well-established scientific evidence as well as the fact that the COVID-19 vaccine is FDA-approved. I am aware that some patients have received questions back from their insurers regarding their receipt of the COVID-19 vaccine. I have personally spoken to several major insurers regarding their COVID-19 vaccine reimbursement policies.

34. If insurance companies stop covering the COVID-19 vaccine for my patients, I will add that to my counseling on getting the vaccine, although I expect few patients to get vaccinated if they must pay out of pocket. Approximately 50% of my patients are covered by Medicare or Medicaid. The COVID-19 reimbursement rate is $155 for Medicare, $147 for Medicaid, $90 for pediatric patients, and between $140 to $150 for other insured adults.

35. The Vaccines for Children ("VFC") program is a critical safety net that provides free vaccines, including COVID-19 vaccines, to eligible children who might not otherwise have access. However, access gaps remain for certain vulnerable populations, especially in light of recent policy changes. From May 19, 2025 (the date of the Secretary's Directive) until the September 2025 ACIP vote, I was unable to order the COVID-19 vaccine for children eligible through the VFC program. During that time, I saw a patient who typically receives their vaccinations through the VFC program. I informed the patient and their parent that the COVID-19 vaccine was currently not available through the VFC portal, and that the vaccine we had on hand was ordered outside of the VFC program and would require out-of-pocket payment. The patient's parent stated that they would decline the vaccine, as they were unable to afford the out-of-pocket cost.

36. My patients who deny the COVID-19 vaccine even after counseling because of skepticism due to the Secretary's May 19 Directive face increased risk of hospitalization and death from COVID-19, as well as higher risk of transmitting the disease to immunocompromised individuals or unvaccinated pregnant persons and children who are unable to get the vaccine from other providers.

37. Further, vaccine counseling and then refusal by the patient has financial ramifications for my practice as I do not bill for that time, and it also takes time away from other

patients or training residents. For example, when a resident is treating a patient and engaging in SCDM regarding the COVID-19 vaccine, and the patient refuses the vaccine, then the resident will request that I or another attending physician see the patient and repeat the SCDM conversation with the patient. There is no code to be reimbursed for these conversations when no vaccine is administered, and we are often having two SCDM conversations with a single patient.

38. If COVID-19 spreads more easily due to lower vaccination rates, my patients, including pregnant persons and children, will face increased illness, which will overwhelm my practice as I will spend more time treating patients with this vaccine-preventable illness. Indeed, when vaccinated patients get COVID-19, it is less severe. Consequently, if patients are not getting vaccinated and then get COVID-19, they will have much more severe illness which requires more of my time and resources to treat.

39. Finally, the Secretary's May 19, 2025 decision to rescind the COVID-19 recommendations for pregnant persons and children and the recent ACIP recommendation to change the CDC immunization schedule to SCDM directly puts me at risk of contracting COVID-19 as I encounter more patients with vaccine-preventable illnesses. If I become sick, I cannot see patients while I am ill.

40. Unless the unsupported May 19 Secretarial Directive and the downgrading of the COVID-19 vaccine for pregnant women, children, and essentially all adults under the age of 65 are vacated, it is reasonably foreseeable that my patients will face preventable illness, suffering, and in some cases death.

41. The harms described above are not confined to past events and are ongoing with respect to the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for children and pregnant women. Since the changes to the

CDC immunization schedule recommendations for Covid-19 vaccination, I continue to have to respond to confusion, hesitancy, and mistrust arising from this inconsistent federal guidance. I have to address Covid-19 vaccinations now with my patients throughout my day, and I must repeatedly spend time correcting misconceptions created and exacerbated by federal statements and abrupt policy shifts. This ongoing disruption directly interferes with my routine care, diverts my clinical time, and undermines confidence in vaccination recommendations that I rely on daily. The Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women and children is undermining my physician-patient relationship and causing needless negative health outcomes to my patients. The harms to me set forth above are ongoing and will continue unless the Directive and the ACIP's and CDC's recent changes to the CDC immunization schedule for Covid-19 vaccination are immediately enjoined and the ACIP and CDC return the evidence-based, transparent process for making vaccine recommendations.

42. The harms identified above are compounding rather than isolated. The harms identified above associated with the Directive, CDC's changes to the CDC immunization schedule for Covid-19 vaccination for pregnant women and children, the January 5, 2026 changes to the childhood immunization schedule—as well as the anticipated harms that will result from any additional changes that may result from the upcoming February 26, 2026 ACIP meeting—are immediate, ongoing, and compounding. Each successive change to CDC immunization schedule builds on unresolved confusion from prior changes and further erodes patient confidence in me as their physician. As a physician, I do not regain lost time, trust, or clarity between policy shifts. Instead, each new change increases the burden on my practice, amplifies patient skepticism with my recommendations during my consultation, increases the time I am spending during each visit,

and diminishes the effectiveness of my clinical counseling. There is a practical limit to how much uncertainty I can absorb while still providing effective care, and in my professional judgment, the cumulative impact of the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the imminent February 26, 2026 ACIP meeting has pushed my clinical practice toward or beyond that limit absent immediate injunctive relief.

43. The harms described above are also compounded by the failure to follow established the GRADE and Evidence-to-Recommendations (EtR) frameworks in evaluating and communicating each of these changes to the CDC immunization schedule. As a practicing physician, I rely on those frameworks to understand what the recommendations actually mean and ensure that vaccination recommendations I am discussing with my patients are grounded in a transparent, systematic assessment of evidence, risks, and benefits. When CDC immunization schedule recommendations are issued or altered without adherence to those frameworks, I am forced to spend additional time independently evaluating what the recommendation actually means, how much weight to give it, and whether it reflects a true change in evidence or a departure from established methodology. That burden does not replace prior work, it is added on top of my existing clinical responsibilities. When this occurs repeatedly, as with the Covid-19 schedule changes, the January 5, 2026 childhood schedule changes, and the anticipated February 2026 ACIP actions, the harm compounds. I do not have the time or practical ability to reconstruct population-level evidence analyses that CDC staff routinely completed and presented to ACP [prior to early 2025] and that ACIP would ordinarily consider in its evidence based review process and that I have relied on throughout my entire career as a practicing physician. Each deviation from those frameworks increases uncertainty, prolongs patient counseling, and further erodes confidence in

my ability to answer questions and provide recommendations to my patients on these vaccinations, pushing my clinical practice toward a breaking point absent immediate injunctive relief.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Arkansas, that the foregoing is true and correct.

Executed on January 25, 2026, in Little Rock, Arkansas.



Robert H. Hopkins, Jr., MD, MACP
Member, American College of Physicians

EXHIBIT 52

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*, *Defendants.*	Case No. 1:25-cv-11916

SUPPLEMENTAL DECLARATION OF DR. PATRICK S. RAMSEY, M.D., MSPH

I, Dr. Patrick S. Ramsey, M.D., MPSH, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I submit this supplemental declaration in support of Plaintiffs' requests for relief in this litigation because my patients' lives are at stake. As a practicing board-certified physician in the field of obstetrics, gynecology, and maternal-fetal medicine, I treat high-risk pregnant patients every day and am greatly concerned about the immediate and irreparable harm caused by the actions of the U.S. Department of Health and Human Services, Secretary Kennedy, the Centers for Disease Control ("CDC"), and other branches of the federal government's public health apparatus.

2. I am aboard-certified in obstetrics and gynecology and maternal-fetal medicine. I received my Doctor of Medicine degree from the University of Wisconsin in 1994, I completed a residency in obstetrics and gynecology at the Mayo Graduate School of Medicine in 1998, and completed a fellowship in maternal and fetal medicine at the University of Alabama – Birmingham in 2001. I also received a Master of Science in Public Health from the University of Alabama –

Birmingham in 2003. I am over the age of 18 years old, and I make this declaration based on my own personal knowledge and experience, and if called to testify, I could and would do so truthfully.

3. I have extensive experience and expertise in the management of infectious diseases affecting women and fetuses during pregnancy. In addition to my clinical and academic work, I have held multiple leadership roles focused on advancing the prevention of infectious diseases in women, contributing to national and regional efforts aimed at improving maternal and fetal health outcomes through policy, education, and collaborative initiatives.

4. I am a member of the Society for Maternal-Fetal Medicine ("SMFM"), which is a professional organization committed to advancing evidence-based public health and medical fare.

5. I have been providing obstetric care for over 24 years and routinely counsel pregnant patients on immunizations recommended during pregnancy, including the Covid-19 vaccine, influenza vaccine, Tdap (tetanus, diphtheria, and whooping cough) vaccine, and more recently, the RSV (respiratory syncytial virus) vaccine.

6. Since it became available in 2001, the Covid-19 vaccine has been the standard of care in my field, as set forth in clinical guidelines issued by SMFM and other professional organizations, to recommend Covid-19 vaccination to all pregnant patients. I have followed those clinical guidelines consistently and have recommended Covid-19 vaccination to my patients in all trimesters of pregnancy, particularly because pregnancy itself is a known well-established risk factor for increased morbidity and adverse outcomes from respiratory infectious like Covid-19 and influenza.

7. I am familiar with the recent ACIP recommendation that the Covid-19 vaccine be downgraded from routinely administered to one obtained through shared clinical decision making ("SCDM") for individuals under 65 years old and pregnant persons. This approach directly

contradicts the standard of care and clinical guidance that I and other SMFM members rely on to deliver safe and effective care to our high-risk pregnant patients. This change undermines the patient-provider relationship, just as prior actions by the Secretary did in the Spring of 2025. This change also exposes me and other obstetric clinicians to unnecessary health and legal risks given the sound scientific evidence regarding Covid-19 vaccination and safety during pregnancy.

8. Based on my training and experience, there is no universal definition or common understanding for what constitutes "SCDM." Instead, "SCDM" can mean something different to different physicians based on their own understanding of the term. I similarly am not aware of any definitive guidance on or authoritative definition of SCDM issued by any of the organizations of which I am a member.

9. For my personal practice, I approach SCDM encounters first by raising the topic of vaccination with my patients. Once doing so, I then listen to my patient's concerns and do my best to respond to each concern individually and with the relevant and appropriate evidence-backed answers and reasoning necessary. I do my best to address misconceptions about the Covid vaccine to help patients make a decision based on evidence-backed science and medicine.

10. SCDM discussions are not separately scheduled and must instead be incorporated into an existing patient session or exam. On average, these conversations last about 10 minutes of an appointment that usually lasts 30 minutes. This means the SCDM portion of a patient encounter takes up roughly one-third of the time I spend with a patient. Prior to the adoption of the SCDM framework, that time would have been dedicated to other important and critical issues of maternal-fetal health, such as general advice for pregnancy or care coordination. This time spent on SCDM also leaves less time for me to properly document or complete patient files. As a result, I now spend more time after hours updating patient files and catching up on work that I was not able to

complete during the workday because of increasing episodes of lengthy SCDM discussions. All of this has resulted from the CDC's adoption of ACIP's SCDM recommendation for the Covid vaccine.

11. These SCDM sessions are becoming more frequent due to the level of misinformation and the belief that the change in recommendation status is a false reflection of the Covid vaccine not being safe or effective. Conversations with patients have become increasingly difficult to navigate, and patients are refusing vaccination at higher levels since the SCDM framework was instituted. On any given day, I receive at least 15–16 patient inquiries about the Covid vaccine. This adds up over the course of a day, a week, and a month.

12. These SCDM discussions are not separately billable and thus are not eligible for reimbursement from a payer if a patient declines vaccination. As a result, the time I reference above—time spent conducting SCDM to combat misinformation and disinformation, and time spent catching up on displaced work after hours—is all uncompensated. This results in deprived earnings and more and more uncompensated work.

13. In addition to patient inquiries, I have also received several questions from providers in the community who are seeking guidance on the current SCDM framework. Members of our practice have expressed confusion and uncertainty, causing us to develop our own practice-level recommendations and to seek the backing and support of our hospital and university.

14. Since the CDC's adoption of the SCDM framework, I have also noticed that patients are experiencing difficulties in accessing or finding the Covid vaccine. Because of the CDC's decision, our practice no longer carries the vaccine because it is no longer routinely recommended. This means my colleagues and I must now write prescriptions or issue recommendations to local pharmacies so that our patients can be vaccinated.

15. Despite the prevalence of misinformation and disinformation, I know that Covid still poses a threat to individuals who do not get vaccinated, and I know that these unvaccinated individuals run the serious risk of suffering severe adverse outcomes. I also know that there is strong evidence that vaccines mitigate the risk of complications during pregnancy, including the Covid vaccine. Nevertheless, patients are declining to be vaccinated at higher levels than ever before. I fear that these increasing numbers of unvaccinated patients will cause complications in their pregnancies and that patients will seek to hold me responsible for not more strenuously or forcefully recommending the Covid vaccine, thus exposing me to legal and professional liability.

16. Despite efforts to conflate the two, "SCDM" and "informed consent" are two distinct concepts. In my view, SCDM is a dialogue between patient and physician, whereas informed consent is a physician-led discussion where the physician tells the patient all of the information they might need to know to make an informed and competent decision as to risky medical interventions or surgery. The Covid vaccine, in my view, is not the kind of medical intervention that warrants or requires detailed informed consent since it is not a high-risk medical intervention.

17. The change to SCDM has resulted in the outcomes described above and is already causing more patients to contract Covid-19. This is even causing members of our practice to get sick, which results in them being pulled form duty and unable to work. This in turn puts greater strain on me and my colleagues who now must do more work to account for the reduced workforce. Based on my observations and experiences, I believe restoring the status quo before the SCDM framework would address and undo the negative outcomes I have described above.

18. The harms described above and detailed in my original Declaration persist and continue to this day. These harms not only continue to have a negative impact on me and my

practice, they also are compounding and worsening as they persist. For these reasons, immediate relief is necessary to prevent further irreparable harm.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Texas, that the foregoing is true and correct.

Executed on January 25, 2026 in San Antonio, Texas.

/s/ Dr. Patrick S. Ramsey

Dr. Patrick S. Ramsey, M.D., MSPH

EXHIBIT 53

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al*., *Defendants.*	Case No. 1:25-cv-11916 District Judge: Hon. Brian E. Murphy Magistrate Judge: Hon. M. Page Kelley

DECLARATION OF JANE DOE 2

I, Jane Doe 2, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old.

2. I reside in Massachusetts.

3. I had planned to receive a Covid booster in Summer 2025.

4. I gave birth to a full-term baby in October 2025.

5. I saw the announcement that the Secretary of the Department of Health and Human Services ("Secretary") made on X on May 27, 2025, rescinding the recommendation that healthy pregnant individuals and children ages 6 months–17 years get the Covid vaccine.

6. I have been vaccinated against Covid and have received Covid vaccine boosters. However, as a pregnant woman, I was at greater risk for morbidity and mortality and severe illness if I contract Covid. If I contracted Covid while pregnant, that would put my unborn child at risk

for preterm birth and other complications, up to and including stillbirth or death. The Secretary's change to the Covid immunization schedule significantly raised my level of anxiety, and my inability to locate a health care practitioner able to administer the vaccine to me caused great distress. I joined this lawsuit because reversing the Secretary's directive would personally benefit me, as well as all other individuals who were also expecting and who were parents of minor children.

7. On May 30, 2025, following news of the Secretary's removal of the recommendation for the Covid vaccine for pregnant women, I attended a pre-scheduled, routine 20-week prenatal checkup. At this time, I asked my OB/GYN about the CDC recommendations for the Covid booster. She recommended that I be vaccinated against Covid and wrote a prescription for me which she sent to a chain pharmacy. She also documented this interaction in my prenatal report, which states, "Unclear where new CDC guidelines are coming from, unclear if data based. At this time, pregnancy still considered [high risk] for Covid infection and complications and vaccine recommended."[1]

8. On June 4, 2025 I scheduled a vaccination appointment with a chain pharmacy specifically for the Covid vaccine.

9. On June 4, 2025, I drove 6.5 miles in my 2018 Honda CR-V to a national chain pharmacy in the middle of my workday to my local pharmacy.

10. However, upon arrival at the pharmacy, as I was filling out my paperwork to receive the vaccine, the pharmacist on staff asked me whether I was pregnant. After I confirmed that I was, she refused to administer the Covid vaccine to me. The pharmacist stated that she could no longer

[1] A true and correct redacted copy of the May 30, 2025 prenatal report is attached hereto as **Exhibit A**.

administer the Covid vaccine due to the new CDC recommendations. She said that she could lose her license, even though she acknowledged the prescription for the Covid vaccine sent by my provider on May 30, 2025.

11. After being denied the covid-19 vaccine, I drove another 6.5 miles back to my home in my 2018 Honda CR-V.

12. My 2018 Honda CR-V gets approximately 31 miles per gallon. *2018 Honda CR-V*, UNITED STATES DEPARTMENT OF ENERGY (Last visited Sept. 16, 2025) https://www.fueleconomy.gov/feg/PowerSearch.do?action=noform&path=1&year1=2018&year2=2018&make=Honda&baseModel=CR-V&srchtyp=ymm&pageno=1&rowLimit=50.

13. A gallon of regular gasoline cost on average $3.11 in Massachusetts the first week of June 2025. *Weekly Massachusetts All Grades All Formulations Retail Gasoline Prices*, U.S. ENERGY INFORMATION ADMINISTRATION (last visited Sept. 16, 2025) https://www.eia.gov/dnav/pet/hist/LeafHandler.ashx?n=pet&s=emm_epm0_pte_sma_dpg&f=w.

14. Based on my 13-mile drive to and from the pharmacy on June 4, 2025 in my 2018 Honda CR-V which gets 31 miles to the gallon, and that gas prices in my area were $3.11 that week, I burned $1.30 in gas going to and returning from the pharmacy on June 4, 2025. My only purpose in going to the pharmacy that day was to be vaccinated against covid-19.

15. If I did not go to the pharmacy for my covid-19 vaccine on June 4, 2025, I would have devoted that time to my work.

16. Upon being denied the covid-19 vaccine on June 4, 2025, I immediately contacted my OB/GYN's office where I spoke with the on-call nurse to alert them that the chain pharmacy was not able to provide me with the vaccine—this caught them off-guard. The nurse reviewed the conflicting guidance between CDC and the American College of Obstetricians and Gynecologists

(ACOG) and determined that they could not administer the vaccine to me either, also citing concerns that their medical license could be at jeopardy. I also looked at the CDC website for guidance, and it stated that pregnant women should receive the Covid vaccine. I sent a message to my OB/GYN via the practice's medical portal with this information to get confirmation that this was indeed accurate.[2]

17. On June 11, 2025, having received no response to my June 4, 2025 portal message, I called my OB/GYN's office because their lack of responsiveness was uncharacteristically slow. The on-call nurse said that my portal message was sent to the Chair of Maternal Health for the practice who then spoke to the Chief Medical Officer (CMO) for the practice. The nurse explained to me that the CMO said that the guidance is not to administer the Covid vaccine right now and that they would revisit this next season. The nurse suggested I follow up with an urgent care and further stated that "it's a dead end with us" because the practice no longer carries the Covid vaccine and would no longer administer it.

18. A few minutes after this phone call, the on-call nurse sent me a message via the practice's medical portal which included an email from the Medical Director and CMO of the hospital regarding the current Covid vaccine status.[3] The CMO's email states:

> There's probably a lot of education that needs to take place this season. The CDC no longer recommends [the Covid vaccine] for children or pregnant women but there is no prohibition against giving it. The CDC now admits to the use of the word may. I can ask if perhaps the urgent cares can keep U.S. stock. But the new vaccine strain is not yet out.

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[2] A true and correct redacted copy of my June 4, 2025, portal message to my OB/GYN practice is attached hereto as **Exhibit B.**

[3] A true and correct redacted copy of the June 11, 2025, portal message from my OB/GYN practice is attached hereto as **Exhibit C.**

19. On June 11, 2025, immediately following this phone call and portal message, I called a local urgent care clinic. This clinic informed me they do not stock the vaccine and did not know if they would be ordering more stock. They also stated that it had been a while since anyone asked for the Covid vaccine.

20. On June 13, 2025, my OB/GYN called and left a voicemail following up on the portal messages from June 4, 2025 and June 11, 2025. She communicated that as an office practice, the practice was looking into the concerning reality that my experience at the chain pharmacy had unveiled: that there are now conflicting guidelines and, therefore, conflicting practices being followed by community pharmacies. She also shared that the practice follows materials from ACOG which strongly supports Covid vaccination during pregnancy.

21. On June 25, 2025, I had my 24-week checkup where I saw a nurse midwife. When I asked again about the Covid vaccine, she said that the practice "supports" me getting the vaccine but does not administer or carry it themselves. She said that the practice had no plans to order the vaccine and to check with the in-house pharmacy.

22. Following this appointment, I called the in-house pharmacy and was told that they also do not stock the Covid vaccine. I followed up with my OB/GYN practice to let them know the situation. [4]

[4] A true and correct redacted copy of my June 25, 2025, portal message to my OB/GYN practice is attached hereto as **Exhibit D**.

23. On June 26, 2025, I received a message via the practice's medical portal from a certified nurse midwife stating that she had called another location of the chain pharmacy which confirmed that they had the Covid vaccine in stock and sent a prescription directly to them.[5]

24. On July 6, 2025, I followed up with the other chain pharmacy location identified by the nurse midwife. My conversation with the pharmacist was confusing. She stated that certain "flexible" pharmacists would administer the Covid vaccine while others would not. When I asked whether it was the chain pharmacy's policy to allow individual pharmacists to determine which vaccines they could administer, she said that normally all pharmacists are on the same page regarding vaccine recommendations but that this is the first time a recommendation did not come from the Advisory Committee on Immunization Practices (ACIP) and, therefore, this is "a grey area." She said to schedule an appointment when a more "flexible" pharmacist, who would be willing to risk their license to vaccinate me, is on staff on July 23. I have scheduled an appointment with this pharmacist for July 23 and hope to receive the vaccine that day. However, I am nervous that should the pharmacist staffing schedule change, I will not be able to receive the vaccine yet again.

25. On July 7, 2025, I learned that a close acquaintance tested positive for Covid earlier that day. This acquaintance had stayed in my home from July 3 until July 6 to celebrate Independence Day, meaning that I and my unborn baby were unknowingly exposed to this deadly illness.

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[5] A true and correct redacted copy of the June 26, 2025, portal message from my OB/GYN practice is attached hereto as **Exhibit E.**

26. The stress of being vulnerable to covid-19 and having unknowingly exposed by unborn baby to covid-19 because the Directive blocked my ability to be vaccinated in June of 2025 exacerbated my underlying anxiety disorder and prenatal depression. I have suffered clinically-significant sleep disturbances as a result of this stress, and I required a dental intervention to address stress-induced tooth-grinding because I am so stressed about having access to covid-19 vaccines and being vulnerable to the disease personally and for my baby. I still suffer from anxiety, depression, and clinically-significant sleep disturbances as a result of being denied the covid-19 vaccine between June 2025 and July 2025.

27. On July 23, 2025, I finally received a COVID-19 vaccination at a national chain pharmacy. The scheduling process was conducted over the phone. I was told I would be seen during a time when a "flexible" pharmacist was on duty.

28. When I arrived at the pharmacy on July 23, 2025, the pharmacist presented me with an attestation form that I was required to sign in order to receive the Covid-19 vaccine. The form included the following statement: "If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC."[6] I was confused by this statement because, on the one hand, pharmacists and my own doctor's office had refused to give me the vaccine because it was supposedly against current recommendations from the CDC and what Secretary Kennedy said in his announcement on X on May 27. On the other hand, I am aware that on the same day that I went to the flexible pharmacist who gave me the Covid shot, the CDC website states:

> "If you are pregnant or were recently pregnant, you are:

[6] A true and correct copy of the attestation form is attached hereto as **Exhibit F.**

> More likely to get very sick from COVID-19 compared to those who are not pregnant.
> More likely to need hospitalization, intensive care, or the use of a ventilator or special equipment to breathe if you do get sick from COVID-19. Severe COVID-19 illness can lead to death.
> At increased risk of complications that can affect your pregnancy and baby including, preterm birth or stillbirth.
>
> COVID-19 vaccination remains the best protection against COVID-19-related hospitalization and death for you and your baby. CDC recommendations align with those from professional medical organizations including the American College of Obstetricians and Gynecologists, Society for Maternal Fetal Medicine, and American Society for Reproductive Medicine."

But then, the CDC website also has a prominently displayed banner stating: "COVID recommendations have recently been updated for some populations. This page will be updated to align with the updated immunization schedule."[7]

29. Since the CDC's current eligibility guidelines conflict with the Secretary's directive, I had to ask the pharmacist during my visit for clarification on that section of the attestation. The pharmacist agreed that the guidelines were unclear. He told me that, in cases like this, he personally chooses to follow the guidance of obstetric and pediatric professional organizations. Relying on his assurance, I signed the attestation and received the vaccine.

30. I am surprised that a major pharmacy chain permits this level of ambiguity and discretion among its pharmacists regarding federal vaccination guidelines.

31. The CDC's actions changing the Child and Adolescent Immunization Schedule to align with Denmark's childhood immunization schedule and downgraded other vaccines to SCDM for pediatric patients have caused stress and anxiety relating to Baby Doe 2 receiving her vaccines.

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[7] A true and correct copy of the CDC website as of July 24, 2025 is attached hereto as **Exhibit G.**

I am concerned as to whether Baby Doe 2's four-month vaccinations will proceed as scheduled, and this concern causes the same symptoms, including loss of sleep and anxiety, as produced by the changes implemented to the Covid-19 vaccine schedule. I will inevitably have to spend time and resources ensuring that Baby Doe receives her four-month vaccinations.

32. Since May 30, 2025, I have personally experienced and witnessed the chaos, confusion, and stress that the Secretary's directive and subsequent changes to the Child and Adolescent Immunization Schedule has caused for me, doctors and pharmacists as to whether the Covid vaccine can be given to pregnant individuals like me. I am grateful that I was finally able to find a "flexible" pharmacist who gave me the vaccine when others would not, but I remain concerned about Baby Doe 2 receiving the vaccines she needs to keep her safe. I am very concerned for other pregnant individuals who are all in the same position as I have been—receiving conflicting and inconsistent guidance from the country's top public health official, from the CDC website, from my own doctor's office, and from the multiple pharmacists from whom I attempted to get the vaccine. It is clear to me that the Secretary's directive is the direct cause of this chaos and confusion. I sincerely hope for all pregnant individuals in this country that this situation gets fixed and clarified so that women who are pregnant do not have to experience what I experienced. That is why I submit this declaration and joined this lawsuit.

33. As a mother, I am very concerned that the CDC's actions to revise the childhood vaccination schedule to recommend shared clinical decision making will impose similar obstacles to those which Jane Doe 3's children have encountered to my own child's ability to obtain a covid-19 vaccine when she becomes eligible in five months.

34. All of the facts set forth in this declaration are based on my personal knowledge.

35. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath.

36. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on January 25, 2026.

Jane Doe 2

/s/

JANE DOE 2

EXHIBIT A

OB/GYN Prenatal Report

Notes

Visit Date: 05/30/25 Last Updated by: [redacted]

35yo G2P0 at 20w1d for routine prenatal care.

No vaginal bleeding, leaking, discharge, dysuria or abdominal pain.

Endorses fetal flutters.

Prenatal chart and labs reviewed.

Level II reviewed, limited anatomy, otherwise normal EFW 22%tile. Needs 4 week f/u, scheduled for 6/27.

Rash in inferior abdominal fold, not c/w yeast. Advised to keep dry and use topical hydrocortisone. Given ABD pads.

Patient inquiring about Covid vaccine booster. Discussed recent CDC recommendations against Covid vaccination in health kids and pregnant women.

Unclear where new CDC guidelines are coming from, unclear if data based. At this time, pregnancy still considered HR for Covid infection and complications and vaccine recommended.

Increased daily water intake and PNVs encouraged.

PTL/SAB precautions reviewed.

FU in 4 weeks

EXHIBIT B

*** From [redacted] on June 4, 2025 at 1:44 pm ***

Hi Dr. [redacted],
Unfortunately today I was refused a vaccination for the Covid vaccine, with the pharmacist citing their license would be in jeopardy, and insisting they had to follow CDC guidelines.

I spoke to [redacted] and the care team and [redacted] and it sounds like I'm the first person to experience this, but she reiterated they can't write a letter or administer the vaccine either for the same reasons- licenses would be in jeopardy.

Can you confirm this is all accurate and do you have any advice on how I can access the vaccine both you & ACOG recommend? The CDC website doesn't actually look like it's been updated, it still states pregnant women should get vaccinated against COVID.

Thanks,
[redacted]

EXHIBIT C

COVID vaccine

From [redacted] on
June 11, 2025 at 9:32 am

Hi [redacted],
Here is the most recent email from our medical director anf hospital CMO regarding the current COVID vaccine status:

His response "There's probably a lot of education that needs to take place this season. The CDC no longer recommends COVID for children or pregnant women but there is no prohibition against giving it. The CDC now admits to the use of the word may. I can ask if perhaps the urgent cares can keep U.S. stock. But the new vaccine strain is not yet out."

So, with that being said I would hold off for now until we get back to URI season and we have a better plan in place to help our patients access vaccination if it is desired.

Thank you,

[redacted]

EXHIBIT D

[redacted]

CNM
1:59 pm
Covid booster

From [redacted] on June 25, 2025 at 1:59 pm

Hi [redacted]
I called [redacted] Community Pharmacy and they don't have any stock of the COVID vaccine and were unsure when or even if they'd get more in stock.

Between [redacted] refusing me the vaccine, and both urgent care and the community pharmacy not even having it in stock, I'm completely unable to access the vaccine as of now, which is stressful considering it was recommended by Dr. [redacted] during my last visit.

I'd appreciate more clarity on how I can receive the vaccine, because as of now I don't feel supported in this endeavor, and have received conflicting information from [redacted]. Between the nurses calling me back, Dr. [redacted] leaving me a voicemail last week, the nurse who sent me your CMO's messaging via the portal, and our latest conversation this morning, the information and messaging varies wildly. The one thing that is clear is that I can't access the vaccine despite the recommendation from Dr. [redacted] that I receive it as a pregnant person at higher risk.

I appreciate any clarity you can provide here.

[redacted]

EXHIBIT E

[redacted]CNM
10:00 am
Covid booster

From [redacted], CNM on
June 26, 2025 at 10:00 am

Hi [redacted],

I just called [redacted] on [redacted] - the pharmacy tech that I spoke with said that they have the COVID vaccine in stock and they do not require any special documentation to administer the COVID vaccine in pregnancy. Just in case, I have also ordered the vaccine to the [redacted] pharmacy.

Our in-house pharmacy advised that there is a website that can help you identify alternative local vaccine access locations - vaxassist.com.

Please feel free to reach out with any questions or concerns.

[redacted]CNM

*** From [redacted] on June 25, 2025 at 1:59 pm ***

Hi [redacted],
I called [redacted] Community Pharmacy and they don't have any stock of the COVID vaccine and were unsure when or even if they'd get more in stock.

Between [redacted] refusing me the vaccine, and both urgent care and the community pharmacy not even having it in stock, I'm completely unable to access the vaccine as of now, which is stressful

EXHIBIT F

CONSENT FOR SERVICES: I have received/read (or had read to me) the Vaccine Information Statement(s), Vaccine Information Fact Sheet(s) and/or Patient Fact Sheet(s) regarding the vaccine(s). I understand the benefits/risks of vaccination. I voluntarily assume full responsibility for any reactions/consequences that may result. I understand I should remain in the vaccine administration area for 15 minutes, or longer if directed, after vaccination to be monitored for potential adverse reactions. In the event of side effects, I understand I should call the pharmacy, my doctor, or 911. I certify the information provided regarding eligibility for the vaccine is accurate and request the vaccine be given to me/the person previously named for whom I am authorized to make this request. If I am signing on behalf of another individual (including a minor), I attest I have the authority to do so. The following must have consent of a parent or guardian: Patients in Alabama/Nebraska under 19 yrs old; patients in South Carolina under 16 yrs old; and patients under 18 yrs old in all other states. If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC. State of Georgia only: I verify a pharmacist asked for my health history and whether I had a physical exam in the past year. Health care providers did not identify conditions(s) that would mean I should not receive vaccine(s)

AUTHORIZATION TO REQUEST PAYMENT: I authorize [redacted] to release information to Medicare, Medicaid or any other third party payer as needed and to request payment of authorized benefits to be made on my behalf to [redacted], I certify the information provided about my Medicare, Medicaid or other coverage is correct

ACCEPTANCE OF FINANCIAL RESPONSIBILITY: Notwithstanding anything previously set forth, I agree I am responsible for and will promptly pay on demand any and all obligations to [redacted] Pharmacy including all self-pay balances as well as charges for services not covered or disallowed by my insurance carrier (for non-COVID-19 vaccines)

DISCLOSURE OF RECORDS: I understand [redacted] may be required to or may voluntarily disclose my health information with respect to this vaccine to my healthcare providers, my insurance plan, health systems and hospitals, and/or state or federal registries. I understand [redacted] will use and disclose my health information as set forth in the [redacted] Notice of Privacy Practices (copy is available in-store, online or by requesting a paper copy from the pharmacy team). State of California only: I agree to have the California Immunization Registry (CAIR) share my immunization data with the health care providers, agencies or schools. State of Florida only: Students 18-23 may opt out of the immunization registry by notifying pharmacy prior to administration

X _____ Date: _____

Signature of patient to receive vaccine or person authorized to make the request (parent/guardian)

EXHIBIT G

COVID-19

COVID-19 Vaccination for Women Who Are Pregnant or Breastfeeding

For Everyone

SEPT. 10, 2024 •

COVID-19 VACCINE RECOMMENDATIONS

COVID-19 vaccine recommendations have recently been updated for some populations. This page will be updated to align with the updated immunization schedule. Learn more.

WHAT TO KNOW

- Everyone ages 6 months and older is recommended to get the updated COVID-19 vaccine, including if you are pregnant, breastfeeding a baby, trying to get pregnant now, or might become pregnant in the future.
- COVID-19 vaccination during pregnancy is safe and effective.
- COVID-19 vaccines are not associated with fertility problems in women or men.
- Infants ages 6 months and older are recommended to get the updated COVID-19 vaccine even if born to mothers who were vaccinated or had COVID-19 before or during pregnancy.
- If you are pregnant or were recently pregnant, you are more likely to get very sick from COVID-19, compared to those who are not pregnant. Additionally, if you have COVID-19 during pregnancy, you are at increased risk of complications that can affect your pregnancy and your baby from serious illness from COVID-19.



Recommendations during and after pregnancy

If you are pregnant or were recently pregnant, you are:

- More likely to get very sick from COVID-19 compared to those who are not pregnant.
- More likely to need hospitalization, intensive care, or the use of a ventilator or special equipment to breathe if you do get sick from COVID-19. Severe COVID-19 illness can lead to death.
- At increased risk of complications that can affect your pregnancy and baby including, preterm birth or stillbirth.

COVID-19 vaccination remains the best protection against COVID-19-related hospitalization and death for you and your baby. CDC recommendations align with those from professional medical organizations including the American College of Obstetricians and Gynecologists, Society for Maternal Fetal Medicine, and American Society for Reproductive Medicine.

Pregnant and have questions about COVID-19 vaccine?

If you would like to speak to someone about the COVID-19 vaccination during pregnancy, you can talk to your healthcare provider. You can also contact MotherToBaby, whose experts can answer questions in English or Spanish. This service is free and confidential.

To reach MotherToBaby:

- **Call:** 1-866-626-6847
- **Text:** 1-855-999-3525 (standard messaging rates may apply)

Safety and effectiveness of COVID-19 vaccination during pregnancy

Studies including hundreds of thousands of people around the world show that COVID-19 vaccination before and during pregnancy is safe, effective, and beneficial to both the pregnant woman and the baby. The benefits of receiving a COVID-19 vaccine outweigh any potential risks of vaccination during pregnancy. Data show:

- **COVID-19 vaccines do not cause COVID-19, including in pregnant women or their babies.** None of the COVID-19 vaccines contain live virus. They cannot make anyone sick with COVID-19, including pregnant women or their babies. Learn more about how vaccines work.
- **It is safe to receive an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech), before and during pregnancy.** Both vaccines show no increased risk for complications like miscarriage, preterm delivery, stillbirth, or birth defects [1] [2].
- **mRNA COVID-19 vaccines during pregnancy are effective.** They reduce the risk of severe illness and other health effects from COVID-19. COVID-19 vaccination might help prevent stillbirths and preterm delivery [1] [2] [3] [4].
- **COVID-19 vaccination during pregnancy builds antibodies that can help protect the baby.** [4] [5]
- **Receiving mRNA COVID-19 vaccines during pregnancy can help protect babies younger than age 6 months from hospitalization due to COVID-19.** [6] [7] [8]
- Most babies hospitalized with COVID-19 were born to pregnant women who were not vaccinated during pregnancy [6] [7] [8].

Recommendations if you are breastfeeding

CDC recommends that women who are breastfeeding a baby, and infants 6 months of age and older, get vaccinated and stay up to date with their COVID-19 vaccines.

Vaccines are safe and effective at preventing COVID-19 in women who are breastfeeding a baby. Available data on the safety of COVID-19 vaccination while breastfeeding indicate no severe reactions after vaccination in the breastfeeding mother or the breastfed child. [9] There has been no evidence to suggest that COVID-19 vaccines are harmful to either women who have received a vaccine and are breastfeeding or to their babies. [10]

Studies have shown that mothers who are breastfeeding a baby and have received mRNA COVID-19 vaccines have antibodies in their breast milk, which could help protect their babies. [9] [10]

CDC also recommends COVID-19 vaccines for children aged 6 months and older.

Possible side effects

Pregnant women have not reported different side effects from women who are not pregnant after vaccination with mRNA COVID-19 vaccines (Moderna and Pfizer-BioNTech vaccines) [1] [2].

- Fever during pregnancy, for any reason, has been associated with adverse pregnancy outcomes.
- Fever in pregnancy may be treated with acetaminophen as needed, in moderation, and in consultation with a healthcare provider.
- Learn more about possible side effects and rare severe allergic reactions after receiving a COVID-19 vaccine.

Recommendations if you would like to have a baby in the future

CDC recommends that women who are trying to get pregnant now or might become pregnant in the future, as well as their partners, stay up to date and get the updated COVID-19 vaccine. COVID-19 vaccines are not associated with fertility problems in women or men.

Common questions

Expand All

What are the long-term effects on the baby if I get a COVID-19 vaccine during pregnancy?

Scientific studies to date have shown no safety concerns for babies born to mothers who were vaccinated against COVID-19 during pregnancy. Based on how these vaccines work in the body, experts believe they are unlikely to pose a risk for long-term health effects. CDC continues to monitor, analyze, and disseminate information from women vaccinated during all trimesters of pregnancy to better understand effects on pregnancy and babies.

When should I get the updated COVID-19 vaccine during pregnancy?

CDC and professional medical organizations, including the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, recommend COVID-19 vaccination at any point in pregnancy. COVID-19 vaccination can protect you from getting very sick from COVID-19. Keeping yourself as healthy as possible during pregnancy is important for the health of your baby.

Which COVID-19 vaccine should I receive if I am pregnant?

You can choose which updated COVID-19 vaccine to get.

Can I get a COVID-19 vaccine at the same time as other vaccines?

Children, teens, and adults, including pregnant women, may get a COVID-19 vaccine and other vaccines, including a flu vaccine, at the same time.

Resources

For Healthcare and Public Health

- Considerations for the Use of COVID-19 Vaccines in the United States
- Management of Anaphylaxis after COVID-19 Vaccination
- COVID-19 Clinical and Professional Resources
- Clinic Poster: Protect yourself and your baby from COVID-19 PDF

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases; Coronavirus and Other Respiratory Viruses Division

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