American Academy of Pediatrics, et al. v. Robert F. Kennedy, Jr., et al., Case No. 1:25-cv-11916-BEM (D. Mass.)

Hearing on Plaintiffs' Motion for Preliminary Injunction (Day 2)

March 4, 2026

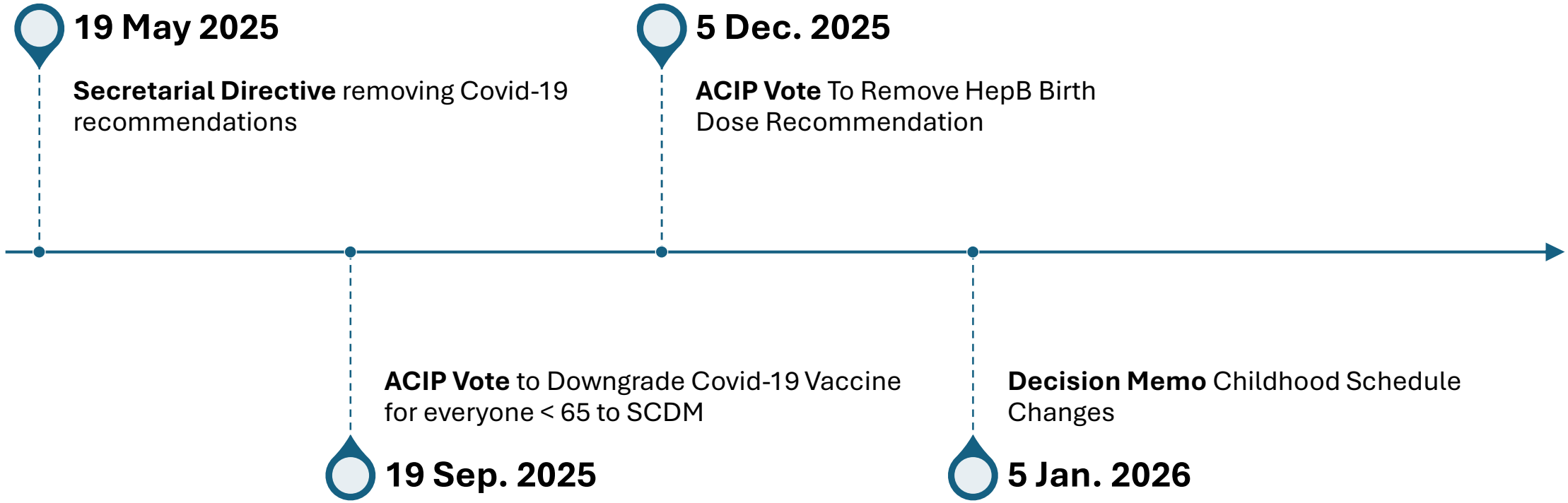
Presumption of Reviewability Under the APA

- Presumption of reviewability
- Very narrow exception
- Agency can limit the scope of its own discretion "by rule or be settled course of adjudication, a general policy by which its exercise of discretion will be governed …" Once an agency so acts, "an irrational departure from the policy (as opposed to an avowed alteration of it) could constitute action that must be overturned as 'arbitrary, capricious, [or] an abuse of discretion." INS v. Yang, 519, U.S. 26, (1996).
- Not the types of action typically regarded as committed to agency discretion.

"since brevity is the soul of wit,
And tediousness the limbs and outward flourishes,
I will be brief."

Hamlet, Act 2, Scene 2, lines 90-92

Inconsistent Use of Process to Change Vaccine Recommendations



Likely to Succeed on Merits that The May 19 Secretarial Directive Announced on May 27, 2025, Was Arbitrary and Capricious

Failed to Engage in Reasoned Decision-Making by Failing to Follow the ACIP Process

May 27, 2025, Video Posted on X

May 19, 2025, Secretarial Directive

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

Internal HHS Memos dated May 12, 2025, disclosed for first time on February 27, 2026

CMC, July 31, 2025, Judge Young: "I wouldn't think that the administrative record in support of that changed recommendation is extensive or hard to ferret out."

Not From or To the ACIP or CDC

Memorandum

Date: May 12th, 2025

To: Secretary Robert F. Kennedy, Jr.

From: Tracy Beth Høeg, MD, PhD (FDA)

Subject: COVID-19 vaccine safety in pregnant women

MEMORANDUM TO THE SECRETARY

THROUGH: HEATHER MELANSON, CHIEF OF STAFF
CORTNEY MCCORMICK, EXECUTIVE SECRETARY

FROM: MATTHEW MEMOLI, M.D., M.S., PRINCIPAL DEPUTY DIRECTOR, NIH

SARA BRENNER, M.D., M.P.H., PRINCIPAL DEPUTY COMMISSIONER, FDA

SUBJECT: Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age

DATE: May 12, 2025

CDC and ACIP Not Consulted

Dr. Fiona Havers, epidemiologist who resigned from CDC on June 16, 2025, because she could "no longer continue while the health secretary, Robert F. Kennedy, Jr., dismantled the careful processes that help formulate vaccination standards in the U.S:"

No career CDC officials knew about the memos until after the fact.

Dr. Jason Goldman, Covid-19 Work Group liaison, "never saw, received, discussed, or was informed of these memoranda."

Dr. José Romero, ACIP Chair from 2018-2021: "highly irregular, inappropriate, and a striking departure from the procedure that had uniformly been followed for decades"

- Unexplained inconsistency as to why they bypassed the ACIP Process
- The ACIP Process provides a structured, transparent, and evidence-based review process for engaging in a “reasoned evaluation of the relevant factors” through the GRADE approach, the EtR framework, and consultation with ACIP Work Groups.

Failed to Provide a Satisfactory Explanation for their Actions

Conclusory

- Conclusory assertion that "healthy kids" and "healthy pregnant women" don't need the Covid vaccine.
  - This explanation "fails under the APA because it is merely conclusory." *See Ass'n of Am. Univs. v. Dep't of Defense*, 792 F.Supp.3d 143, 171 (D. Mass. 2025) (holding that the DOD's justification for a change to reimbursement rate policy related to university research was A&C because its conclusory justification did not provide a reasoned basis for the change);
  - *NIH I,* 770 F.Supp.3d 277, 305 (D. Mass. 2025) (holding that NIH's justification for a change to reimbursement rate policy related to university research was A&C because it was conclusory given that it did not "provide any reasoning, rationale, or justification at all").

False/Misleading Statements in the Video

RFK: “Last year, the Biden Administration urged healthy children to get yet another COVID shot despite the **lack of any clinical data** to support the repeat booster strategy in children”

Makary: “there’s **no evidence** that healthy kids need it today”

Bhattacharya: “That ends today. It’s common sense and **it’s good science**”

An Abundance of Data to Support the Repeat Booster Strategy Presented at the April 15, 2025, ACIP Meeting

Dr. Fiona Havers: “So in summary for pediatrics, rates of Covid 19 hospitalizations are highest among the youngest age groups, although among school age children, hospitalization rates are generally have been higher for influenza than for Covid -19. More than half of children and adolescents hospitalized with COVID-19 had more than one underlying condition. And this increased with increasing age, **but a substantial proportion of children had no underlying medical conditions**. And the most common underlying conditions also varied by age groups. And again, as we saw, the vast majority of children who were hospitalized with Covid had not received the most recently recommended Covid 19 vaccine during the 2023 – 24 season.” (Havers Decl. ¶ 11).

An Abundance of Data to Support the Repeat Booster Strategy

- Dr. Robert Schechter, COVID-19 Work Group Chair: **26,000-43,000** deaths from October 1, 2024—March 22, 2025
- Dr. Ruth Link-Gelles: “the VE [vaccine effectiveness] should be interpreted as the added benefit of 24-25 COVID-19 vaccination in a population with high levels of infection induced immunity, vaccine-induced immunity, or both.”
- Dr. Lakshmi Panagiotakopoulos: “This graph shows the number of Covid-19 and influenza deaths among people ages 0 to 17 years between September 2023 and August 2024. For children less than one, the number of deaths from Covid-19 were higher than the number of deaths from flu.” The graph showed a total of 152 deaths of children 0-17 in this time period from COVID-19.

Makary/Prasad Article

- FDA Commissioner Marty Makary published an article just a week before the Directive, co-authored by Vinay Prasad (Director of the Center of Biologics Evaluation and Research in the FDA), stating that "pregnancy and recent pregnancy" are factors which "increase a person's risk of severe COVID-19." See Fourth Am. Compl. ¶ 94.
- May 12, 2025, memos do not address the Makary/Prasad article or the data presented at the April 15, 2025, ACIP meeting.

Pretext

- "the evidence tells a story that does not match the explanation the Secretary gave for his decision." *Dep't of Commerce v. New York*, 588 U.S. 752, 784 (2019).
- Just like in *State Farm*: Supreme Court determined the National Highway Traffic Safety Administration's decision to rescind the rule that new motor vehicles be equipped with automatic seatbelts and airbags was arbitrary and capricious because the agency was too quick to dismiss the safety benefits of automatic seatbelts for the court to conclude that the recission was the product of reasoned decision-making. Here, the Secretary's video on X and the purported "assessments" demonstrate that the Defendants were far too quick to dismiss the safety, efficacy, and public health benefits of the Covid vaccine for children and pregnant women for this court to conclude that the May 2025 Action was the product of reasoned decision-making. *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 129 (1983)
- Also like *NIH I*: NIH's failure to explain why bringing the federal government in line with private foundations in terms of funding indirect cost rates in the research grant context made rate change policy arbitrary and capricious. Here, the failure to explain the decision to change Covid vaccine policy despite the presentation at the April 2025 ACIP meeting and the FDA Commissioner's article just one week before the May 2025 Action is arbitrary and capricious. *Mass. v. Nat'l Insts. of Health*, 770 F.Supp.3d 277 (D. Mass. 2025)

Failed to Take Into Account Serious Reliance Interests

Failed to take into account reliance interests

Defendants claim that Plaintiffs had no "reliance interests" on CDC recommendations in place before the May 2025 Action because the potential for revision or withdrawal of an immunization recommendation always exists.

This misses the point:

- Plaintiffs have reliance interests in the appropriate process being followed in reaching vaccine recommendations. They rely on robust, evidence-based analysis frameworks and guidance so that they can appropriately counsel their patients on vaccines.
- Vaccine process and policy changes indisputably impact the health care ecosystem, and those ramifications have to be considered before such changes are made.

ACIP Was Constituted In Violation of FACA

Therefore, votes should be set aside

Preparing Membership Balance Plans

GSA Committee Management Secretariat Guidance

"The corresponding FACA Final Rule reiterates this requirement at 41 CFR § 102-3.30(c), and, for discretionary (agency authority or authorized by statute) advisory committees being established, renewed, reestablished, or merged **requires** agencies to provide a description of their plan to attain fairly balanced membership during the charter consultation process with the Committee Management Secretariat (CMS)(41 CFR § 102-3.60(b)(3))." (Emphasis added).

(6) CANDIDATE IDENTIFICATION PROCESS

Summarize the process intended to be used to identify candidates for the FAC, key resources expected to be tapped to identify candidates and the key persons (by position, not name) who will evaluate FAC balance. The summary should:
(a) describe the process
(b) identify the agency key staff involved (by position, not name)
(c) briefly describe how FAC vacancies, if any, will be handled by the agency; and
(d) state the membership term limit of FAC members, if applicable

The ACIP Secretariat, including the DFO, solicits candidate names through the following channels:

- **Procedures for application for ACIP membership are detailed on the ACIP web site at http://www.cdc.gov/vaccines/acip/req-nominate.htm. The ACIP Secretariat accepts applications in a continuous process throughout the year, and the ACIP Steering Committee finalizes a proposed nomination package annually during November-December.**

- **Solicitation of potential candidates is conducted via e-mail request that is distributed widely on an annual basis, sent to all 30 ACIP liaison organizations, ex officio members, current and past ACIP members, professional organizations such as the National Medical Association and the National Hispanic Medical Association, academic centers, and other contacts in the field of vaccinology.**

- **Solicitation of potential candidates is posted annually in the Federal Register.**

- **Applications are solicited at ACIP meetings. A web link URL is provided on a meeting slide, and procedures for application are announced at the opening of meetings, which are broadcast via the internet ("webcast") to an audience that can exceed 10,000 viewers.**

- **Applications for membership are reviewed in depth by the ACIP Steering Committee, which requires that interested applicants submit a current, complete CV and at least one letter of recommendation from a non-HHS source. The ACIP Steering Committee selects two proposed candidates for each vacant position based on the quality of the candidate's technical expertise, balance of specialty areas (e.g., pediatrics, internal medicine, family medicine, nursing, consumer representative, state health department expertise, public health, etc.) and geographic distribution of recommended candidates. Members are deemed Special Government Employees.**

The Committee comprises up to 19 voting members, including one consumer representative. ACIP members are selected based on their expertise and experience and qualifications necessary to contribute to the accomplishments of the Committee's objectives. Therefore, members are selected based upon the following criteria:

- expertise in the field of immunization practices;
- multi-disciplinary expertise in public health;
- expertise in the use of vaccines and immunologic agents;
- knowledge of vaccine development, evaluation, safety and delivery;
- or, in the case of the consumer representative, knowledge about consumer perspectives and/or social and community aspects of immunization programs.

ACIP MBPs in FACA DATABASE

1/12/2012	2012 MBP
12/18/2013	2013 MBP
11/18/2014	2014 MBP
12/7/2015	2015 MBP
7/19/2017	2017 MBP
3/27/2018	2018 MBP
2/5/2020	2020 MBP
1/29/2024	2024 MBP

Candidate Review Meeting Agenda

ACIP Candidate Review Meeting
CDC Roybal Campus Building 24 – conference room 8106
Thursday, August 24, 2017 1:00-3:00 p.m. EDT

Dial in: 1-866-453-2647
Participant Passcode: 9745001

CHAIR: Amanda Cohn, Executive Secretary, ACIP

Overview
We will meet to review candidates for ACIP membership. Members rotating off the committee (June 30, 2018) are:

Edward Belongia	Internal Medicine; Epidemiology
Nancy Bennett	Internal Medicine; Preventive Medicine
Cynthia Pellegrini	Consumer Representative
Laura Riley	Obstetrics/Gynecology; Maternal Fetal Medicine

A summary table of ACIP members, their expertise and other characteristics is attached.

Submission Process
We need to nominate four candidates including one consumer representative. We will nominate one principal and one alternate nominee for each position, for a total of eight nominees. The nomination package will be sent to DHHS, through CDC/OD, for their decision regarding appointments.

Selection Process
We have a total of **31** applications, including new applicants as well as those who have applied previously. Following our usual practice, we will aim to select candidates whose area of expertise/specialty/board certification is similar to that of the outgoing members.

Prior Steering Committee Meetings

ACIP Steering Committee Meetings
2018 - 2019

Meeting Date	Day	Time	Topic
2018			
August 23	Thursday	1:00-3:00	Select nominees for ACIP Membership 2019-2023
September 6	Thursday	1:00-2:30	October 2018 – prepare agenda
2019			
January 10	Thursday	2:00-3:30	Prepare February 2019 Agenda
May 2	Thursday	2:00-3:30	Prepare June 2019 Agenda
August 22	Thursday	2:00-3:30	Select nominees for ACIP Membership 2020-2024
September 5	Thursday	2:00-3:30	Prepare October 2019 Agenda
2020			
January 9	Thursday	2:00-3:30	Prepare February 2020 Agenda
May 7	Thursday	2:00-3:30	Prepare June 2020 Agenda
August 27	Thursday	2:00-3:30	Select nominees for ACIP Membership 2021-2025
September 10	Thursday	2:00-3:30	Prepare October 2020 Agenda

Federal Register Notices Soliciting ACIP Nominations (last 20 years)

11/24/2006	71 FR 67872-01 CDC seeks nominations for ACIP; deadline is December 18, 2006, by mail. U.S. citizenship required; service up to four years; nominees selected for expertise and diversity.
11/9/2007	72 FR 63611-01 CDC solicits nominations for ACIP membership; applications must be postmarked by November 30, 2007. Nominees must be U.S. citizens with expertise in disease prevention; terms may be up to four years.
11/26/2008	73 FR 72055-01 CDC solicits nominations for potential ACIP membership (experts in immunization and public health). Applications must be postmarked by December 15, 2008. Nominees must be U.S. citizens; up to four-year terms.
10/16/2009	74 FR 53284-01 CDC solicits nominations for ACIP membership (experts in immunization); applications due by November 15, 2009, by mail. Nominees should be U.S. citizens; appointments up to four years.
8/11/2011	76 FR 49771-01 CDC is soliciting nominations for membership on the ACIP (15 experts). Deadline for receipt of applications is November 18, 2011, via email. U.S. citizenship required, terms up to four years, and federal employees excluded.
3/13/2012	77 FR 14805-01 CDC solicits nominations for ACIP (15 experts), with applications due by November 16, 2012, submitted via email. Nominees must be U.S. citizens, not federal full-time employees, and are selected on expertise; service up to four years.
3/11/2013	78 FR 15370-01 CDC requests nominations for ACIP membership (15 experts); deadline is November 15, 2013, via email. Appointees serve up to four years and must have expertise related to immunization and be U.S. citizens not employed full-time by the government.

Federal Register Notices Soliciting ACIP Nominations (last 20 years)

1/26/2016	81 FR 4302-01 CDC seeks nominations for ACIP membership (15 experts), with applications due by November 4, 2016 via email. Members serve up to four-year terms and must be U.S. citizens, not full-time federal employees.
5/24/2016	81 FR 32759-02 CDC is soliciting nominations for membership on the ACIP (15 experts); applications must be received by June 30, 2016 via email. Federal employees not considered; terms may be up to four years. **Expertise in immunization and related fields required.**
4/6/2018	83 FR 14855-02 CDC requests nominations for membership on the ACIP (15 experts). Nominations due by August 1, 2018, by email. Nominees must be U.S. citizens, not full-time federal employees, and may serve four-year terms. **Selection based on expertise and committee objectives.**
6/5/2023	88 FR 36584-01 The CDC seeks nominations for appointment to the ACIP (up to 20 experts in vaccines and immunization practices). Nominations due by August 1, 2023, submitted online. Nominees must be U.S. citizens, not full-time federal employees, and may serve up to four-year terms.
7/18/2024	89 FR 58378-01 The CDC is soliciting nominations for membership on the ACIP, which consists of up to 19 experts in the fields of immunization practices and public health. Nominations must be received no later than August 15, 2024. Submission is online, and **nominees should have expertise in relevant subjects**. Appointments are for up to four years, and nominees must be U.S. citizens who are not full-time federal employees.

ACIP VOTES IN SEPTEMBER ON COVID AND HepB IN DECEMBER WERE ARBITRARY AND CAPRICIOUS

The September 2025 and December 2025 Actions are arbitrary & capricious because Defendants failed to engage in reasoned decision-making.

- The ACIP Process provides a structured, transparent, and evidence-based review process for engaging in a "reasoned evaluation of the relevant factors" through the GRADE approach, the EtR framework, and consultation with ACIP Work Groups.
- Defendants have not offered any explanation for why they bypassed the GRADE approach, the EtR framework, and consultation with ACIP Work Groups entirely in handling the September 2025 and December 2025 Actions.
- An unexplained inconsistency

September 2025 Vote to change Covid vaccine recommendation for adults from routine to SCDM

- ACIP did not apply the GRADE approach or follow the EtR framework
- Did not consult with the Covid Work Group prior to the vote.
- The CDC published no explanation or guidance in the MMWR as to how clinicians should engage in SCDM with patients.

December 2025 Action: Vote to change HepB recommendation

- Change from routine to “individual-based decision-making for parents deciding whether to give the HepB vaccine, including the birth dose, to infants born to women who test negative for the virus,” or to choose to wait to give the HepB vaccine series until the baby is at least two months old.
  - A few presenters presented on the HepB vaccine, including a climate scientist and someone with no medical training or professional experience. None of the presenters presented new safety concerns or effectiveness issues that would prompt reconsideration of the HepB vaccine birth dose.
  - No Work Group presented at this ACIP meeting on HepB, and no EtR analysis was conducted or presented at the meeting.
  - No evidence or data was presented justifying the two-month age restriction for the first dose of the HepB vaccine.

Unexplained inconsistency = APA Violation

- This disregard for established process is exactly the kind of **"unexplained inconsistency"** that makes agency action arbitrary and capricious.
  - *Data Marketing P'ship, LP v. U.S. Dep't of Labor*, 45 F.4th 846, 857 (5th Cir. 2022) (holding that an advisory opinion that adopted a definition of "working owner" that was materially different from the definitions in prior opinions was arbitrary and capricious due to the **unexplained inconsistency**)
  - *National Cable & Telecommunications Association v. Brand X Internet Services*, 545 U.S. 967, 981(2005) ("Unexplained inconsistency is, at most, a reason for holding an interpretation to be an arbitrary and capricious change from agency practice under the Administrative Procedure Act.")

The September 2025 and December 2025 Actions are arbitrary & capricious because Defendants have failed to otherwise provide a satisfactory explanation for their actions.

Failed to consider evidence

- Defendants have failed to provide any indication that ACIP or the Defendants considered the mountain of high-quality evidence the supported the prior recommendations.
  - As discussed during the last hearing, before prior ACIPs voted to adopt recommendations, they conducted multi-stage, data-driven reviews over multiple meetings, with the evidentiary basis for each recommendation documented and transparently evaluated. We identified **Exhibit 23** to the PI motion, which outlines that process as to HepB specifically.
  - We also talked about the one time a routine vaccination was downgraded on the CDC schedule to SCDM—the Prevnar vaccine—and directed the court to Summary **Exhibit 22** of the PI motion.

No New Data or Studies

- No new data or studies were reviewed, considered, or identified to justify or provide any reasonable connection to the September 2025 or December 2025 Actions.
  - Simply put, “the evidence tells a story that does not match the explanation” given for these decisions. *Dep’t of Commerce v. New York*, 588 U.S. 752, 784 (2019).
  - Defendants were far too quick to dismiss the safety, efficacy, and public health benefits of the Covid and HepB vaccines for this court to conclude that the September 2025 and December 2025 Actions were the product of reasoned decision-making. *Motor Vehicle Mfrs. Ass’n v. State Farm*, 463 U.S. 129 (1983)

Fails to consider that the HepB strategy they adopted had failed in the 1980s

- Reverts to a failed 1980s targeted or risk-based approach.
- ACIP recommended a universal birth dose of the HepB vaccine in 1991.
- PI brief at p.20:
  - “[a] targeted strategy that focused on vaccinating only infants with HepB-positive mothers was implemented throughout the 1980s and was unsuccessful at decreasing rates of disease. A 1991 CDC MMWR that recommended switching to universal vaccination explicitly stated: ‘Over one-third of patients with acute hepatitis B do not have readily identifiable risk factors.’ This makes targeted approaches ineffective. Similarly, 35–65 of HBsAg-positive mothers had no identifiable risk factors and would never have been flagged under targeted screening. The 1991 switch to universal vaccination reduced pediatric hepatitis B cases by 99% (from 16,000 to fewer than 20 annually)”.

Factors Not Considered

- The public health difference between placing a vaccine on the routine schedule and SCDM is stark. Placing a vaccine on the routine schedule does not create a mandate, but the routine schedule ensures that immunizations will be part of the preventive standard of practice for children and the default approach. SCDM has the opposite effect. **The evidence shows that SCDM depresses acceptance and, ultimately, the rate of vaccine administration.***
- data on the reductions of the incidence and prevalence of diseases following widespread vaccination
- modeling of potential outbreaks if there is a reduction in vaccination rates or loss of herd immunity;
- any evidence from the FDA that any of the vaccines are not safe and effective;
- citaions to peer-reviewed published research concluding that the vaccines administered under prior iterations of the schedule were ineffective in preventing disease or mitigating symptoms of disease or the need for hospitalization;
- data establishing that any of the vaccines on the schedule are harmful;
- evidence of consultations with professional organizations;
- changes to practice guidelines published by Plaintiffs or other professional organizations;

Defendants failed to take into account serious reliance interests with the September and December 2025 Votes

No Reliance Interest Because CDC Schedule is Impermanent Misses the Point

- Plaintiffs have reliance interests in the appropriate process being followed in reaching vaccine recommendations. They rely on robust, evidence-based analysis frameworks and guidance so that they can appropriately counsel their patients on vaccines.
  - The September 2025 Action provided no scientific analysis for Plaintiffs and their members to evaluate and explain to patients and provided none of the guidance that typical accompanies SCDM recommendations so that vaccine providers can appropriately advise patients.
  - The December 2025 Action provided no scientific analysis for the Plaintiffs and their members to evaluate and explain to patients, especially in light of the considerable evidence and analyses that support routine recommendation of the HepB vaccine in the first place (see Exhibit 23), nor did it provide any guidance so that vaccine providers could appropriately advise patients on whether to administer the HepB vaccine at all, or whether to delay it by two months.

IRREPARABLE HARM

Economic Harm in APA Cases Warrants Injunctive Relief

- Economic harm qualifies as irreparable harm in APA cases
  - "[w]hile economic loss ordinarily does not warrant preliminary injunctive relief, that is only the case if the damages are recoverable. The costs of complying with challenged regulations have been recognized as irreparable given the obstacles faced when suing for monetary damages." *California v. Kennedy*, 802 F.Supp.3d 273, 283 (D. Mass. 2025) (holding that plaintiffs demonstrated irreparable economic harm where they were incurring compliance costs associated with challenged provisions and plaintiffs had no recourse to recover incurred costs if challenged regulations were later found invalid because they were suing in the APA context).
  - *See also Rosario-Urdaz v. Rivera-Hernandez*, 350 F.3d 219, 222 (1st Cir. 2003) (reversing a preliminary injunction denial where "the district court made no findings concerning the many potential obstacles to [ ] a damage award, including whether the individual defendants would be entitled to qualified immunity")
  - *See also Wages & White Lion Invs., L.L.C. v. FDA*, 16 F.4th 1130, 1142 (5th Cir. 2021) (noting that "complying with [an agency order] later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs")
- Consideration of recoverability is especially relevant in the APA context, which does not allow for monetary damages. *See California*, 802 F.Supp.3d at 283 (citing *Kentucky v. Biden*, 23 F.4th 585, 611 (6th Cir. 2022) (finding economic damages irreparable because "the APA does not waive federal sovereign immunity from money-damages claims")).

Harm to the public is irreparable harm

Multiple cases support that threats to public health are relevant to the **irreparable harm** analysis, not just the balance of equities and public interest analysis for a preliminary injunction:

- *Mass. v. Nat'l Insts. of Health*, 770 F.Supp.3d 277, 321 (D. Mass. 2025) ("*NIH I*") (holding that "the suspension of ongoing clinical trials and the resulting threats to **patients' lives** represents a dire risk of a quintessentially irreparable harm" (emphasis added)).
- "Threats to public health and safety constitute irreparable harm that will support an injunction." *Cigar Masters Providence, Inc. v. Omni Rhode Island, LLC*, No. 16-471-WES, 2017 WL 4081899, at *14 (D.R. I. Sept. 14, 2017) (granting a preliminary injunction requiring a cigar bar to hire an engineering firm to change its filters and to otherwise examine its existing ventilation system to conduct necessary maintenance or repairs to bring the business in compliance with applicable regulations because, among other things, the threat of secondhand smoke to the **health and safety** of the plaintiff's tenants, employees, patrons, and guests—including staff and **members of the public**—constituted irreparable harm to support an injunction).
- *Sierra Club v. U.S. Dep't of Agric., Rural Utils. Serv.*, 841 F.Supp.2d 349, 358 (D.D.C.) (granting a preliminary injunction against continuing with the expansion of a power plant before completing an environmental impact statement because, among other things, the Sierra Club environmental organization demonstrated irreparable injury by submitting affidavits supporting that the expansion of the coal-fired power plant would cause irreparable harm by emitting substantial quantities of air pollutants that **endanger human life and the environment**).

FRE 1006 Summary Exhibits On Irreparable Harm

Next Meeting

Compare agenda for upcoming ACIP meeting to previous agenda

March 18-19, 2026 Meeting

Matters to be Considered: The agenda will include updates on ACIP Workgroups and discussions on COVID-19 vaccine injuries and Long-COVID and ACIP recommendation methodology. Recommendation votes may be scheduled for COVID-19 vaccine injuries and Long-COVID and ACIP recommendation methodology. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda, visit

https://www.cdc.gov/acip/meetings/index.html

[nothing more to be found on this link as of 3.3.26]

Centers for Disease Control and Prevention

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**	

Compare agenda for upcoming ACIP meeting to previous agenda

March 18-19, 2026 Meeting

Matters to be Considered: The agenda will include updates on ACIP Workgroups and discussions on COVID-19 vaccine injuries and Long-COVID and ACIP recommendation methodology. Recommendation votes may be scheduled for COVID-19 vaccine injuries and Long-COVID and ACIP recommendation methodology. Agenda items are subject to change as priorities dictate. For more information on the meeting agenda, visit

https://www.cdc.gov/acip/meetings/index.html.

[nothing more to be found on this link as of 3.3.26]

Final Agenda

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**	

Agenda for upcoming meeting does not fulfill mission set forth in ACIP Charter

March 18-19, 2026 Meeting

Matters to be Considered: The agenda will include updates on ACIP Workgroups and discussions on COVID-19 vaccine injuries and Long-COVID and ACIP recommendation methodology. Recommendation votes may be scheduled for COVID-19 vaccine injuries and Long-COVID and ACIP recommendation methodology. Agenda items are subject to change as priorities dictate.

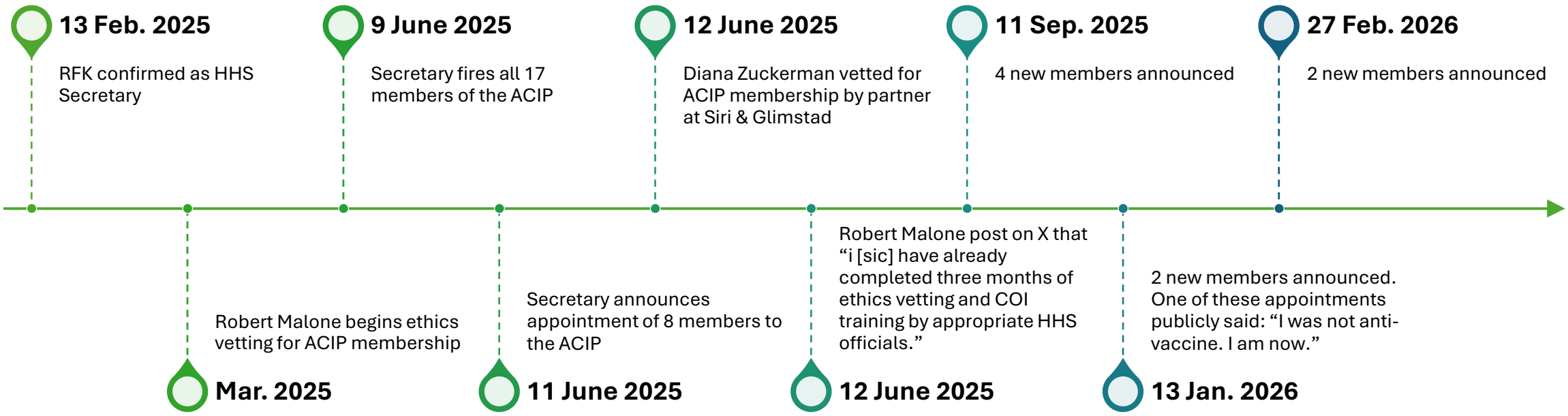
ACIP Charter signed by RFK 12/3/25

- 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.
- 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.
- 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.

Focus all on harm, no agenda item on benefits

- No discussion contemplated on immunogenicity (ability of a foreign substance, such as a vaccine, to provoke an immune response in the body)
- No discussion on effectiveness
- No discussion on epidemiology - Epidemiology is the study and analysis of the distribution (who, when, and where), patterns and determinants of health and disease conditions in a defined population, and application of this knowledge to prevent diseases. It is the cornerstone of public health.
- No discussion on doses
- No discussion on disease burden
- Failing to consider overall balance of benefits and harms
- Not looking at overall vaccine tendencies in the US
- Measles not on the agenda

Reconstitution of the ACIP



PRETEXTUAL REASON FOR FIRING THE ACIP: "PERSISTENT CONFLICTS OF INTEREST"

WSJ COMMENTARY	RECENT DATA ON ACIP CONFLICTS
• "The committee has been plagued with persistent conflicts of interest and has become little more than a rubber stamp for any vaccine." • "Four out of eight ACIP members … voted in 1997 on" a rotavirus vaccine with whom they had financial ties to pharmaceutical companies developing other rotavirus vaccines. • "In 2000, the House issued the results of an investigation of ACIP and another vaccine advisory committee under the [FDA] … It found that enforcement of conflict-of-interest rules was weak to nonexistent." • "A 2009 HHS inspector-general report echoed these findings."	• "Although annual prevalence rates of reported COIs were high in the early 2000s, reaching 43% for ACIP and 27% for VRBPAC, they were considerably lower in 2016-2024 for both committees, at 6.2% for ACIP and 1.9% for VRBPAC." • "The most frequently reported COI was research support, reflecting members' expertise, with the prevalence of conflicts that were related to personal income (consulting, stock/royalties/ownership) less than 1% for both committees since 2016." • "Policy changes placing caps on FDA advisory committee COI rates in 2007 and greater awareness and scrutiny of COIs in agency decision-making may have spurred these large declines." • "In conclusion, reported COI prevalence rates have declined for ACIP and VRBPAC over the last 25 years and **were at historically low levels through 2024**."

BROKEN PROMISE TO RELEASE CONFLICTS DISCLOSURES ON NEW ACIP MEMBERS

HHS spokesperson stated: “[b]efore starting work on ACIP, the new members’ ethics agreements will be made public. Every ACIP member will be vetted in accordance with their ethics agreements before they are permitted to participate in each meeting agenda item.” (ECF 245, Fourth Amended Complaint, ¶ 75(c))

Nothing has been disclosed