

KRISTIN K. MAYES

Attorney General

(Firm State Bar No. 14000)

Joshua D. Bendor (AZ Bar No. 031908)

Clinton N. Garrett (AZ Bar No. 022457)

Syreeta A. Tyrell (AZ Bar No. 034273)

Alexa G. Salas (AZ Bar No. 039722)

Office of the Arizona Attorney General

2005 N. Central Avenue

Phoenix, AZ 85004-1592

(602) 542-3333

Joshua.Bendor@azag.gov

Clinton.Garrett@azag.gov

Syreeta.Tyrell@azag.gov

Alexa.Salas@azag.gov

ACL@azag.gov

Attorneys for Plaintiff State of Arizona

*Additional Counsel Listed on Signature
Page*

ROB BONTA

Attorney General of California

Neli Palma

Senior Assistant Attorney General

Kathleen Boergers (CA Bar No. 213530)

Nimrod Pitsker Elias (CA Bar No. 251634)

Supervising Deputy Attorneys General

Katherine Milton (CA Bar No. 284803)

Marnie G. Ganotis (CA Bar No. 206178)

Deputy Attorneys General

California Department of Justice

455 Golden Gate Avenue, Suite 11000

San Francisco, CA 94102-7020

(415) 510-4400

Neli.Palma@doj.ca.gov

Kathleen.Boergers@doj.ca.gov

Nimrod.Elias@doj.ca.gov

Katherine.Milton@doj.ca.gov

Marnie.Ganotis@doj.ca.gov

Attorneys for Plaintiff State of California

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA**

STATE OF ARIZONA; STATE OF
CALIFORNIA; STATE OF COLORADO;
STATE OF CONNECTICUT; STATE OF
DELAWARE; STATE OF MAINE;
STATE OF MARYLAND; STATE OF
MICHIGAN; STATE OF MINNESOTA;
STATE OF NEW JERSEY; STATE OF
NEW MEXICO; STATE OF NEW YORK,
STATE OF OREGON; STATE OF
RHODE ISLAND; STATE OF
VERMONT; STATE OF WISCONSIN;
JOSH SHAPIRO, in his official capacity as

Case No. 3:26-cv-01609-VC

**FIRST AMENDED COMPLAINT
FOR DECLARATORY AND
INJUNCTIVE RELIEF**

Judge: Hon. Vince Chhabria
Action Filed: February 24, 2026

1 Governor of the Commonwealth of
2 Pennsylvania,

3 Plaintiffs,

4
5 v.

6 ROBERT F. KENNEDY, JR., in his
7 official capacity as Secretary of the
8 DEPARTMENT OF HEALTH AND
9 DEPARTMENT OF HEALTH AND
10 HUMAN SERVICES; ERICA
11 SCHWARTZ, in her official capacity as
12 Director of the CENTERS FOR DISEASE
13 CONTROL AND PREVENTION;
14 CENTERS FOR DISEASE CONTROL
15 AND PREVENTION,

16 Defendants.
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INTRODUCTION

1. On January 5, 2026, the Centers for Disease Control and Prevention (“CDC”) issued a “Decision Memo” that delivered an unprecedented attack on the nation’s evidence-based childhood immunization schedule. Under the direction of Health and Human Services (“HHS”) Secretary Robert F. Kennedy, Jr., a longtime anti-vaccine activist, the CDC stripped seven childhood vaccines of their universally recommended status, in favor of senseless complexity and equivocation that will make children sicker and strain state resources (the “Kennedy Schedule”).

2. The Kennedy Schedule is the culmination of a series of unlawful actions in furtherance of Secretary Kennedy’s idiosyncratic and unscientific hostility to vaccines.

3. The Advisory Committee on Immunization Practices (“ACIP”) has historically been populated with leading medical scholars and public health experts, in accordance with its founding purpose of advising federal health leaders on “the most effective application in public health practice of specific preventive agents . . . [for] communicable disease control.” Smith, et al., *History and Evolution of the Advisory Committee on Immunization Practices – United States, 1964–2014*, MMWR Morb. Mortal. Wkly. Rep. 2014; 63(42), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm>.

4. ACIP is a federal advisory committee established under the Federal Advisory Committee Act (“FACA”). FACA mandates that ACIP be “fairly balanced,” and that its recommendations not be “inappropriately influenced by the appointing authority or by any special interest.” 5 U.S.C. § 1004(b)(2)–(3). Numerous other federal laws—including the 21st Century Cures Act, the Vaccines for Children statute, and the Affordable Care Act—establish that ACIP’s recommendations are necessary and integral to national health policy.

5. Secretary Kennedy promised Congress during his confirmation process that he would leave ACIP undisturbed. In June 2025, he broke that promise by abruptly firing

1 all seventeen ACIP voting members and then unlawfully repopulating ACIP with a
2 majority of his own anti-vaccine acolytes (the “Kennedy Appointees”).

3 6. Shortly thereafter, ACIP reversed nearly thirty years of CDC policy
4 recommending that the hepatitis B vaccine be universally administered at birth as part of
5 a three-dose series, in favor of the recommendation that the vaccine should generally not
6 be administered at birth and that subsequent doses should be contingent on consultation
7 and testing.

8 7. This rogue recommendation from an unlawfully reconstituted ACIP posed
9 an immediate threat to public health. But Defendants’ pretense of *any* reliance on ACIP—
10 even a zombie ACIP—did not continue for long.

11 8. On January 5, 2026, three individuals who had no affiliation to CDC and
12 no statutory or regulatory role in CDC’s vaccine policy development—the Director of the
13 National Institutes of Health (Jayanta Bhattacharya), the Administrator for the Centers
14 for Medicare and Medicaid Services (Mehmet Oz), and the Commissioner of Food and
15 Drugs (Martin Makary)—bypassed ACIP entirely by presenting a “Decision Memo” to
16 then-Acting CDC Director Jim O’Neill urging him to remove seven vaccines from the
17 CDC’s list of universally recommended childhood vaccines.

18 9. O’Neill signed the Decision Memo that same day (misdating it “2025”),
19 and thus—without warning or consultation—eviscerated CDC’s longstanding guidance
20 that vaccines protecting against rotavirus, meningococcal disease, hepatitis A, hepatitis
21 B, influenza, COVID-19, and respiratory syncytial virus (“RSV”) (the “Demoted
22 Vaccines”) should be universally administered.

23 10. In unilaterally promulgating and approving this radical change to the
24 science-based childhood immunization schedule, Defendants disregarded the extensive
25 and well-established evidence supporting ACIP’s and CDC’s pre-Kennedy
26 recommendations. Defendants did not utilize established scientific decision-making
27 frameworks, they identified no changed circumstances, and they ignored the clear risk to
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1 public health posed by downgrading routine vaccinations without notice or public
2 comment.

3 11. In lieu of undertaking the deliberate and legally required process to
4 promulgate major changes to U.S. vaccine standards, Defendants offered two pretexts for
5 their policy whims.

6 12. First, the Decision Memo ironically promotes its attack on “non-consensus”
7 vaccines (those purportedly not recommended by a majority of “peer countries”) as an
8 antidote to diminished public trust in vaccines. But Kennedy himself is among the most
9 prominent anti-vaccine activists in the country, and the Decision Memo’s suggestion,
10 without evidence, that these vaccines are unsafe will only exacerbate this distrust.

11 13. Second, relying on a report authored by two individuals with a documented
12 history of unscientific opposition to vaccines, the Decision Memo purports to align the
13 U.S. vaccine schedule with schedules in “peer countries,” with a particular focus on
14 Denmark.

15 14. But Denmark is not a “peer country” in relation to vaccines because, among
16 other things, unlike the U.S., it has a small, homogenous population and universal
17 healthcare. And Denmark’s vaccine policies are a global outlier that cannot be retrofitted
18 to the U.S. Even Danish health officials are baffled by Defendants’ reliance on
19 Denmark.¹

20 15. While Denmark and other countries are free to pursue vaccine policies
21 based on their unique demographics and health profiles, the CDC’s previous vaccine
22 recommendations have been transformative life-saving interventions in the U.S. Among
23 children born in the U.S. between 1994 and 2023 alone, researchers have estimated that
24 “routine childhood vaccinations will have prevented approximately 508 million cases of
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27 ¹ See Mandavilli, A., *R.F.K. Jr. Likely to Swap U.S. Childhood Vaccine Schedule for*
28 *Denmark’s*, https://www.nytimes.com/2025/12/19/health/kennedy-childhood-vaccine-schedule-denmark.html?unlocked_article_code=1.DFA.MhnI.-hP2Za6kYplM&smid=nytcore-ios-share.

1 illness, 32 million hospitalizations, and 1,129,000 deaths, resulting in direct savings of
2 \$540 billion and societal savings of \$2.7 trillion.”²

3 16. The Decision Memo cloaks its radical departure from public health and
4 science in the faux-authoritative assertion that, despite overwhelming scientific evidence
5 about the safety, efficacy, and population-level benefits of the CDC’s previously routinely
6 recommended vaccines, seven of those vaccines should be administered only after
7 “shared clinical decision-making” (“SCDM”).

8 17. Because that decision lacks scientific basis, it arbitrarily misleads patients
9 about the safety and efficacy of the Demoted Vaccines and thereby undermines public
10 health.

11 18. Additionally, because CDC’s childhood immunization schedule has always
12 been based on scientific evidence, medical providers and Plaintiff States have historically
13 relied heavily on it. The schedule is incorporated in state statutes, interwoven in public
14 health infrastructure, instrumental in guiding provider-patient consultation, and central to
15 public education campaigns and public health monitoring.

16 19. The Kennedy Schedule will damage public health by decreasing vaccine
17 uptake and increasing rates of vaccine-preventable diseases, including by creating
18 confusion, spreading misinformation contrary to established scientific evidence, and
19 increasing vaccine hesitancy.

20 20. The Kennedy Schedule also undermines Plaintiff States’ immunization,
21 public health, and Medicaid programs and will cause them to incur substantial costs in
22 preparing for, responding to, and treating higher incidences of vaccine-preventable
23 illnesses and disease outbreaks.

24 21. In appointing unqualified ACIP members who issued a dangerous hepatitis
25 B recommendation without requisite deliberation, analysis, or process—and then by
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27 ² Zhou F., et al., *Health and Economic Benefits of Routine Childhood Immunizations in*
28 *the Era of the Vaccines for Children Program — United States, 1994–2023*, MMWR
Morb. Mortal. Wkly. Rep 2024; 73:682–85, <http://dx.doi.org/10.15585/mmwr.mm7331a2>.

1 bypassing ACIP entirely to issue the Kennedy Schedule—Defendants acted in a manner
2 that is arbitrary and capricious and contrary to law.

3 22. Plaintiff States seek declaratory and injunctive relief to declare the Kennedy
4 Schedule and the appointments of the Kennedy Appointees unlawful and to have them
5 set aside.

6 JURISDICTION

7 23. This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331,
8 1346, and 2201(a) because this is an action against the United States arising under the
9 laws of the United States and executive-department regulations. Jurisdiction is also
10 proper under the judicial review provisions of the Administrative Procedure Act (“APA”)
11 because Plaintiff States are challenging final agency action and seeking declaratory and
12 injunctive relief, not monetary damages. 5 U.S.C. §§ 702, 704.

13 VENUE

14 24. Venue is proper in this judicial district under 28 U.S.C. § 1391(e) because
15 the California Attorney General and the State of California have offices at 455 Golden
16 Gate Avenue, San Francisco, California and at 1515 Clay Street, Oakland, California, and
17 therefore reside in this district, and no real property is involved in this action. This is a
18 civil action in which Defendants are United States agencies and officers sued in their
19 official capacity.

20 DIVISIONAL ASSIGNMENT

21 25. Assignment to the San Francisco Division or the Oakland Division of this
22 District is proper pursuant to Civil Local Rule 3-2(c)–(d) and 3-5(b) because Plaintiffs
23 maintain offices in the District.

24 PARTIES

25 I. Plaintiffs

26 26. Plaintiff State of Arizona, represented by and through its Attorney General
27 Kris Mayes, is a sovereign state of the United States of America. Attorney General Mayes
28

1 is Arizona's chief legal officer and is authorized to pursue this action on behalf of the
2 State of Arizona. *See* A.R.S. § 41-193(A).

3 27. Plaintiff State of California is a sovereign state in the United States of
4 America. California is represented by Rob Bonta, the Attorney General of California,
5 who is the chief law enforcement officer of California.

6 28. Plaintiff State of Colorado is a sovereign state in the United States of
7 America. Colorado is represented by Phil Weiser, the Attorney General of Colorado. The
8 Attorney General acts as the chief legal representative of the State and is authorized by
9 Colo. Rev. Stat. § 24-31-101 to pursue this action.

10 29. Plaintiff State of Connecticut is a sovereign state of the United States of
11 America. Connecticut is represented by and through its chief legal officer, Attorney
12 General William Tong, who is authorized under General Statutes § 3-125 to pursue this
13 action on behalf of the State of Connecticut.

14 30. Plaintiff State of Delaware is a sovereign state of the United States of
15 America. This action is brought on behalf of the State of Delaware by Attorney General
16 Kathleen Jennings, the "chief law officer of the State." *Darling Apartment Co. v.*
17 *Springer*, 22 A.2d 397, 403 (Del. 1941). Attorney General Jennings also brings this action
18 on behalf of the State of Delaware pursuant to her statutory authority. Del. Code Ann.
19 tit. 29, § 2504.

20 31. Plaintiff State of Maine is a sovereign state of the United States of America.
21 Maine is represented by Aaron M. Frey, the Attorney General of Maine. The Attorney
22 General is authorized to pursue this action pursuant to 5 Me. Rev. Stat. Ann. § 191.

23 32. Plaintiff State of Maryland is a sovereign state of the United States of
24 America. Maryland is represented by and through its chief legal officer, Attorney General
25 Anthony G. Brown.

26 33. Plaintiff State of Michigan is a sovereign state of the United States of
27 America. Michigan is represented by Attorney General Dana Nessel, who is the chief
28 law enforcement officer of Michigan.

1 34. Plaintiff State of Minnesota, represented by and through its Attorney
2 General Keith Ellison, is a sovereign state of the United States of America. The Attorney
3 General's powers and duties include acting in federal court in matters of State concern.
4 *See* Minn. Stat. § 8.01. The Attorney General has authority to pursue this action on behalf
5 of the State of Minnesota.

6 35. Plaintiff State of New Jersey is a sovereign state in the United States of
7 America. New Jersey is represented by Attorney General Jennifer Davenport, who is the
8 chief law enforcement officer of New Jersey.

9 36. Plaintiff State of New Mexico, represented by and through its Attorney
10 General, is a sovereign state of the United States of America. Attorney General Raúl
11 Torrez is the chief legal officer of the State of New Mexico and is authorized to prosecute
12 all actions and proceedings on behalf of New Mexico when, in his judgment, the interest
13 of the State requires such action. N.M. Stat. Ann. § 8-5-2(B). Attorney General Torrez
14 is also authorized to appear before federal courts to represent New Mexico when, in his
15 judgment, the public interest of the state requires such action. N.M. Stat. Ann. § 8-5-2(J).
16 This action is brought pursuant to Attorney General Torrez's statutory authority.

17 37. Plaintiff State of New York, represented by and through its Attorney
18 General Letitia James, is a sovereign State of the United States of America. As the State's
19 chief legal officer, the Attorney General is authorized to sue on the State's behalf.

20 38. Plaintiff State of Oregon is a sovereign state of the United States. Oregon
21 is represented by Attorney General Dan Rayfield. The Attorney General is the chief legal
22 officer of Oregon and is authorized to institute this action.

23 39. Plaintiff State of Rhode Island, represented by and through its Attorney
24 General Peter F. Neronha, is a sovereign state of the United States of America. Attorney
25 General Neronha is Rhode Island's chief legal officer and is authorized to pursue this
26 action on behalf of the State of Rhode Island.

40. The State of Vermont is a sovereign state of the United States of America. Vermont is represented by its Attorney General, Charity R. Clark, who is the chief legal officer of Vermont and has authority to represent the State in this matter.

41. Plaintiff State of Wisconsin is a sovereign state of the United States of America. Wisconsin is represented by Joshua L. Kaul, the Attorney General of Wisconsin. Attorney General Kaul is authorized to sue on behalf of the State.

42. Plaintiff Josh Shapiro brings this suit in his official capacity as Governor of the Commonwealth of Pennsylvania. The Pennsylvania Constitution vests “[t]he supreme executive power” in the Governor, who “shall take care that the laws be faithfully executed.” Pa. Const. art. IV, § 2. The Governor oversees all executive agencies in Pennsylvania and is authorized to bring suit on their behalf. 71 P.S. §§ 732-204(c), 732-301(6), 732-303.

II. Defendants

43. Defendant Robert F. Kennedy, Jr. is the Secretary of HHS. He is sued in his official capacity.

44. Defendant HHS is an agency of the United States government. 5 U.S.C. § 552(f)(1), § 701(b)(1).

45. Defendant CDC is a division within HHS and operates under the general supervision and authority of the HHS Secretary. U.S. Dep’t of Health & Human Servs., *Agencies & Offices*, <https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html> (accessed February 10, 2026).

46. Defendant Erica Schwartz is the Director of the CDC. She is charged with the supervision and management of all decisions and actions of that agency. She is sued in her official capacity. Schwartz replaced Acting Director Jayanta Bhattacharya, who had replaced then-Acting Director O’Neill in February 2026.

ALLEGATIONS

III. ACIP has a critical, statutorily mandated role in shaping U.S. vaccine policy.

47. ACIP is integral to the development of U.S. vaccine policy. It functions as a federal advisory committee to the CDC and is charged with advising the HHS Secretary,

1 through the CDC Director, on fulfilling HHS and CDC’s statutory obligations. *See, e.g.*,
 2 42 U.S.C. § 243(a); 42 U.S.C. § 247(b)(a); Dep’t of Health & Human Servs., *Charter of*
 3 *the Advisory Committee on Immunization Practices* (“Charter”) 1 (Apr. 1, 2024, as
 4 amended Dec. 3, 2025).

5 48. Under the 21st Century Cures Act, ACIP *must* consider *any* newly licensed
 6 vaccine or any new indication (clinical use) for an existing vaccine. 21 U.S.C. § 360bbb-
 7 4 note.

8 49. By law, ACIP’s recommendations set the floor for which vaccines must be
 9 covered under State Plans for Medicaid and the Children’s Health Insurance Program. 42
 10 U.S.C. § 1396a(a)(10)(A); 42 U.S.C. § 1396d(a)(13)(B), (a)(4)(B), (r)(1)(B)(iii); 42
 11 U.S.C. § 1397bb(a)(7)(A); 42 C.F.R. § 457.520.

12 50. The Affordable Care Act also requires insurers to cover, without cost-
 13 sharing, all vaccines recommended by ACIP. 42 U.S.C. § 300gg-13(a)(2).

14 51. Among ACIP’s essential functions is its responsibility to establish, review,
 15 and revise the schedule for pediatric vaccines covered by the Vaccines for Children
 16 (“VFC”) Program, which has helped protect Medicaid-eligible children, among others,
 17 from vaccine-preventable disease for over thirty years. *See* 42 U.S.C. § 1396s(e).

18 52. State Medicaid programs, in turn, rely on the VFC Program to meet their
 19 own statutory obligations to provide a pediatric vaccine distribution program under which
 20 “each vaccine eligible child” is entitled to receive free vaccines. *See* 42 U.S.C. §§
 21 1396a(a)(62), 1396s(a)(1)(A). The VFC program “[p]rovides publicly purchased
 22 vaccines for eligible children at no charge to VFC Program-enrolled providers in all states
 23 and U.S. territories” and supplies more than fifty percent of vaccines for children in the
 24 U.S. *About the Vaccines for Children (VFC) Program*, CDC (Sep. 30, 2025),
 25 <https://www.cdc.gov/vaccines-for-children/about/index.html>; Sean T. O’Leary, et al.,
 26 *Pediatricians’ Experiences with and Perceptions of the Vaccines for Children Program*,
 27 National Library of Medicine (Mar. 2020), [https://pmc.ncbi.nlm.nih](https://pmc.ncbi.nlm.nih.gov/articles/PMC10206937/)
 28 [.gov/articles/PMC10206937/](https://pmc.ncbi.nlm.nih.gov/articles/PMC10206937/).

53. ACIP was designated as a federal advisory committee under FACA in 1972. Smith, et al., MMWR Morb. Mortal. Wkly. Rep. (2014). It therefore must comply with FACA and its provisions. 5 U.S.C. § 1001 *et seq.*; *Charter* at 1.

54. FACA requires that membership of federal advisory committees be “fairly balanced in terms of the points of view represented and the functions to be performed.” 5 U.S.C. § 1004(b)(2), (c); 41 C.F.R. § 102-3.60(b). HHS therefore established procedures and controls for ACIP to comply with FACA and its “fairly balanced” membership requirement. *Id.*; *see also Charter* at 1; Ctrs. for Disease Control and Prevention, *Advisory Committee on Immunization Practices Policies and Procedures (“Policies & Procedures”)* (Jun. 2022), <https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf>; Ctrs. for Disease Control and Prevention, Membership Balance Plan (“MBP”).

55. FACA also requires that agency heads develop and follow procedures to ensure that advisory committee recommendations are “the result of [its] independent judgment,” and not “inappropriately influenced by the appointing authority or by any special interest.” 5 U.S.C. § 1004(b)(3), (c); *see also* 41 C.F.R. § 102-3.105(g).

56. Under the Public Health Service Act, 42 U.S.C. § 243(a), the Secretary must assist states “in the prevention and suppression of communicable diseases and with respect to other public health matters,” “cooperate with and aid” states “in the enforcement of their quarantine and other health regulations,” and advise the states “on matters relating to the preservation and improvement of the public health.”

57. In furtherance of these critical public health functions, ACIP advises the CDC Director on the “use of vaccines and related agents for effective control of vaccine preventable diseases in the civilian population of the United States.” *Charter* at 1.

58. In an ordinary process, the Director either adopts ACIP’s recommendations for the routine administration of vaccines to children and adults, or the Director sets forth his disagreement through a detailed process. *Policies & Procedures* at 8.

1 59. If approved, ACIP’s recommendations are published as official CDC/HHS
2 recommendations in the CDC’s Morbidity and Mortality Weekly Report and are reflected
3 in the CDC’s immunization schedules for their respective age groups. *Id.*

4 60. If the Director disagrees with an ACIP recommendation, he must state his
5 concerns in an internal decision memo back to ACIP. *Id.* ACIP may then revise its
6 recommendation or further brief the Director through a second internal memo. *Id.* If the
7 CDC Director still disagrees with ACIP’s recommendation, the ACIP Secretariat must
8 publish a notice in the Federal Register “that articulates the Director’s views and proposed
9 decision” and provides a thirty-day comment period. *Id.*

10 61. In 2010, ACIP adopted the Grading of Recommendations, Assessment,
11 Development, and Evaluation (“GRADE”) framework, “a widely used system of
12 assessing evidence and making recommendations,” and incorporated it into ACIP’s
13 Policies and Procedures. Campos-Outcalt, D. & Temte, J., *Advisory Committee on*
14 *Immunization Practices*, JAMA at 1 (Oct. 22, 2025), doi:10.1001/jama.2025.20060.
15 Historically, ACIP has used GRADE to ensure that its recommendations are grounded in
16 evidence and robust scientific inquiry. *Id.*

17 62. ACIP’s work is aided by Work Groups that analyze data and develop
18 evidence-based recommendation options to present to ACIP using the GRADE
19 framework. *Id.* at 4.

20 63. The GRADE framework consists of five tables that contain “a clear
21 description of the outcomes assessed (benefits and harms), the results of a comprehensive
22 search of relevant databases, a list describing all of the data included in the review, an
23 assessment of potential biases of each study, a meta-analysis of all included studies with
24 quantification of observed benefits and harms, and an overall rating of the quality of the
25 evidence.” *Id.*

26 64. The GRADE assessment has historically been completed by CDC staff who
27 present their findings to the ACIP Work Groups for review and consideration. *Id.* The
28

1 Work Groups subsequently present the information derived from the GRADE assessment
2 to the entire ACIP prior to a vote. *Id.*

3 65. After each ACIP vote, the GRADE assessment must be made publicly
4 available to ensure that “[e]very step and decision [leading to the ACIP’s votes are]
5 completely transparent to clinicians, researchers, and the public at large.” *Id.*

6 66. Since approximately 2019, ACIP has used the Evidence to
7 Recommendations (“EtR”) framework to consider several additional variables beyond
8 GRADE’s assessment on vaccine efficacy and safety. *Id.* These variables include “the
9 magnitude of the public health problem being addressed, costs vs benefits, feasibility of
10 the intervention, views of community stakeholders, and effects on equity.” *Id.*

11 67. The addition of EtR was intended to improve transparency in ACIP’s
12 decision-making process. The ACIP EtR User’s Guide explains that “[t]he purpose of
13 EtR framework is to help panels making recommendations move from evidence to
14 decisions, and to provide transparency around the impact of additional factors on
15 deliberations when considering a recommendation.” Ctrs. for Disease Control and
16 Prevention, *ACIP Evidence to Recommendation User’s Guide* at 3 (Oct. 1, 2020),
17 [https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020](https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf)
18 [.pdf](https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf).

19 **IV. Defendants decimated ACIP and replaced its members with a majority of**
20 **unqualified vaccine skeptics who changed CDC’s hepatitis B vaccine**
recommendation without basis.

21 68. In a May 19, 2025 email disclosed by the Senate Committee on Health,
22 Education, Labor, and Pensions (HELP) and published by the *New York Times*, the
23 Deputy Chief of Staff for Policy at HHS wrote that “Bobby” (likely Secretary Kennedy)
24 “has asked for the following changes to be made for the next ACIP meeting: 1. Replace
25 the members with the ten identified[,] 2. Add votes on ‘joint decision making’ for Hep B
26 (for healthy children and potentially others) and multi-dose flu for pregnant women and
27 children.” See HELP Comm. Minority Staff, *Emails Revealing Secretary Kennedy’s*
28 *Politicization of CDC*, Doc. A17-1 (Jun. 23, 2026),

1 https://www.help.senate.gov/imo/media/doc/cdc_emails.pdf; Sheryl G. Stolberg, *Inside*
2 *the C.D.C.'s Mad Scramble to Meet Kennedy's Demands*, N.Y. TIMES, Jun. 25, 2026,
3 <https://www.nytimes.com/2026/06/25/us/politics/kennedy-cdc-emails.html>.

4 69. Meeting notes taken that same day by Dr. Demetre Daskalakis, then
5 Director of National Center for immunization and Respiratory Diseases, confirm that
6 Secretary Kennedy directed that the newly reconstituted ACIP add to its meeting agenda
7 the elimination of the Hepatitis B vaccine for healthy children. HELP Comm., Doc. A17-
8 19.

9 70. On June 9, 2025, Kennedy abruptly dismissed all seventeen ACIP voting
10 members via an opinion column in the *Wall Street Journal* and a post on X.

11 71. Two days later, Kennedy purported to replace the dismissed ACIP members
12 with eight of his own appointees—all without following the applicable procedural
13 requirements or FACA's "fairly balanced" mandate. Defendants did not issue the
14 required Federal Register notice, broadly solicit nominations or applications, consult with
15 ACIP's Steering Committee to select qualified members with requisite expertise and
16 viewpoints, or complete the proper vetting process. *See Policies & Procedures* at 16-20;
17 *MBP* at 16–18.

18 72. In doing so, Kennedy violated the legal and regulatory scheme governing
19 how ACIP members must be appointed. On September 11, 2025, he appointed four more
20 members to ACIP in a similarly unlawful and haphazard manner and subsequently
21 reassigned one appointee, Martin Kulldorff, within HHS. He made other new ACIP
22 appointments after the issuance of the Kennedy Schedule—Kimberly Biss and Adam
23 Urato, announced on January 13, 2026, and Sean Downing and Angelina Farella,
24 announced on February 27, 2026.

25 73. ACIP's Charter provides that "[m]embers shall be selected from authorities
26 who are knowledgeable in the fields of immunization practices and public health, have
27 expertise in the use of vaccines and other immunobiologic agents in clinical practice or
28

1 preventive medicine, have expertise with clinical or laboratory vaccine research, or have
2 expertise in assessment of vaccine efficacy and safety.” *Charter* at 4.

3 74. ACIP’s Membership Balance Plan requires members to possess “expertise
4 in the field of immunization practices; multi-disciplinary expertise in public health;
5 expertise in the use of vaccines and immunologic agents; knowledge of vaccine
6 development, evaluation, safety and delivery; or, in the case of the consumer
7 representative, knowledge about consumer perspectives and/or social and community
8 aspects of immunization programs.” *MBP* at 2.

9 75. The ACIP Steering Committee (comprised of staff from each of the major
10 CDC centers) must also consider whether potential nominees will achieve the “balance
11 of specialty areas” necessary to accomplish the ACIP’s functions and to achieve a fairly
12 balanced viewpoint, including “pediatrics, internal medicine, family medicine, nursing,
13 consumer issues, state and local health department perspective[s], academic
14 perspective[s], [and] public health perspective[s].” *Id.* at 3.

15 76. ACIP’s Policies and Procedures reinforce that its medical professional
16 voting members must be “technically qualified people trained in a clinical medical field
17 who possess in-depth knowledge of vaccines and immunization.” *Policies & Procedures*
18 at 2. They underscore that all ACIP members be “acknowledged experts with an
19 outstanding record of achievement in their own fields and an understanding of the
20 immunization issues covered by ACIP.” *Id.* at 2. And they emphasize that “individuals
21 chosen for membership on ACIP have significant vaccine and immunization expertise,
22 including crosscutting knowledge and experience in the various aspects of the
23 immunization field.” *Id.* at 17.

24 77. Indeed, prior to the Kennedy Appointments, the overwhelming majority of
25 ACIP voting members had prolific experience studying and/or administering vaccines
26 and almost invariably had contributed to the understanding of vaccines and their
27 administration through original research reports in peer-reviewed medical, scientific, and
28 public health journals. For example, of the seventeen ACIP members dismissed by

1 Secretary Kennedy, fifteen had extensive records of conducting and publishing the results
2 of vaccine-related research in peer-reviewed medical, public health, and scientific
3 journals and one had an extensive track record overseeing public health immunization
4 programs. The seventeenth member was a highly respected medical school faculty
5 member with experience in pediatrics, internal medicine, and primary care, the settings
6 in which most routinely administered vaccines are provided in the U.S.

7 78. The requirements that ACIP members possess particular expertise and
8 levels of professional achievement are designed to ensure that ACIP achieves its principal
9 objective, to “provide advice and guidance to the Director of the CDC regarding use of
10 vaccines and related agents for effective control of vaccine-preventable diseases in the
11 civilian population of the United States,” *Charter* at 1, and its statutorily conferred
12 functions to issue evidence-based vaccine recommendations and determine the vaccines
13 available through the VFC, *Policies & Procedures* at 5.

14 79. The Kennedy Appointees lack the requisite scientific knowledge and
15 expertise to advise HHS and CDC on the “use of vaccines and related agents for effective
16 control of vaccine-preventable diseases” at the population-level. *Charter* at 1.

17 80. Indeed, Defendants purposefully populated ACIP with unqualified
18 individuals whose minority anti-vaccine views align with Kennedy’s views, and over
19 whom Defendants can exert inappropriate influence, in violation of FACA.

20 81. At least nine of the thirteen ACIP members actively serving at the time
21 Defendants issued the Kennedy Schedule—Hillary Blackburn, Evelyn Griffin, Joseph
22 Hibbeln, Retsef Levi, Robert Malone, Kirk Milhoan, James Pagano, Raymond Pollak,
23 and Catherine Stein—lack the experience and/or professional qualifications required by
24 ACIP’s Charter. And, other unqualified members—Biss, Downing, Farella, and Urato—
25 have since been added. According to ACIP’s website, Malone is no longer a member of
26 ACIP.

27 82. PubMed, which is maintained by the National Library of Medicine,
28 comprises over 39 million citations for biomedical literature from MEDLINE, life science

1 journals, and online books. It is considered the “gold standard” for identifying scientific
2 publications related to the life sciences.

3 83. Based on searches of PubMed and other publicly available databases and
4 sources, ten of the current Kennedy Appointees—Biss, Blackburn, Downing, Farella,
5 Griffin, Hibbeln, Milhoan, Pagano, Pollak, and Urato—have no documented prior
6 experience conducting research on vaccines, vaccination, vaccine safety, or vaccine
7 policy and have not held positions relating to the administration or distribution of
8 vaccines. Two of the current Kennedy Appointees—Levi and Stein—have only a very
9 small number of publications or any prior experience in one or more of these areas, in no
10 way comparable to the extensive experience and documented expertise previously
11 deemed a pre-requisite for appointment as a voting member of ACIP.

12 84. At least nine of the current ACIP members—Biss, Farella, Griffin, Levi,
13 Cody Meissner, Milhoan, Vicky Pebsworth, Stein, and Urato—have publicly disclosed
14 views on vaccines that align with the Secretary’s own minority anti-vaccination views, or
15 that are otherwise contrary to the scientific consensus on the safety and efficacy of
16 vaccines.

17 85. The Kennedy-appointed ACIP therefore now consists of individuals whose
18 lay knowledge of vaccines, together with their anti-vaccine views, undermine the
19 scientific consensus on vaccine safety and efficacy. *See generally* Schirring, L. & Van
20 Beusekom, M., *RFK Jr. announces new ACIP members, including vaccine critics*, Ctr.
21 for Infectious Disease Research and Policy (Jun. 12, 2025); Glenza, J., *Who are the eight*
22 *new vaccine advisers appointed by Robert F. Kennedy?* The Guardian (Jun. 13, 2025).

23 86. Aaron Siri is an anti-vaccine activist aligned with Kennedy who has sought
24 to enjoin the distribution of vaccines, including a children’s polio vaccine. An individual
25 who was interviewed for an ACIP seat in June 2025, but not appointed, has attested under
26 oath that an attorney at Siri’s law firm questioned her regarding her views on the
27 childhood vaccine schedule. The interviewee observed that when her answers were not
28 what the interviewer “was looking for ... [the interviewer] ended the interview very

1 quickly after that.” *See* Declaration of Diana Zuckerman, Ph.D., 1:25-cv-11916-BEM,
2 Dkt. 242.

3 87. Contrary to what Congress intended and what FACA requires, ACIP’s
4 reconstitution has rendered its recommendations no longer reliably independent. Its
5 decisions are now tainted by Secretary Kennedy’s inappropriate influence.

6 88. Concurrently, the Administration sought to limit the CDC Director’s
7 independence, including her authority to reject ACIP recommendations that have been
8 inappropriately influenced by the Secretary or the White House.

9 89. In an email dated August 19, 2025, HHS’s liaison to the White House, Matt
10 Buckham, instructed then-CDC Director Susan Monarez about “the absolute need for
11 political review of major policy decisions at CDC.” HELP Comm., Doc. G2-2. Mr.
12 Buckham further explained that, “[a]s you are aware, there are key priorities of the White
13 House and the Secretary underway with your team at CDC and we want to ensure that
14 [the Immediate Office of the Secretary] and CDC political leadership all have eyes on the
15 decisions for approval/changes before they go into effect.” *Id.*

16 90. In September 2025, Dr. Monarez testified before Congress that Secretary
17 Kennedy “demanded two things of me that were inconsistent with my oath of office and
18 the ethics required of a public official. He directed me to commit in advance to approving
19 every Advisory Committee on Immunization Practices (ACIP) recommendation
20 regardless of the scientific evidence. He also directed me to dismiss career officials
21 responsible for vaccine policy, without cause. He said if I was unwilling to do both, I
22 should resign.” *Restoring Trust Through Radical Transparency: Reviewing Recent*
23 *Events at the Centers for Disease Control and Prevention and Implications for Children’s*
24 *Health: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions, 119th Cong.*
25 *2 (2025) (statement of Susan Collier Monarez, Former Dir., Ctrs. for Disease Control &*
26 *Prevention),* [https://www.help.senate.gov/imo/media/doc/e7a31f2a-d31c-42bb-1a95-](https://www.help.senate.gov/imo/media/doc/e7a31f2a-d31c-42bb-1a95-38e6abef8195/Monarez%20Testimony.pdf)
27 [38e6abef8195/Monarez%20Testimony.pdf](https://www.help.senate.gov/imo/media/doc/e7a31f2a-d31c-42bb-1a95-38e6abef8195/Monarez%20Testimony.pdf); *see also* Kerry Cullinan, *Kennedy Wanted*
28 *CDC to ‘Rubber Stamp’ His Decisions. Former Officials Tell Senate*, Health Pol’y Watch,

1 Sep. 18, 2025, [https://healthpolicy-watch.news/kennedy-wants-cdc-to-rubber-stamp-his-](https://healthpolicy-watch.news/kennedy-wants-cdc-to-rubber-stamp-his-decisions-top-officials-tell-senate/)
2 [decisions-top-officials-tell-senate/](https://healthpolicy-watch.news/kennedy-wants-cdc-to-rubber-stamp-his-decisions-top-officials-tell-senate/).

3 91. Previously, CDC relied on the advice of a lawfully constituted ACIP,
4 comprised of qualified experts, to recommend for over thirty years that all children
5 receive a dose of the hepatitis B vaccine at birth, followed by two more doses of the
6 vaccine.

7 92. In an unprecedented reversal, the Kennedy Appointees recommended at the
8 December 4–5, 2025 ACIP meeting that CDC eliminate the recommendation for the
9 universal birth dose of the hepatitis B vaccine, and that vaccination instead generally be
10 contingent on whether the mother tests positive for the virus. That meeting was marked
11 by confusion and protests by two ACIP members who pointed out that members had not
12 been properly consulted and did not know what they were voting on.

13 93. The CDC adopted this recommendation on December 16, 2025.

14 94. The Kennedy Appointees also voted at the December 4–5, 2025 meeting to
15 recommend that prior to obtaining subsequent doses of the hepatitis B vaccine for their
16 children, parents consult with their health care providers to determine “if post-vaccination
17 anti-HBs serology testing should be offered” to assess a child’s titer levels, which
18 measure the concentration of specific antibodies in the blood to determine immunity, past
19 infections, or autoimmune activity. It is unclear whether, or when, the CDC adopted this
20 recommendation.

21 95. Unlike the prior recommendations, no scientific study has ever assessed this
22 approach, let alone supported its efficacy.

23 96. The current chair of ACIP, Kirk Milhoan, stated during a break at the
24 December 5, 2025 ACIP meeting that the committee felt “a little bit like puppets on a
25 string as opposed to really being [an] independent advisory panel.” *See Declaration of*
26 *Jason M. Goldman, MD, MACP, 1:25-cv-11916-BEM, Dkt. 162.*

1 97. In justifying their rogue recommendations, the Kennedy Appointees relied
2 on vague anecdotes about purported stakeholder “dissatisfaction” and other explanations
3 that disregarded, downplayed, or contradicted well-established scientific evidence.

4 98. The Kennedy Appointees disregarded the weight of all available scientific
5 data showing that the birth dose, and the overall hepatitis B three-dose series, are highly
6 safe and effective. As one expert stated, there is “no evidence of increased risks for any
7 adverse events, including serious adverse events, when the hepatitis B vaccine is given
8 shortly after birth compared with administration at 1 month of age or later.” Abers,
9 Michael S., et al., *Universal Hepatitis B Vaccination at Birth—Risks of Revising the*
10 *Recommendation*, JAMA (Dec. 3, 2025), [https://jamanetwork.com/journals/](https://jamanetwork.com/journals/jama/fullarticle/2842435)
11 [jama/fullarticle/2842435](https://jamanetwork.com/journals/jama/fullarticle/2842435).

12 99. Likewise, the Kennedy Appointees presented no evidence establishing that
13 a departure from the current recommended dosing is effective.

14 100. Reflecting their unscientific approach, the Kennedy Appointees and Dr.
15 Tracy Beth Høeg—the Acting Director of the Food and Drug Administration’s (“FDA”)
16 Center for Drug Evaluation and Research—repeatedly cited and relied on Denmark’s
17 immunization practices at the December 4-5, 2025 meeting.

18 101. Høeg gave a presentation to ACIP suggesting that Denmark’s more limited
19 childhood immunization schedule, which protects against only ten diseases (compared to
20 seventeen in the U.S., at the time), could serve as a model for the U.S.

21 102. But Denmark differs materially from the U.S. in myriad ways, including
22 because it has a homogenous population that is a tiny fraction of the U.S.’s size, a different
23 burden of disease, universal healthcare, and fewer circulating infectious diseases than the
24 U.S. Denmark is therefore also able to detect and treat diseases more expeditiously than
25 the U.S.

26 103. Experts have stressed that “[U.S.] vaccination policies were developed and
27 revised to address real-world challenges related to hepatitis B epidemiology, populations
28 at risk, continuity of care, access to care, costs, and other considerations [] *that are unique*

1 to the U.S. and its healthcare system.” Ulrich, A.K., et al., *Universal Hepatitis B*
 2 *Vaccination at Birth* at 13, Ctr. for Infectious Disease Research and Policy (Dec. 2, 2025),
 3 [https://www.cidrap.umn.edu/sites/default/files/searchable-download/Universal%20Hep](https://www.cidrap.umn.edu/sites/default/files/searchable-download/Universal%20Hepatitis%20B%20Vaccination%20at%20Birth%202Dec2025.pdf)
 4 [atitis%20B%20Vaccination%20at%20Birth%202Dec2025.pdf](https://www.cidrap.umn.edu/sites/default/files/searchable-download/Universal%20Hepatitis%20B%20Vaccination%20at%20Birth%202Dec2025.pdf) (emphasis added).

5 104. Among the experts who have warned ACIP that Denmark should not be
 6 treated as a “model” or “peer” nation is CDC hepatitis expert Dr. Adam Langer, who
 7 counseled against this approach at the December 4-5, 2025 meeting.

8 105. In sum, Kennedy reconstituted ACIP in an unlawful manner that failed to
 9 follow the procedures required to comport with FACA, as implemented by ACIP’s own
 10 Charter, Membership Balance Plan, and Policies and Procedures. As a result, ACIP now
 11 consists of unqualified appointees who ignored extensive evidence that a universal birth
 12 dose of the hepatitis B vaccine is safe and effective and arbitrarily recommended changing
 13 the CDC’s official policy on the hepatitis B vaccine.

14 106. Secretary Kennedy’s attack on ACIP’s and the CDC’s basic scientific
 15 functionality is ongoing. The New York Times recently reported that “interviews with
 16 more than 30 current and former employees reveal [CDC] is now tightly controlled by
 17 [Secretary] Kennedy and his associates, and its scientists are finding it increasingly
 18 difficult to do their jobs effectively.” Apoorva Madavilli, *‘Zombified’ C.D.C. Hobbled by*
 19 *Cuts, Struggles to Fulfill Scientific Mission*, N.Y. TIMES, Sep. 26, 2026,
 20 <https://www.nytimes.com/2026/09/26/health/cdc-staff-cuts-rfk-jr.html>.

21 **V. The acting CDC Director bypassed ACIP and purported to radically alter the**
 22 **childhood immunization schedule via the Decision Memo.**

23 107. Purging ACIP of subject-matter experts and reconstituting it with vaccine
 24 skeptics who weakened CDC’s hepatitis B recommendation was only a precursor to the
 25 even more lawless and destructive action that soon followed.

26 108. On January 5, 2026, CMS’s Dr. Mehmet Oz, NIH’s Dr. Jayanta
 27 Bhattacharya, and FDA’s Dr. Martin Makary—none of whom were affiliated with
 28 CDC—sent then-acting CDC director Jim O’Neill a “Decision Memo” recommending
 that he review and approve “a revised childhood and adolescent immunization schedule.”

1 O'Neill—who has two Humanities degrees, but no medical or scientific background—
2 approved and signed the Decision Memo the same day, misdating it “January 5, 2025.”

3 109. Ignoring federal law that requires vaccine recommendations to originate
4 from a properly constituted ACIP following an evidence-based decision-making process,
5 the Decision Memo fragments the formerly unified childhood immunization schedule into
6 three confusing and partially-overlapping tiers: (1) “immunizations recommended for all
7 children,” (2) “immunizations recommended for certain high-risk groups or populations,”
8 and (3) “immunizations based on [SCDM].” Høeg-Kulldorff Rep. at 2–3; *see also*
9 Decision Memo at 8.

10 110. The first tier, “immunizations recommended for all children,” consists of
11 eleven vaccines that the Memo deems “consensus vaccines”: measles, mumps, rubella,
12 diphtheria, tetanus, pertussis, polio, Haemophilus influenzae type B (Hib), pneumococcal
13 disease, human papillomavirus (HPV), and varicella. Høeg-Kulldorff Rep. at 18–19; *see*
14 *also* Decision Memo at 4.

15 111. The second tier, “immunizations recommended for certain high-risk groups
16 or populations,” encompasses those immunizations against RSV, hepatitis B, dengue,
17 meningococcal disease, and hepatitis A. Høeg-Kulldorff Rep. at 2; *see also* Decision
18 Memo at 5.

19 112. The third tier of vaccines are “not routinely recommended for all children”
20 and should instead be administered if “individually based and informed by a discussion
21 between the health care provider and the patient or parent/guardian” through SCDM.
22 Høeg-Kulldorff Rep. at 18; *see also* Decision Memo at 5. This tier overlaps with the
23 second tier, and consists of vaccines for hepatitis A, hepatitis B, rotavirus, meningococcal
24 disease, influenza, and COVID-19. Decision Memo at 2.

25 113. In demoting certain vaccines to SCDM or risk-based recommendations, the
26 Decision Memo implies that the long-established schedule recommended by ACIP poses
27 a potential risk to public health.
28

1 114. The Decision Memo, however, does not provide a scintilla of scientific
2 evidence to support its unscientific insinuation. Instead, it relies on specious assertions
3 and non-scientific rationales.

4 115. The Decision Memo first suggests that its recommendations will ameliorate
5 “decreased vaccine uptake and trust” that has led to falling childhood vaccinations rates
6 in recent years. But the Decision Memo cites zero evidence that its recommendations
7 will have this effect. Instead, the effect—and likely intent—of demoting numerous
8 vaccines from being routinely recommended to SCDM is to reduce uptake of the
9 vaccines.

10 116. Kennedy is among the most prominent anti-vaccine activists in the country
11 and has significantly contributed to eroding trust in vaccines long established as safe and
12 effective.

13 117. In 2019, Kennedy spread misinformation about the measles vaccine in the
14 country of Samoa that experts believe contributed directly to the deaths of over eighty
15 people. See T. Yang, *The perils of RFK Junior’s anti-vaccine leadership for public*
16 *health*, The Lancet, (Jan. 11, 2025) [https://www.thelancet.com/journals/lancet](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)02603-5/fulltext)
17 [/article/PIIS0140-6736\(24\)02603-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)02603-5/fulltext).

18 118. In a 2023 interview, Kennedy falsely stated that “[t]here’s no vaccine that
19 is safe and effective.” See [https://www.congress.gov/congressional-record/volume-](https://www.congress.gov/congressional-record/volume-171/issue-29/senate-section/article/S903-1)
20 [171/issue-29/senate-section/article/S903-1](https://www.congress.gov/congressional-record/volume-171/issue-29/senate-section/article/S903-1).

21 119. Suggesting that certain vaccines are not safe enough to be routinely
22 recommended does not foster trust in vaccines—rather, it undermines trust and
23 diminishes uptake, consistent with Kennedy’s long-held objective in his role as an anti-
24 vaccine activist.

25 120. Furthering Defendants’ effort to undermine, not promote, trust in vaccines,
26 the Decision Memo asserts without basis that “knowledge gaps concerning [the] safety”
27 of vaccines is a “current problem.” Decision Memo at 3.

1 121. The Decision Memo states that President Trump issued a December 5, 2025
2 memorandum directing Defendants to “review best practices from peer, developed
3 nations regarding core childhood vaccination recommendations” and to “update the
4 [U.S.] core childhood vaccine schedule to align with such scientific evidence and best
5 practices” if they determined them to be “superior” to existing recommendations.
6 Decision Memo at 1.

7 122. The two-paragraph presidential memorandum asserted that the U.S. is a
8 “high outlier in the number of vaccinations recommended for all children,” compared to
9 “[p]eer, developed countries” like Denmark, Japan, and Germany. It also stated without
10 elaboration that “[o]ther current [U.S.] childhood vaccine recommendations also depart
11 from policies in the majority of developed countries.” *Aligning United States Core*
12 *Childhood Vaccine Recommendations with Best Practices from Peer, Developed*
13 *Countries*, Presidential Memoranda (Dec. 5, 2025),
14 [https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-ch](https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries)
15 [ildhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries](https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries);
16 Decision Memo at 1.

17 123. President Trump is not a medical expert, and his political directive gave
18 Defendants no legal basis to bypass ACIP and flout statutory and procedural requirements
19 to make a consequential public health determination.

20 124. The Decision Memo also incorporates an “Assessment of the U.S.
21 Childhood and Adolescent Immunization Schedule Compared to Other Countries,”
22 authored by Høeg and Kulldorff, a current HHS official and a former ACIP Kennedy
23 Appointee.

24 125. The thirty-three-page Høeg-Kulldorff Report provides the sole evidentiary
25 pretext for the Kennedy Schedule. While Defendants admit that differences in global
26 vaccine recommendations “sometimes reflect the unique epidemiology of diseases in
27 each region,” they assert without basis that the differences “more often arise from
28 uncertain science and knowledge gaps.” Decision Memo at 4.

1 126. On information and belief, CDC vaccine experts delivered a presentation
2 on vaccine schedule comparisons by country to Defendants on or around December 18,
3 2025. The presentation advised that, “Across the U.S., Germany, Denmark, Japan,
4 Canada, and Australia, most childhood vaccines are recommended in all countries,” and
5 that small differences “reflect public health strategy not disagreement about [vaccine]
6 safety.”

7 127. Defendants disregarded the presentation’s findings and pushed through the
8 Kennedy Schedule by unlawfully bypassing ACIP.

9 128. Defendants’ unilateral decision to issue the Kennedy Schedule even
10 blindsided vaccine experts at the CDC, who were cut out of the agency’s decision-making
11 process.

12 129. By law, any recommendation should have originated with a properly
13 constituted ACIP, and Defendants should have meaningfully considered input from CDC
14 scientists, outside experts, and the public, before overturning decades of evidence-based
15 vaccine recommendations. Indeed, CDC’s preparation for changes to the immunization
16 schedule, including consultation with ACIP Work Groups, often began years before any
17 ACIP votes took place.

18 130. Instead, Defendants took unilateral and unprecedented action to undermine
19 the childhood immunization schedule, in furtherance of their ideological hostility to
20 vaccines.

21 131. Relying on the Høeg-Kulldorff Report, Defendants recommended that six
22 childhood vaccines be stripped of their routinely recommended status and instead be
23 subject to SCDM.

24 132. Defendants also created unnecessary and dangerous confusion around the
25 recommendation for a seventh immunization, RSV, by nominally moving it from the
26 universally recommended routine status to an immunization recommended for certain
27 high-risk groups or populations, without actually changing the substantive
28

1 recommendation that infants should get the immunized if their mothers were not
2 vaccinated during pregnancy.

3 133. Defendants assert that, when applying the already-opaque SCDM standard,
4 it is “important to consider personal and family preferences, beliefs, and knowledge” such
5 as “when a patient presents specific information regarding the pre-and-post licensure
6 safety data of a vaccine or presents specific familial experience with a vaccine.” Høeg-
7 Kulldorff Rep. at 18.

8 134. Contrary to Defendants’ assertions, SCDM is intended for situations in
9 which “individual factors meaningfully shift the risk-benefit assessment and population-
10 level benefit is uncertain.” Scott, J., *CIDRAP Op-Ed: Quiet dismantling: How ‘shared
11 decision-making’ weakens vaccine policy and harms kids*, CIDRAP (Jan. 6, 2026),
12 [https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-
13 shared-decision-making-weakens-vaccine-policy](https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-shared-decision-making-weakens-vaccine-policy).

14 135. According to the CDC, “The key distinction between routine, catch-up, and
15 risk-based recommendations and shared clinical decision-making recommendations is the
16 default decision to vaccinate. For routine, catch-up, and risk-based recommendations, the
17 default decision should be to vaccinate the patient based on age group or other indication,
18 unless contraindicated.” *ACIP Shared Clinical Decision-Making Recommendations*,
19 Ctrs. for Disease Control and Prevention. (Updated Jan. 7, 2025),
20 [https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.ht
21 ml](https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html).

22 136. In contrast, for SCDM, the decision whether to vaccinate “may be informed
23 by the best available evidence of who may benefit from vaccination; the individual’s
24 characteristics, values, and preferences; the health care provider’s clinical discretion; and
25 the characteristics of the vaccine being considered.” *Id.* But “there is not a prescribed
26 set of considerations or decision points in the decision-making process.” *Id.*

27 137. Because SCDM recommendations mean that there are no clear
28 recommendations for a specific group of people, they have historically been reserved for

1 vaccines about which, after considering all available evidence, true uncertainty exists at
2 a population level about whether the risks outweigh the benefits.

3 138. Prior to the Kennedy Schedule, the CDC had used SCDM sparingly. In the
4 past, SCDM was used for hepatitis B vaccination among certain adults sixty years of age
5 or older, serogroup B meningococcal vaccination in adolescents and young adults, human
6 papillomavirus (“HPV”) vaccination for adults aged twenty-seven to forty-five, and a
7 particular pneumococcal vaccine in patients sixty-five years or older. Kempe, A., et al.,
8 *Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do*
9 *Physicians Think?* Journal of general internal medicine. 2021;36(8):2283–91.
10 doi:10.1007/s11606-020-06456-z.

11 139. Most recently, ACIP recommended adult RSV vaccines based on SCDM
12 for a specific age group, but that recommendation was changed after one year to a risk-
13 based recommendation.

14 140. In these instances, there were specific nuances to each vaccine that made
15 SCDM appropriate. Melgar M, et al., *Use of Respiratory Syncytial Virus Vaccines in*
16 *Older Adults: Recommendations of the Advisory Committee on Immunization Practices -*
17 *United States, 2023.* MMWR Morb. Mortal. Wkly. Rep. Jul 21, 2023; 72(29):793–801.
18 doi:10.15585/mmwr.mm7229a4; Britton A., et al., *Use of Respiratory Syncytial Virus*
19 *Vaccines in Adults Aged ≥ 60 Years: Updated Recommendations of the Advisory*
20 *Committee on Immunization Practices - United States, 2024.* MMWR Morb. Mortal.
21 Wkly. Rep. Aug 15, 2024; 73(32):696–702. doi:10.15585/mmwr.mm7332e1.

22 141. In recommending that safe and effective vaccines be subject to SCDM
23 absent any new evidence to support that shift, Defendants have distorted scientific
24 evidence and sown doubt and confusion about these vaccines, without even providing
25 clear guidance to clinicians about what this decision-making process should entail. *See,*
26 *e.g., CDC Urges ‘Shared Decision-Making’ on Some Childhood Vaccines; Many Unclear*
27 *About What That Means.* *Annenberg Science Knowledge Surveys.* Annenberg Public
28 Policy Center, University of Pennsylvania (Jan. 5, 2026), <https://www.annenbergpublic>

1 [policycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-](https://www.policycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/)
2 [unclear-about-what-that-means/](https://www.policycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/).

3 **VI. The Kennedy Schedule will cause increased death and illness.**

4 142. Defendants adopted the Kennedy Schedule without conducting a systematic
5 review of the best available scientific evidence and without providing any reasoned
6 explanation for departing from decades of data showing that the Demoted Vaccines
7 prevent disease transmission, serious illness, hospitalization, and death in the U.S.

8 143. As of the time of this complaint's filing, the Kennedy Schedule conflicts
9 with ACIP's recommendations for each of the Demoted Vaccines—including even the
10 unscientific hepatitis B recommendation from the Kennedy Appointees—infusing further
11 confusion into national vaccine policy.

12 144. The Høeg-Kulldorff Report presents a handful of cherry-picked studies,
13 superficial comparisons, and speculative claims about the relative risks and benefits of
14 vaccines. This is a grossly inadequate substitute for the years of careful research and
15 transparent deliberation required to inform even slight modifications to the prior schedule.

16 145. Beyond failing to consider the best available scientific evidence,
17 Defendants failed to consider the following factors, among others: (a) the impact the
18 schedule changes would have on disease prevalence, hospitalizations, and death—and,
19 consequently, on state public health and healthcare systems; (b) public input, including
20 from state and local public health experts charged with administering vaccination
21 programs and issuing accurate, evidence-based information about CDC-recommended
22 vaccines; (c) independent expert input, including that of CDC career scientists and outside
23 experts; (d) financial impact on patients, such as the impact of increased and lengthier
24 consultations with medical professionals to discuss routine vaccinations; or (e) increased
25 burden on medical professionals resulting from more frequent and lengthier
26 consultations, as well as confusion about who should get certain vaccines absent clear
27 guidance from the CDC.

1 146. The Kennedy Schedule contradicts, or needlessly casts doubt on, decades
2 of scientific evidence demonstrating the safety and efficacy of the Demoted Vaccines that
3 were removed from the “consensus” list:

4 **Rotavirus**

5 147. Rotavirus is a viral infection of the gut that can cause severe diarrhea,
6 dehydration, or death. See Childhood Immunization Schedule by Recommendation
7 Group (“*CDC Imm. Sched. Index*”), Ctrs. for Disease Control and Prevention (last visited
8 Feb. 24, 2025), <https://www.hhs.gov/childhood-immunization-schedule/index.html>. By
9 1980, rotavirus was the most common cause of severe gastroenteritis in infants and young
10 children in the U.S. Cortese, M.M. & Penina, H., *Epidemiology and Prevention of*
11 *Vaccine-Preventable Diseases, Chapter 19: Rotavirus*, Ctrs. for Disease Control and
12 Prevention (Apr. 25, 2025), [https://www.cdc.gov/pinkbook/hcp/table-of-](https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-19-rotavirus.html)
13 [contents/chapter-19-rotavirus.html](https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-19-rotavirus.html).

14 148. In 2006, after one of the currently available rotavirus vaccines was licensed
15 in the U.S., the CDC recommended immunizing all babies against the disease starting at
16 two months. Yandell, K. & McDonald, J., *The Facts on the Vaccines the CDC No Longer*
17 *Recommends for All Children*, FactCheck.org, [https://www.factcheck.org/2026/01/the-](https://www.factcheck.org/2026/01/the-facts-on-the-vaccines-the-cdc-no-longer-recommends-for-all-kids/)
18 [facts-on-the-vaccines-the-cdc-no-longer-recommends-for-all-kids/](https://www.factcheck.org/2026/01/the-facts-on-the-vaccines-the-cdc-no-longer-recommends-for-all-kids/).

19 149. Pre-vaccine, there were an estimated 2.7 million annual rotavirus infections
20 in the U.S., with “95% of children experienc[ing] at least one rotavirus infection by age
21 five.” Cortese & Haber. Rotavirus infections resulted in “410,000 physician visits, more
22 than 200,000 emergency department visits, [and] 55,000 to 70,000 hospitalizations.” *Id.*
23 A 2018 review by CDC researchers estimated “20 to 60 deaths annually in children
24 younger than [five]” before the vaccine became routinely recommended. *Id.*; Yandell &
25 McDonald.

26 150. Pre-vaccine, rotavirus infections generated an estimated \$1 billion in annual
27 direct and indirect costs. Scott, J., *Quiet Dismantling*.

1 151. Routinely administering the rotavirus vaccine has proven to be highly
2 effective for protecting against rotavirus infections. Since 2006, there has been a “marked
3 reduction in rotavirus disease burden in the [U.S.],” as documented by data on
4 hospitalizations and emergency department care for diarrhea among young children. *Id.*
5 For example, as a result of routine immunization, the CDC estimates that among a sample
6 of children younger than five, between 2007 and 2011, “an average annual 280,000 clinic
7 visits, 62,000 emergency department visits, and 45,000 hospitalizations for rotavirus
8 disease were averted.” *Id.*

9 152. The Høeg-Kulldorff Report failed to consider the effectiveness of rotavirus
10 immunization in reducing hospitalizations. *See* Høeg-Kulldorff Rep. at 20–21.

11 153. Defendants also failed to consider existing data demonstrating that
12 “[r]otavirus vaccination has resulted in a significant and sustained reduction of disease
13 prevalence . . . in the [U.S.].” Hallowell, B., et al., *Trends in the Laboratory Detection of*
14 *Rotavirus Before and After Implementation of Routine Rotavirus Vaccination—United*
15 *States 2000—2018*, MMWR Morb. Mortal. Wkly. Rep. (Jun. 21, 2019), Ctrs. for Disease
16 Control and Prevention, <https://www.cdc.gov/mmwr/volumes/68/wr/mm6824a2.htm>.

17 154. The currently available rotavirus vaccines have also been established as
18 safe. The Høeg-Kulldorff Report does not question the safety of the available rotavirus
19 vaccines, but instead notes that the previously available vaccine was removed from the
20 market due to an “excess risk of intussusception [i.e., obstructed bowel syndrome].”
21 Høeg-Kulldorff Rep. at 21. In fact, the currently available rotavirus vaccines have been
22 shown to be safe with a “very small risk” of intussusception. John Hopkins Bloomberg
23 School of Public Health, *Rotavirus Vaccine Safety* (accessed Feb. 5, 2026),
24 <https://publichealth.jhu.edu/sites/default/files/2024-02/rota-brief4-safety2022ax.pdf>.
25 Experts and public health officials agree that the benefits of rotavirus vaccination far
26 outweigh the risks of intussusception.

27 155. The report also gives a misleadingly low estimate of pre-vaccine deaths that
28 directly conflicts with CDC’s own estimate of twenty to sixty deaths annually in children

1 younger than five before routine immunization. *See* Høeg-Kulldorff Rep. at 20.
2 Specifically, the report contends that “among all U.S. children [under fifteen], there were
3 an average of 3.3 deaths per year” which, after the implementation of routine vaccination,
4 was reduced to 1.6 deaths per year from 2009 to 2020. *Id.* at 20-21. The report then
5 surmises that “[t]here may be many reasons for this very small decrease in mortality that
6 are unrelated to the vaccine, including improved medical care, changes in diagnostic
7 practices or random fluctuations.” *Id.*

8 156. The Høeg-Kulldorff Report’s low death estimates conflict with CDC data
9 collected near the time that the routine immunization recommendation was implemented.
10 The report further relies on a specific “rotavirus diagnostic code” listed on death
11 certificates between 1999 and 2005, *id.*, which likely resulted in an underestimation of
12 deaths. Yandell & McDonald.

13 157. While mischaracterizing the number of deaths due to rotavirus, the Høeg-
14 Kulldorff Report entirely ignores the tens of thousands of physician appointments,
15 emergency room visits, and hospitalizations for rotavirus disease that have been averted
16 by vaccination.

17 158. Finally, seventeen of the purported twenty “peer nations” in the Høeg-
18 Kulldorff Report recommend the rotavirus vaccine. Yet the report disregards this fact,
19 instead mentioning only the three “peer nations” that do not recommend it and providing
20 no analysis as to why that supports a change in vaccination policy in the U.S. Høeg-
21 Kulldorff Rep. at 21.

22 **Meningococcal**

23 159. Meningococcal disease is a bacterial infection that can affect the brain and
24 spinal cord or the bloodstream and can cause loss of limbs, deafness, seizures, or death.
25 *CDC Imm. Sched. Index.* It “is rare but among the most devastating infections in
26 medicine, with a 10% to 15% case-fatality rate, death within 24 hours of first symptoms,
27 and survivors left with amputations and brain damage.” Scott, J., *Quiet Dismantling*.

1 160. N. meningitidis is the leading cause of bacterial meningitis in children
2 between ages two and eighteen in the U.S. There are six serogroups that cause most
3 meningococcal disease—serogroups A, B, C, W, X and Y. *Meningococcal Vaccine*
4 *Safety*, Ctrs. for Disease Control and Prevention (Dec. 20, 2024),
5 <https://www.cdc.gov/vaccine-safety/vaccines/meningococcal.html>. The quadrivalent
6 meningococcal conjugate vaccine (MenACWY) protects against meningococcal disease
7 caused by serogroups A, C, W, and Y. *Id.* Another vaccine, known as MenB, protects
8 against meningococcal disease caused by serogroup B. *Id.* A third vaccine combines the
9 two types to provide coverage against serogroups A, B, C, W, and Y (MenABCWY
10 vaccine).

11 161. These meningococcal vaccines are safe. According to the CDC “[f]indings
12 from vaccine safety monitoring systems and scientific studies have shown that
13 MenACWY and MenB vaccines have a favorable safety profile,” and the “body of
14 scientific evidence overwhelmingly supports their safety.” *Id.*

15 162. Prior to the Kennedy Schedule, ACIP routinely recommended the
16 MenACWY vaccine for all adolescents aged eleven and twelve, with a booster at age
17 sixteen due to waning protection and increased risk in later adolescence. ACIP also
18 recommended the MenB vaccine based on SCDM for healthy persons aged sixteen to
19 twenty-three (with sixteen to eighteen framed as the preferred age window) and separately
20 recommended the MenB vaccine routinely for persons at increased risk.

21 163. The difference in vaccine uptake based on recommendation type (routine
22 vs. SCDM) is evident. U.S. adolescent coverage for MenACWY is high, with
23 approximately ninety percent receiving at least one dose and sixty percent receiving the
24 recommended booster dose. On the other hand, MenB vaccine uptake has been
25 substantially lower under SCDM, with approximately thirty-two percent of adolescents
26 receiving at least one dose and only fourteen percent completing the two-dose MenB
27 series.

1 164. Without presenting any new evidence concerning vaccine efficacy or safety
2 or demonstrating that the prior routine recommendation for MenACWY was
3 inappropriate, the Kennedy Schedule moved the MenACWY vaccine into the SCDM
4 category with the MenB vaccine.

5 165. Instead of addressing any existing and relevant evidence, the Høeg-
6 Kulldorff Report makes various unsupported assertions and irrelevant comparisons to
7 justify its conclusion.

8 166. First, it asserts that the “incidence of meningococcal disease has declined
9 during the past decades,” and summarily concludes, without basis, that “the magnitude of
10 the decline appears to be independent of vaccination policy.” Høeg-Kulldorff Rep. at 21.

11 167. Second, it relies on a one-page summary of a 2011 World Health
12 Organization (WHO) “position paper” recommending that only those countries with
13 “more than 2 cases per 100,000 population/year maintain a ‘*large scale meningococcal*
14 *vaccination program*’” (emphasis in original). *Id.* at 23, 33. Based on the WHO’s
15 “suggested cut-off” and the purported lack of “large-scale double-blind placebo-
16 controlled randomized trials” for currently available meningococcal vaccines, the report
17 concludes that “the meningococcal vaccine should not be part of the consensus
18 recommended vaccine schedule.” *Id.* at 23.

19 168. But the report’s reliance on the WHO threshold is misplaced. WHO
20 vaccine position papers provide “global vaccine and immunization recommendations for
21 diseases that have an international public health impact” and are therefore developed for
22 a global audience and do not consider unique U.S. public health needs, as CDC must do
23 when formulating domestic vaccine policy. *See Strategic Advisory Group of Experts on*
24 *Immunization (SAGE)*, World Health Organization (last visited Feb. 20, 2026),
25 [https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/position-](https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/position-papers)
26 [papers](https://www.who.int/teams/immunization-vaccines-and-biologicals/policies/position-papers). And, in particular, the WHO threshold cited in the Høeg-Kulldorff Report “was
27 designed for reactive mass campaigns during epidemics in the African Meningitis Belt,
28 not for routine preventative care in high-income nations.” Scott, J., *Quiet Dismantling*.

169. The Høeg-Kulldorff Report’s conclusion also ignores its own purported criteria for determining “consensus recommended” vaccines, as the report acknowledges that fifteen purported “peer nations” recommend the meningococcal vaccine for all children. Høeg-Kulldorff Rep. at 23–24. Indeed, the “United Kingdom, Ireland, Italy, the Netherlands, Portugal, Australia, Canada, and Germany “all have routine meningococcal programs despite low incidence,” with Germany expanding “its program in January 2025 to include meningococcal B.” Scott, J., *Quiet Dismantling*.

Hepatitis A

170. Hepatitis A is a viral, highly contagious liver infection that can result in liver failure or death. *CDC Imm. Sched. Index*. The hepatitis A vaccine was first licensed as a two-dose vaccine for children twenty-four months or older in 1995. Ctrs. for Disease Control and Prevention, *Hepatitis A Vaccination Coverage Among U.S. Children Age 12–23 Months—Immunization Information System Sentinel Sites, 2006–2009*, MMWR Morb. Mortal. Wkly. Rep. (Jul. 2, 2010), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5925a3.htm>.

171. In 1996 and 1999, ACIP “recommended routine hepatitis A vaccination for children [24 months or older] in communities with the highest rates of the disease.” *Id.* In 2005, the FDA licensed the vaccine for use beginning at twelve months, and in May 2006, ACIP routinely recommended the vaccine for “all children aged 12–23 months, regardless of risk category or location.” *Id.*

172. Routinely vaccinating for hepatitis A has been highly effective in reducing the incidence of the virus in the U.S. According to the CDC, one year after ACIP adopted its routine recommendation in 2006, the incidence of hepatitis A “reached a historic low.” *Id.*

173. Hepatitis A vaccines have also been proven safe, with millions of doses administered since licensure in 1995. Ctrs. for Disease Control and Prevention, *Hepatitis A Vaccine* (Jan. 31, 2025), <https://www.cdc.gov/hepatitis-a/vaccination/index.html>. As recently as January 2025, the CDC confirmed that both types of hepatitis A vaccines

1 (single antigen vaccines for solely hepatitis A and combination vaccines for both hepatitis
2 A and B) are safe and highly effective, even for people with compromised immune
3 systems. *Id.* Further, the CDC has stated that the “potential risks of hepatitis A are much
4 higher than any risks associated with [the] hepatitis A vaccine.” *Id.*

5 174. The Høeg-Kulldorff Report asserts, without attribution, that “high [hepatitis
6 A] endemic communities” in the U.S. had “disappeared” by the time the hepatitis A
7 vaccine was universally recommended for all children in 2006, at which time the “annual
8 incidence rate . . . was very low.” Høeg-Kulldorff Rep. at 20. It further asserts that the
9 incidence of hepatitis A “remains similarly low” and that the annual mortality rate is only
10 “1 per 10 million, with the highest rate among older men.” *Id.* The report also claims
11 that “reliable safety data is limited” due to a lack of “proper placebo-controlled
12 randomized trial[s]” for the currently available FDA-approved hepatitis A vaccines. *Id.*
13 Based on the purportedly “low U.S. incidence and mortality, and the lack of randomized
14 placebo-controlled safety data,” the report sweepingly concludes that “the benefit-risk
15 ratio is at best very low for most children” and the hepatitis A vaccine thus “should not
16 be recommended for all children.” *Id.*

17 175. The Høeg-Kulldorff Report’s contention that “reliable safety data is
18 limited” for hepatitis A vaccine due to a lack of “proper placebo-controlled randomized
19 trial[s]” is misleading. That contention “relies on a very narrow definition of a proper
20 clinical trial and dismisses other types of studies that can be used to help establish vaccine
21 safety.” Yandell & McDonald. However, the available data, which is significant, shows
22 no vaccine-related serious adverse events for the hepatitis A vaccines.

23 176. Moreover, although young children are not themselves at high risk of death
24 or severe illness from hepatitis A during childhood, they are at risk in later years, and in
25 the meantime they can also transmit the virus to susceptible adults, including those with
26 certain health conditions. *Id.* Pediatric hepatitis A vaccination protects children as they
27 age into adolescence and adulthood, and protects others with whom they come into
28 contact.

177. With no new evidence or data presented to support a change in recommendation to SCDM, Defendants arbitrarily and capriciously ignored the established scientific data confirming the safety and efficacy of hepatitis A vaccination as well as the individual and public health benefits of routinely administering the hepatitis A vaccines to all children.

Hepatitis B

178. Hepatitis B is a viral liver infection that can result in chronic liver infection, liver failure, liver cancer, or death. *CDC Imm. Sched. Index*. Over time, the ACIP's hepatitis B immunization recommendations have shifted from a "risk-based vaccination" strategy to a universal birth dose strategy, successively refining recommendations to address specific gaps. Ulrich, A. K., et al. at 2.

179. In 1991, ACIP recommended hepatitis B vaccinations at birth for all newborns. Since then, the hepatitis B birth dose has provided a critical safety net to protect infants against maternal hepatitis B transmission, including in instances where mothers are "infected after testing or due to errors or delays in communication of test results." *Id.* at 2. "[B]ecause tests are not 100% accurate, the chance of being infected after testing but before delivery is real, and not all women have equal access to health care" in the U.S. Moser, C.A., *Former vaccine advisory committee member: Public health cannot fix health care system problems*, STAT News (Sep. 24, 2025), <https://www.statnews.com/2025/09/24/acip-meeting-cdc-vaccine-advisory-committee-former-member-trust/>.

180. For example, in Arizona, nearly half of mothers enrolled in Medicaid who gave birth in 2024 received no or inadequate prenatal care, and of those that *did* receive prenatal care, seventy-two percent were not screened for hepatitis B.

181. According to the Johns Hopkins Bloomberg School of Public Health, "[w]hen given within 24 hours of birth, the vaccine is up to 90% effective in preventing perinatal infection" and completion of the full three dose series "achieve[s] full immunity that lasts at least 30 years." John Hopkins Bloomberg School of Public Health, *Hepatitis*

1 *B Vaccination is an Essential Safety Net for Newborns* (Sep. 24, 2025),
 2 <https://publichealth.jhu.edu/2025/why-hepatitis-b-vaccination-begins-at-birth>. The birth
 3 dose also has been shown “to reduce a person’s risk of liver cancer by 84% and death
 4 from liver disease by 70%.” *Id.*

5 182. The safety and efficacy of the hepatitis B vaccine in its standard three-dose
 6 series—administered at birth, one month and six months—“has been rigorously studied
 7 and continuously monitored since licensure.” Abers, M.S., et al. Moreover, “[r]esults of
 8 randomized trials, large national safety monitoring programs, and long-term follow-up
 9 studies consistently demonstrate that the hepatitis B vaccine is safe regardless of vaccine
 10 timing, [and] no safety benefits were identified for a delayed first dose versus vaccination
 11 at birth.” Ulrich, A. K., et al. at 2.

12 183. In December 2025, the Kennedy appointed-ACIP voted to eliminate the
 13 universal birth dose recommendation for hepatitis B (unless opted-into through SCDM)
 14 and to recommend the dose only for babies born to mothers whose hepatitis B status is
 15 positive or unknown. As Dr. Jason Goldman, President of the American College of
 16 Physicians, remarked during the December meeting, the Kennedy Appointees’ vote to
 17 eliminate the universal birth dose was “an unnecessary solution looking to find a problem
 18 to solve” and it “will only endanger children and increase risk of death for millions.”
 19 Samantaroy, S., *CDC Committee Delays Hepatitis B Vaccine for Newborns in Critical*
 20 *Guidelines Shift*, Health Policy Watch (Dec. 5, 2025), [https://healthpolicy-](https://healthpolicy-watch.news/cdc-panel-revises-hep-b-vaccine-recommendation/)
 21 [watch.news/cdc-panel-revises-hep-b-vaccine-recommendation/](https://healthpolicy-watch.news/cdc-panel-revises-hep-b-vaccine-recommendation/).

22 184. For infants born to mothers who tested negative for hepatitis B, the
 23 Kennedy Appointees specifically recommended that those infants receive the initial dose
 24 “no earlier than 2 months of age.” For those who choose to get the vaccine earlier, the
 25 Kennedy Appointees recommended that the decision be made by parents through SCDM.

26 185. But “[t]here is no evidence of increased risk for any adverse events,
 27 including serious adverse events, when the hepatitis B vaccine is given shortly after birth
 28 compared with administration at 1 month of age or later.” Abers, M. S., et al.

1 186. At the December 4-5, 2025 ACIP meeting, the Kennedy Appointees
 2 acknowledged that there currently is no scientific evidence of harm in giving the hepatitis
 3 B vaccine to infants, or any difference in giving the initial dose of the vaccine at any point
 4 earlier than two months. One ACIP member—Hibbeln—specifically observed that
 5 “there was no data presented that two months is an appropriate cut-off” for the hepatitis
 6 B vaccine. Stobbe, M., *RFK Jr.’s chosen vaccine advisers say not all babies need a*
 7 *hepatitis B shot at birth*, Associated Press (Dec. 5, 2025),
 8 <https://www.pbs.org/newshour/health/rfk-jr-s-chosen-vaccine-advisers-say-not-all-babies-need-a-hepatitis-b-shot-at-birth>.
 9

10 187. The Kennedy Schedule is even more damaging as it no longer reflects *any*
 11 birth dose recommendation for the hepatitis B vaccine, although the CDC purports to
 12 have adopted ACIP’s December 2025 recommendation.

13 188. The Kennedy Appointees also voted to recommend that serological testing
 14 be used as an alternative to completion of the full vaccination series, contradicting CDC
 15 guidance that such testing is a “known correlate of protection *only* when testing follows
 16 a documented 3-dose series.” Schillie, S., et al., *Prevention of Hepatitis B Virus Infection*
 17 *in the United States: Recommendations of the Advisory Committee on Immunization*
 18 *Practices*, MMWR Recomm. Rep. 2018; 67(No. RR-1):1–31. DOI:
 19 <http://dx.doi.org/10.15585/mmwr.rr6701a1> (emphasis added).

20 189. In addition to lacking any reasoned scientific support, the Kennedy
 21 Appointees’ hepatitis B recommendation was not responsive to U.S. public health needs
 22 or real-world challenges related to hepatitis B epidemiology, and places individuals at
 23 risk from false assurance of protection after incomplete immunization.

24 **Influenza**

25 190. Influenza is a viral respiratory infection that can cause pneumonia, sinus
 26 and ear infections, worsen underlying heart or lung conditions, and lead to death. CDC
 27 *Imm. Sched. Index*. The disease can trigger acute cardiac events. Woodruff, R.C., et al.,
 28 *Acute Cardiac Events in Hospitalized Older Adults With Respiratory Syncytial Virus*

1 *Infection*, JAMA Internal Medicine (June 1, 2024),
 2 <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2817609>. Influenza
 3 typically causes a major epidemic in the U.S. annually, starting in late fall and early
 4 winter, but often extending into early spring.

5 191. Three influenza viruses circulate routinely in humans: influenza A(H1N1),
 6 influenza A(H3N2), and influenza B. Annual vaccination has historically been
 7 recommended because protection from influenza vaccine wanes and circulating influenza
 8 A viruses mutate, requiring the strain in the vaccine to be periodically updated to afford
 9 the best protection.

10 192. The primary goal of influenza vaccines is to prevent severe disease, often
 11 defined as illness that results in hospitalization and death.

12 193. Influenza vaccines were first developed in the 1940s, with specific groups
 13 recommended to receive the vaccine starting in 1960. Prior to the Kennedy Schedule,
 14 recommendations involved an extensive review of epidemiologic data, data on illness
 15 severity and disease burden, influenza transmission, vaccine effectiveness, safety,
 16 feasibility and cost-effectiveness. Neuzil, K.M., et al., *Evolution of the pediatric influenza*
 17 *vaccination program in the United States*. Pediatrics, 129 Suppl. 2 (Mar. 1, 2012),
 18 doi:10.1542/peds.2011-0737B.

19 194. Beginning in 2002, influenza vaccination for children six to twenty-three
 20 months old was “encouraged.” Bridges, C.B., et al., *Prevention and control of influenza.*
 21 *Recommendations of the Advisory Committee on Immunization Practices (ACIP)*,
 22 MMWR Morb. Mortal. Wkly. Rep., Ctrs. for Disease Control and Prevention (Apr. 25,
 23 2003). However, following a severe influenza season in 2003-04 with a high number of
 24 pediatric influenza deaths reported, CDC issued a full recommendation for children aged
 25 6 - 23 months to be vaccinated based on studies showing that children in that age group
 26 had hospitalization rates comparable to older adults with underlying medical conditions.
 27 Neuzil K.M., & Harper S.A., et al., *Prevention and control of influenza:*
 28 *recommendations of the Advisory Committee on Immunization Practices (ACIP)*,
Guideline Practice Guideline, MMWR Morb. Mortal. Wkly. Rep., Ctrs. for Disease

Control and Prevention (May 28, 2004); Izurieta, H.S., et al., *Influenza and the rates of hospitalization for respiratory disease among infants and young children*, N. Engl. J. Med. (Jan. 27, 2000), doi:10.1056/NEJM200001273420402.

195. Recommendations were expanded to include children aged two to four years in 2006. Kroger, A.T., et al., *Advisory Committee on Immunization Practices Centers for Disease C, Prevention. General recommendations on immunization: recommendations of the Advisory Committee on Immunization Practices (ACIP). Practice Guideline*. MMWR Morb. Mortal. Wkly. Rep., Ctrs. for Disease Control and Prevention (Dec. 1, 2006). After extensive debate about the merits of a universal recommendation versus a risk-based recommendation, influenza vaccines were gradually expanded and have been recommended for all individuals in the U.S. aged six months and older since 2010. Neuzil K.M., et al.

196. The Høeg-Kulldorff Report asserts that there is a “scarcity of reliable safety data” regarding the influenza vaccines. *Id.* at 24. To the contrary, the influenza vaccines have one of the longest and most established track records of safety. Per the CDC, “[t]he body of scientific evidence overwhelmingly supports their safety,” including “[f]indings from vaccine safety monitoring systems and scientific studies have [] show[ing] that flu vaccines have an excellent safety profile” and that “[h]undreds of millions of Americans have safely received flu vaccines for more than 50 years.” *Influenza (Flu) Vaccine Safety*, Ctrs. for Disease Control and Prevention (Updated Dec. 24, 2024), <https://www.cdc.gov/vaccine-safety/vaccines/flu.html>. Multiple studies of influenza vaccines in children have confirmed their safety. Gidengil, C., et al., *Safety of vaccines used for routine immunization in the United States: An updated systematic review and meta-analysis*, Vaccine (Jun. 23, 2021), doi:10.1016/j.vaccine.2021.03.079. The Høeg-Kulldorff Report ignores this data.

197. The Høeg-Kulldorff Report dismisses a study showing that the “childhood influenza vaccine reduces hospitalization” by claiming that it was based on “a notoriously biased study design, with highly implausible results.” *Id.* at 24. In doing so, the report

1 relies on an article authored solely by Kulldorff in an unscientific source and a book
2 published by a discredited physician known for his anti-vaccine publications. *Id.* at 24,
3 33.

4 198. Based on this self-citation and unscientific source material, the report
5 concludes that “[b]ased on both the evidence and uncertainties, the influenza vaccine
6 should not be recommended for all children.” *Id.* at 24.

7 199. Experts have recognized that this conclusion is fatally flawed. As to
8 mortality, the Høeg-Kulldorff Report “exploits a statistical impossibility: because death
9 from influenza is a rare event in healthy children, a randomized trial would require
10 millions of participants to demonstrate a mortality benefit, a scale that has never existed
11 for any pharmaceutical product.” Scott, J., *Quiet Dismantling*.

12 200. On the other hand, the dangers of not getting children vaccinated against
13 influenza are all too real. Influenza is a leading cause of vaccine-preventable deaths
14 among children. From 2004 to 2023, between thirty-seven and 199 children died of
15 influenza every year in the U.S. *See Flu and Children*, Ctrs. for Disease Control and
16 Prevention (Updated Sep. 5, 2025), <https://www.cdc.gov/flu/highrisk/children.html>.

17 201. Last year, during the 2024 to 2025 influenza season, there were 289
18 pediatric deaths. Reinhart, K., et al., *Influenza-Associated Pediatric Deaths - United*
19 *States, 2024-25 Influenza Season*. MMWR Morb. Mortal. Wkly. Rep. (Sep. 25, 2025),
20 <https://www.cdc.gov/mmwr/volumes/74/wr/mm7436a2.htm>. Excluding the 2009 to
21 2010 influenza A (H1N1) pandemic, this is the highest number of pediatric influenza
22 deaths since reporting began. *Id.* Nearly half of children who died had no underlying
23 medical conditions and eighty-nine percent of those with known vaccination status were
24 not fully vaccinated. *Id.*

25 202. Rather than acknowledge this data, the Høeg-Kulldorff Report
26 misleadingly relied on a study that “did not identify hospitalization or death benefits of
27 flu vaccination . . . [and] did not include any trials with data on those outcomes. It did,
28

1 notably, find evidence that flu shots worked to reduce influenza in children.” Yandell &
2 McDonald.

3 **COVID-19**

4 203. COVID-19 is a viral respiratory infection that can result in pneumonia,
5 blood clots, liver, heart, or kidney damage, long COVID, or death. *CDC Imm. Sched.*
6 *Index*. COVID-19 can also trigger acute cardiac events. Woodruff, R.C., et al.

7 204. The primary goal of COVID-19 vaccines is to prevent severe disease (i.e.,
8 illness that results in hospitalization and death).

9 205. While rates of hospitalization and death were highest during 2020 and 2021,
10 especially prior to the widespread availability of vaccines, and have declined in recent
11 years, COVID-19 remains a significant public health problem. In the U.S. from 2023 to
12 2024, there were an estimated 33 million COVID-19–associated illnesses, 7.7 million
13 outpatient visits, 879,100 hospitalizations, and 100,800 deaths. Koumans, E.H.A., et al.,
14 *Estimated Burden of COVID-19 Illnesses, Medical Visits, Hospitalizations, and Deaths*
15 *in the US From October 2022 to September 2024*, JAMA Internal Medicine (Jan. 5,
16 2026), doi:10.1001/jamainternmed.2025.7179.

17 206. For the 2024 to 2025 season, preliminary estimates from CDC indicated
18 that from October 1, 2024 to October 1, 2025, COVID-19 caused between an estimated
19 14 to 21 million illnesses, 3.4 to 4.8 million outpatient visits, 390 to 550 thousand
20 hospitalizations, and between 45,000 and 64,000 deaths. *Preliminary Estimates of*
21 *COVID-19 Burden for 2024-2025*, Ctrs. for Disease Control and Prevention (Figure
22 Updated Feb. 6, 2026), [https://www.cdc.gov/covid/php/surveillance/burden-](https://www.cdc.gov/covid/php/surveillance/burden-estimates.html)
23 [estimates.html](https://www.cdc.gov/covid/php/surveillance/burden-estimates.html).

24 207. Infants less than six months are among the groups currently experiencing
25 the highest hospitalization rates.

26 208. Although their impact was most visible when they were first available and
27 COVID-19 hospitalization rates were still extremely high, COVID-19 vaccines continue
28 to have a large public health impact.

209. From September 24, 2023 to August 11, 2024, after the first waves of the COVID-19 pandemic had passed, a CDC-led study estimated that COVID-19 vaccines averted approximately 107,000 hospitalizations, 18,000 admissions to the intensive care unit, and more than 6,700 deaths. Wiegand, R.E., et al., *Estimating COVID-19 associated hospitalizations, ICU admissions, and in-hospital deaths averted in the United States by 2023-2024 COVID-19 vaccination: A conditional probability, causal inference, and multiplier-based approach*, Vaccine (Mar. 7, 2025), doi:10.1016/j.vaccine.2025.126808. This is comparable to the burden of disease prevented by influenza vaccination in a typical season.

210. Across nine states from August 29, 2024 to September 2, 2025, COVID-19 vaccination reduced the risk of COVID-19–associated emergency department or urgent care visits among children aged nine months to four years by seventy-six percent and by an estimated fifty-six percent for children and adolescents aged five to seventeen, compared to those who did not receive a vaccine for that season. Irving, S.A., et al., *Effectiveness of 2024-2025 COVID-19 Vaccines in Children in the United States - VISION, August 29, 2024-September 2, 2025*, MMWR Morb. Mortal. Wkly. Rep. (Dec. 11, 2025), doi:10.15585/mmwr.mm7440a1. In addition, multiple studies have shown that COVID-19 vaccination was associated with lower risk of post-COVID-19 symptoms, including long COVID, in children. Scott J., et al., *Updated Evidence for Covid-19, RSV, and Influenza Vaccines for 2025-2026*, N. Engl. J. Med. (Dec. 4, 2025), doi:10.1056/NEJMsa2514268.

211. ACIP’s COVID-19 Work Group held discussions over the course of many months in 2024 and early 2025 regarding moving away from routine annual COVID-19 vaccination for all persons six months and older, including whether to move to risk-based recommendations for COVID-19 vaccination for people in certain age groups.

212. On April 15, 2025, at the last ACIP meeting before Defendants’ extensive interference and the appointment of the Kennedy Appointees, CDC staff and the COVID-

1 19 Work Group presented multiple times on COVID-19 epidemiology and vaccine
2 coverage and safety to prepare the committee for its June 2025 meeting.

3 213. On information and belief, the COVID-19 Work Group was undertaking a
4 nuanced discussion of the age cutoff at which infants and very young children should
5 routinely receive the COVID-19 vaccine. The group recognized that COVID-19
6 vaccination is especially important for pregnant women, pediatric patients under two
7 years old, people sixty-five years and older, and those of any age with weakened immune
8 systems or chronic medical conditions.

9 214. Infants and very young children under two are at high risk for severe
10 COVID-19 infection merely because of their age. Unlike many adults, the majority of
11 children in this age group hospitalized with COVID-19 have no underlying medical
12 conditions. *Current Epidemiology of COVID-19*, Advisory Committee on Immunization
13 Practices (Jun. 25, 2025), [https://www.cdc.gov/acip/downloads/slides-2025-06-25-](https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/02-MacNeil-COVID-508.pdf)
14 [26/02-MacNeil-COVID-508.pdf](https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/02-MacNeil-COVID-508.pdf). Among children, hospitalization rates for those zero to
15 four years old vary widely depending on the age group in question. For example, infants
16 younger than six months, those six to twelve months old, and those twelve to twenty-three
17 months old have hospitalization rates that are much higher than children aged two to four.
18 *See* Ctrs. for Disease Control and Prevention, *Respiratory Virus Hospitalization*
19 *Surveillance Network (RESP-NET)* (Updated Jan. 30, 2026), [https://www.cdc.gov/resp-](https://www.cdc.gov/resp-net/dashboard/index.html)
20 [net/dashboard/index.html](https://www.cdc.gov/resp-net/dashboard/index.html).

21 215. Without observing these nuances, on May 27, 2025, Secretary Kennedy
22 announced on X, without input from career CDC COVID-19 experts, that CDC was
23 changing its COVID-19 vaccination policy and no longer recommended COVID-19
24 vaccines for healthy children and pregnant women. Kennedy S. (May 27, 2025),
25 <https://x.com/SecKennedy/status/1927368440811008138>.

26 216. On May 30, 2025, Defendants officially changed the publicly-available
27 immunization schedule on CDC's website to indicate that COVID-19 vaccines were
28 changed to SCDM for all children. Defendants also provided no guidance to clinicians

or parents as to which groups were most at risk of severe disease or as to which groups the benefits of vaccination clearly outweighed the risks.

217. After firing the former ACIP members and appointing the Kennedy Appointees, Defendants scheduled an ad hoc meeting for September 18–19, 2025. This meeting deviated significantly from established procedures and the required presentation of scientific data. Ultimately, the Kennedy Appointees retroactively voted to change the COVID-19 vaccine recommendation to SCDM for everyone six months and older.

218. The Kennedy Schedule incorporates the Kennedy Appointees' prior decision to demote the COVID-19 vaccine to SCDM for everyone six months and older without reasoned evidentiary basis.

RSV

219. RSV is a viral respiratory infection that causes seasonal outbreaks of respiratory disease and is especially dangerous for infants and young children. *CDC Imm. Sched. Index*. Such outbreaks typically start in October or November and end in April or May.

220. RSV presents with symptoms typical of other respiratory viruses, with milder cases involving nasal congestion, rhinorrhea and sore throat. Woodruff, R.C., et al. Like COVID-19 and influenza, RSV can also trigger acute cardiac events such as heart failure exacerbations or acute myocardial infarction. *Id.* Mortality associated with severe RSV appears to be greater than with influenza.

221. RSV is the leading cause of hospitalization in U.S. infants, causing an estimated annual 58,000 to 80,000 hospitalizations in children less than five years old. Moline HL, et al., *Respiratory Syncytial Virus Disease Burden and Nirsevimab Effectiveness in Young Children From 2023-2024*, JAMA Pediatrics (Feb. 1, 2025), doi:10.1001/jamapediatrics.2024.557. Nearly one to two of every hundred infants in the U.S. are hospitalized for RSV in their first year of life. Sun, J.W., et al., *Risk of adverse events after Omicron XBB-adapted BNT162b2 COVID-19 vaccination in the United States*, Vaccine (Jan. 25, 2025), doi:10.1016/j.vaccine.2024.126629.

222. As with the COVID-19 and influenza vaccines, the primary goal of RSV vaccines, as well as monoclonal antibodies, is to prevent severe disease.

223. Because of their underdeveloped airways, very young infants are particularly vulnerable to severe RSV disease, and hospitalization rates in infants are highest for those less than two months of age. Still, all infants entering their first RSV season are at high risk of severe disease, regardless of any underlying medical conditions.

224. Indeed, for the nearly eighty percent of infants hospitalized for RSV, age is their only risk factor, while a higher proportion of hospitalized older children have underlying medical conditions that predispose them to severe RSV disease that increases with age. Wang, D., et al., *Characteristics of Children Aged 0 to 23 Months Hospitalized With Respiratory Syncytial Virus*, Pediatrics (2025), doi:10.1542/peds.2024-069719.

225. There are three ways to protect infants against RSV hospitalization. The first is a maternal RSV vaccine administered during pregnancy, which transfers maternal antibodies to infants. Fleming-Dutra, K.E., et al., *Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus-Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices - United States, 2023*, MMWR Morb. Mortal. Wkly. Rep. (Oct. 13, 2023), doi:10.15585/mmwr.mm7241e1. The maternal RSV vaccine was first approved by FDA and CDC, per ACIP's recommendation, in 2023. *Id.*

226. There are also two long-acting monoclonal antibody immunizations—nirsevimab (introduced during the 2023 to 2024 season) and clesrovimab (introduced during 2025 to 2026 season)—that are given to infants. Moulia, D.L., 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*, MMWR Morb. Mortal. Wkly. Rep. (Aug. 28, 2025), doi:10.15585/mmwr.mm7432a3; Jones, J.M., 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, MMWR Morb. Mortal. Wkly. Rep. (Aug. 25, 2023),
doi:10.15585/mmwr.mm7234a4.

227. All three immunizations were extensively evaluated for safety and efficacy by the FDA, CDC, and ACIP, including careful examination of data from clinical trials of the maternal vaccine. Fleming-Dutra, K.E., et al.; Moulia, D.L., et al.; Jones, J.M., et al.

228. At least one study found that in its first year of use the nirsevimab monoclonal antibody immunization reduced the incidence of RSV lower respiratory tract infection by eighty-seven percent and associated hospitalizations by ninety-eight percent compared to unimmunized children. Hsiao, A., et al., *Effectiveness of Nirsevimab Against RSV and RSV-Related Events in Infants*, Pediatrics (Jul. 22, 2025), <https://publications.aap.org/pediatrics/article/156/2/e2024069510/202651/Effectiveness-of-Nirsevimab-Against-RSV-and-RSV?autologincheck=redirecintensted>. It also reduced pediatric RSV-associated intensive care unit (“ICU”) admissions as well as acute respiratory failure among infants admitted to with respiratory symptoms during RSV season. Zambrano, L.D., et al., *Nirsevimab Effectiveness Against Intensive Care Unit Admission for Respiratory Syncytial Virus in Infants – 24 States, December 2024–April 2025*, MMWR Morb. Mortal. Wkly. Rep. (Nov. 20, 2025), Ctrs. For Disease Control and Prevention, <https://www.cdc.gov/mmwr/volumes/74/wr/mm7437a1.htm>.

229. The Kennedy Schedule now lists the RSV prevention products only as “Recommended for Certain High-Risk Groups or Populations,” but the Høeg-Kulldorff Report contains no reasoning explaining this decision. Høeg-Kulldorff Rep. at 19.

230. In substance, the recommendation to vaccinate infants less than eight months old did not change in the U.S., as all infants under eight months are still recommended to receive protection from either maternal vaccination or a monoclonal antibody. However, the change in designation from a routine to a risk-based recommendation is highly confusing, even to experts.

231. Defendants moved RSV into the tier of vaccines that are recommended for certain “high-risk groups or populations.” The Decision Memo describes this risk group as including people with different risk-benefit profiles, which “can either be because of underlying comorbidities, unusual exposure to the disease, or the risk of disease transmission to others.” Decision Memo at 5. But, at the same time, a table in the Høeg-Kulldorff Report on RSV prevention products (monoclonal antibodies) is accompanied by a footnote stating that “[a]ll children” should receive one dose of monoclonal antibody if their mother was not vaccinated for RSV during pregnancy. Høeg-Kulldorff Rep. at 2.

232. This convoluted and contradictory recommendation replaced the prior recommendation that simply made clear that all infants less than eight months are at high risk of severe disease from RSV and require protection.

233. The high-risk approach has been tried before, including by administering short-acting monoclonal antibody against RSV to infants who met specific criteria (e.g., infants born preterm, infants with congenital heart disease). But, despite this targeted approach, up to 80,000 infants in the U.S. were hospitalized each year, many for intensive care.

VII. Reliance on purported “peer countries” lacks any reasoned basis.

234. The Kennedy Schedule is unsupported by any new evidence or research showing that the Demoted Vaccines are any less safe, effective, or necessary than when ACIP and CDC first recommended them.

235. As one expert put it, the change was “based on a political directive, not scientific rigor,” and “the same body of evidence that supported universal vaccination [in December 2025] still supports it today.” Frieden, T., *A Giant Step Backward for Children’s Health*, The Formula, <https://tomfrieden.substack.com/p/a-giant-step-backward-for-childrens>.

236. Defendants’ decision to base the Kennedy Schedule on the vaccine policies of supposed “peer countries” is confounding and dangerous. For one thing, Defendants

misrepresent those policies. And regardless, as Dr. Adam Langer stated at the December 4-5, 2025 ACIP meeting, the U.S. has no true “peer” nations in terms of vaccine policy.

237. Defendants’ reliance on vaccine policies in Denmark and other dissimilar countries disregards the unique public health features that led the U.S., over many decades, to adopt its prior childhood immunization schedule. These factors include demographic diversity, population size, disease risks and burden, and a lack of universal access to preventative and remedial care and other safety net services. *Id.*; Ulrich, A.K., et al. at 13.

238. Denmark, the primary benchmark for the Kennedy Schedule, has a homogenous population of six million people. Scott, J., *Quiet Dismantling*. The U.S. has a diverse population of approximately 330 million people. *Id.* Denmark has universal healthcare and a robust public health system with the capacity to screen every pregnant woman for hepatitis B and ensure follow-up care. *Id.* The country also maintains a Civil Registration System linking maternal test results with infant health records, facilitating any necessary follow-up care. *Id.* By contrast, the U.S. has significant health disparities, including nearly 27 million uninsured people, in which nearly fifteen percent of pregnant women go unscreened for hepatitis B. *Id.* And, among those who test positive for the disease, few receive follow-up care. *Id.*

239. Contrary to assertions in the Høeg-Kulldorff Report, it is Denmark, not the U.S., that is the vaccine outlier among wealthy nations. Canada, the United Kingdom, Germany, and Australia all recommend at least three more childhood vaccines than Denmark. *See id.*

VIII. Defendants’ decision to change the routine immunization schedule will mislead and confuse patients and reduce vaccination rates.

240. The demotion of safe and effective vaccines from routinely recommended to an inferior status is not a matter of technical nomenclature—rather, it misleads patients about the medical evidence underlying those recommendations. The impact of that confusion will be immediate and destructive.

1 241. Historically, the CDC has placed a vaccine on the routine immunization
2 schedule when the scientific evidence clearly shows that the vaccine is safe and effective,
3 and that patients and the public benefit from routine immunization against a disease.

4 242. Of course, it is always the patient (or parent's) choice whether to accept a
5 given vaccine.

6 243. As noted, SCDM is appropriate when "individual factors meaningfully shift
7 the risk-benefit assessment and [the] population-level benefit is uncertain." Scott, J.,
8 *Quiet Dismantling*.

9 244. That is not true of any of the Demoted Vaccines.

10 245. Defendants' change to the immunization schedule therefore misleads
11 patients about the safety and efficacy of the Demoted Vaccines.

12 246. By misleading patients in this way, Defendants' change in official CDC
13 policy will reduce vaccination rates for the diseases against which the Demoted Vaccines
14 protect.

15 247. It is well-established in psychology, economics, and public health that
16 making a behavior into a default increases its frequency. This is true for decisions ranging
17 from seatbelt use to retirement savings, and it also applies to immunization.

18 248. The vaccines historically placed on the routine immunization schedule were
19 essentially the CDC's recommended default decision, and for good reason—the scientific
20 evidence clearly showed that they were safe, effective, and important to public health.

21 249. Providers and patients alike had therefore relied on the CDC's routine
22 recommendations, and the data supporting those recommendations, to inform their
23 decision-making around immunization in an efficient and evidence-based manner. By
24 changing the default in official CDC policy, Defendants' actions will naturally and
25 predictably reduce vaccination rates. Indeed, that is their intent.

26 250. Furthermore, unlike countries with universal healthcare, "[m]ore than 100
27 million Americans lack usual access to primary care," meaning that an "instruction to
28

1 ‘discuss with your clinician’ is not neutral guidance,” but “a barrier” to getting vaccinated.
2 Scott, J., *Quiet Dismantling*.

3 251. The Kennedy Schedule will therefore likely have a disproportionate impact
4 on uninsured or underinsured populations and those with limited or no access to a primary
5 care provider.

6 252. In addition, the Decision Memo redefines SCDM to include factors that
7 doctors are unlikely to be able to assess with precision during a routine patient visit. For
8 example, the Decision Memo states that “[w]ith [SCDM], the characteristics of the
9 individual are considered, including their likelihood of being exposed to the diseases,
10 their risks of morbidity and mortality if contracting the diseases, their likelihood of
11 benefiting from the vaccine, their likelihood of vaccine adverse reactions, and their risk
12 of transmitting the disease to others.” Decision Memo at 5.

13 253. The Decision Memo also redefines SCDM to include subjective factors like
14 “personal and family preferences, beliefs, and knowledge” that doctors are unlikely to be
15 able to assess (although patients can of course take them into account) and encourages
16 patients to confront their doctors with licensure safety data that may not offer a complete
17 picture of the safety profile of a particular vaccine. *See id.*

18 254. The Decision Memo does not include any studies or other basis to support
19 this redefinition of SCDM, nor does it consider how redefining SCDM in this manner
20 will affect clinical practice, vaccination rates, or disease rates, among other factors.

21 **IX. Defendants’ actions inflict increased medical costs, administrative burdens,
22 and other harms on states.**

23 255. Plaintiff States rely extensively on CDC and ACIP’s evidence-based
24 recommendations to guide and implement state vaccine policies, and to promote public
25 health in a manner that does not place excessive and senseless strain on state healthcare
26 resources.

27 256. When CDC’s recommendations are science-based, objective, and
28 consistent—as they have been for decades, across many presidential administrations—
states are able to allocate their healthcare resources efficiently and non-redundantly.

Defendants' transformation of CDC and ACIP into unscientific arms of Kennedy's anti-vaccine advocacy eviscerates this reliance, imposing costs and burdens on Plaintiff States.

A. Burden on administration of Plaintiff States' legal codes.

257. ACIP recommendations are inextricably linked with state legal codes. Until June 2025, nearly 600 statutes and regulations across forty-nine states, territories, and Washington, D.C. incorporated ACIP recommendations by reference, often requiring states to use or consider ACIP recommendations to formulate and implement vaccine policies. *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, Ass'n of State and Territorial Health Offs. (June 23, 2025). ACIP's recommendations are often incorporated into state scope of practice laws, school entry requirements, and insurance coverage requirements, among other places. *Id.*

258. This interdependence reflects the Secretary's express statutory obligations to "assist States . . . in the prevention and suppression of communicable diseases," "cooperate with and aid" states "in the enforcement of their quarantine and other health regulations," and advise the States "on matters relating to the preservation and improvement of the public health." 42 U.S.C. § 243(a).

259. Just as states recognize administrative efficiencies by piggybacking on reasoned IRS guidance regarding taxable income and deductions, they likewise—until now—had been able to trust that CDC and ACIP's guidance reflected the best available evidence to inform public health policy.

260. As a measure of ACIP's prestige—and of how it was previously unfathomable that ACIP would be politically compromised or wholly bypassed—state immunization laws often refer specifically to "ACIP's recommendations."

261. As such, ACIP's childhood immunization schedule, as adopted by the CDC, is a lynchpin of state laws designed to monitor compliance with immunization guidelines.

262. Defendants' unlawful reconstitution of ACIP, followed by their unlawful bypass of it entirely, therefore injects immediate confusion and uncertainty into the administration of many of Plaintiff States' public health laws and regulations. If CDC's

1 childhood immunization schedule is no longer a product of lawful ACIP
2 recommendations—and if it does not reflect scientific consensus—then states must
3 undertake the massive administrative burden and expense of untethering their laws from
4 CDC and ACIP.

5 263. Many Plaintiff States will find their existing state laws compromised by
6 CDC sidestepping ACIP and by both CDC and ACIP’s loss of reliable scientific expertise
7 and evidence-based decision-making. The States have a unique sovereign or quasi-
8 sovereign interest in enforcing their own legal codes, which Defendants’ unscientific
9 policy changes now impose substantial pressure on these States to change.

10 264. For example, Arizona and Minnesota laws permit pharmacists to administer
11 all FDA-approved vaccines recommended by ACIP to children over six years old, and to
12 administer certain vaccines recommended by ACIP to children over three years old.
13 A.R.S. § 32-1974(A)(1), (3); Minn. Stat. § 151.01, subd. 27(6). The Kennedy Schedule
14 creates confusion regarding what it means for a vaccine to be “recommended” by ACIP,
15 which will cause parents and patients to place greater demands on primary care doctors
16 for routine immunizations and may cause fewer pharmacies to offer pediatric vaccines.

17 265. Arizona must also establish a “child immunization reporting system” to
18 “collect, store, analyze, release and report immunization data.” A.R.S. § 36-135(A). And
19 the director of the state Medicaid program, the Arizona Healthcare Cost Containment
20 System (“AHCCCS”), must prepare a biennial report indicating the number of two-year-
21 old children enrolled in AHCCCS “who received the immunizations recommended by
22 the” CDC. A.R.S. § 36-2904(N).

23 266. The Kennedy Schedule turns the previously simple assessment required by
24 § 36-2904(N) into a morass of uncertainty and confusion. If the only vaccines now
25 “recommended by the” CDC are the purported “consensus vaccines,” then Arizona law
26 no longer provides for the tracking of important diseases, several of which Arizona
27 requires for childcare and school entry. On the other hand, if the “recommend[ation]” is
28 contingent on an individualized assessment based on SCDM, then the director is suddenly

1 encumbered by a complex data collection and reporting challenge. In either event, the
2 action has senselessly harmed and burdened AHCCCS and compromised the collection
3 and reliability of public health data.

4 267. Similarly, New Mexico’s Department of Health is statutorily required to
5 operate the Statewide Immunization Information System (“NMSIIS”). N.M. STAT. ANN.
6 § 24-5-7 (2004); *see also* N.M. CODE R. § 7.5.5.1-18 (LexisNexis 2025). NMSIIS is a
7 statewide registry that promotes cost effective and efficient disease prevention by tracking
8 and recording immunizations for children and adults. N.M. Dep’t of Health, *Statewide*
9 *Immunization Information System (NMSIIS)*, [https://www.nmhealth.org/about/phd/idb/](https://www.nmhealth.org/about/phd/idb/imp/siis/)
10 [imp/siis/](https://www.nmhealth.org/about/phd/idb/imp/siis/) (last visited Feb. 5, 2026). Currently, NMSIIS operates based on the early 2025
11 ACIP recommendations for vaccine recommenders. However, the CDC’s and ACIP’s
12 changes to the childhood immunization schedule will require New Mexico to spend more
13 than \$150,000 over the next six to eight months to update its immunization information
14 systems.

15 268. New Mexico’s Legislature already enacted significant changes to its Health
16 Code during an emergency session in 2025 to address concerns related to ACIP
17 recommendations, 2025 N.M. Laws, 1st Spec. Sess., ch. 5, §§ 1–6, but many of these
18 provisions will sunset and expire on July 1, 2026, *see, e.g.*, 2025 N.M. Laws, 1st Spec.
19 Sess., ch. 5, §§ 1–6. Additionally, other provisions scattered across New Mexico’s Health
20 Code remain tethered to ACIP recommendations. *See, e.g.*, N.M. STAT. ANN. § 24-1-38
21 (2017) (requiring New Mexico hospitals licensed by the Department of Health to offer
22 patients sixty-five years and older the flu vaccine prior to discharge between October 1
23 and March 1 and “in accordance with the latest recommendations of the advisory
24 committee on immunization”).

25 269. Likewise, because of the changes in ACIP recommendations, Delaware
26 Health and Social Services/the Delaware Division of Public Health updated Delaware’s
27 Communicable Disease Regulations in Fall of 2025. *See* 27 Del. Reg. 863 (May 2024).
28 These regulations previously referenced ACIP as the source for determining vaccines and

1 vaccine schedules for children entering schools. The regulations had to be updated to
2 include reference to the American Academy of Pediatrics (“AAP”), the American College
3 of Obstetricians & Gynecologists, and the American Academy of Family Physicians
4 (“AAFP”). These updates required legal review, interagency coordination, and public
5 notice. They are currently going through administrative processes and are scheduled for
6 publication on May 11, 2026.

7 270. In late 2025, Delaware updated its statutes relating to public school
8 enrollees’ vaccination requirements to remove references to ACIP. This update also
9 required legal review, interagency coordination and public notice. *See* Del. Code tit. 14,
10 § 131.

11 271. All states set specific immunization requirements for children to enroll in
12 school, and many of these laws also incorporate ACIP’s recommendations. *See* Ctrs. for
13 Disease Control and Prevention, *State School Immunization Requirements and Vaccine*
14 *Exemption Laws* 8, 14–15 (Feb. 2022).

15 272. Rhode Island, for example, requires that all preschool students be
16 appropriately immunized for hepatitis A, hepatitis B, rotavirus, and other vaccine-
17 preventable diseases in accordance with ACIP’s Recommended Childhood Immunization
18 Schedule, recognizing that ACIP recommendations “represent the standard of care for
19 vaccination practice in the United States.” 216 R.I. Code R. 30-05-3.3, -3.5.1(A).

20 273. Rhode Island incorporates ACIP recommendations throughout its school
21 age immunization regulations, *see* 216 R.I. Code R. 30-05-3.5.2(A), and immunization,
22 testing, and screening regulations for health care workers, *see generally* 216 R.I. Code.
23 R. 20-15-7.

24 274. Rhode Island explicitly requires the three-dose series of hepatitis B “in
25 accordance with” ACIP recommendations for children entering grades K-12, college, or
26 university. 216 R.I. Code R. 30-05-3.5.2(A)(4)(a), -3.6.1(A)(3).

1 275. Rhode Island requires that the Rhode Island Department of Health include
2 vaccines recommended by ACIP and AAP as part of its childhood immunization program.
3 R.I. Gen. Laws § 23-1-44.

4 276. Rhode Island references ACIP and AAP recommendations in determining
5 healthcare services funding contributions by insurers to fund its childhood immunization
6 program. R.I. Gen. Laws § 23-1-46.

7 277. The actions taken by the Defendants are likely to increase the administrative
8 burden for the Rhode Island Department of Health and other State agencies who may be
9 required to update their regulatory and statutory frameworks to stabilize and maintain
10 access to vaccines.

11 278. The actions taken by the Defendants are likely to increase vaccine hesitancy
12 in Rhode Island, which will put the community at higher risk for a vaccine-preventable
13 disease outbreak or exposure and will in turn increase the burden on the State agencies
14 tasked with responding to outbreaks and maintaining vaccine access for children in Rhode
15 Island.

16 279. In Connecticut, the Commissioner of Public Health determines the standard
17 of care for children in Connecticut and bases that standard of care on the recommended
18 immunization schedules published by ACIP, as well as the AAP and AAFP. Conn. Gen.
19 Stat. § 19a-7f(a). The federal guidance change for certain vaccines that are required for
20 school and childcare entry creates compliance challenges including confusion for parents,
21 childcare operators, and school nurses, as the federal guidance change specifically affects
22 vaccines for which Connecticut has mandatory school and childcare entry requirements,
23 including hepatitis A, hepatitis B, meningococcal, and influenza. Addressing such
24 confusion has required Connecticut to devote substantial communication resources to,
25 among other things, encourage continued compliance with State school and childcare
26 entry immunization requirements.

27 280. Similarly, to address concerns about the trustworthiness of ACIP's
28 recommendations as incorporated in State regulations, the Colorado State Board of Health

recently adopted, via an emergency rule, regulations incorporating the 2025 AAP Recommended Child and Adolescent Immunization Schedule. *See* 6 CCR 1009-2. Meanwhile, other statutory provisions still rely on ACIP, along with the recommendations from other nationally recognized health organizations. *See, e.g.*, C.R.S. § 25-4-2403 (providing that the Colorado Department of Public Health and Environment may address “the ability of the department of health care policy and financing to purchase vaccines recommended by ACIP” and other nationally recognized health organizations); C.R.S. § 10-16-104(18)(b) (outlining that coverage for preventative health services must include “recommendations established by the ACIP”).

281. In Pennsylvania, references to ACIP and its standards occur in several statutes and regulations. For example, the Childhood Immunization Insurance Act, which requires any health insurance policy to cover “child immunizations,” defines “child immunizations” as “[i]mmunizations, including the immunizing agent, reimbursement for which shall not exceed 150% of the average wholesale price, which, as determined by the Department of Health, conform with the standards of the [ACIP].” 40 P.S. § 3502; *see also* 31 Pa. Code § 89.806 (addressing coverage of child immunizations by referring to ACIP standards). The Pharmacy Benefit Reform Act authorizes pharmacists to administer certain vaccines and provides that the “administration of injectable medications, biologicals and immunizations be in accordance with a definitive set of treatment guidelines established by a physician and the [ACIP] guidelines or another competent authority approved by the board.” 40 P.S. § 4556.

282. The Kennedy Schedule may also impact insurance coverage for immunizations in Minnesota, as Minnesota law relies on ACIP recommendations to define immunizations that are considered preventive items and services, and prohibits insurers from requiring prior authorization for immunizations recommended by the ACIP. Minn. Stat. §§ 62Q.46, subd. 1(2); 62M.07, subd. 2(4).

283. While Michigan law does not explicitly reference ACIP and CDC recommendations, the Michigan Department of Health and Human Services (“MDHHS”)

1 has historically relied on ACIP and CDC recommendations in educating and issuing
2 guidance to providers. For example, MDHHS previously used the CDC immunization
3 schedule to advise providers enrolled in the VFC program which vaccines they should
4 carry.

5 284. As a result of the Kennedy Schedule, Plaintiff States must now expend time
6 and resources to ensure that the public has access to accurate information about vaccine
7 safety and efficacy.

8 285. Many Plaintiff States must also expend time and resources mitigating
9 inconsistencies between their legal codes and the CDC's recommendations, ensuring that
10 they are not inadvertently exacerbating the threat to public health by relying on guidance
11 that is no longer trustworthy.

12 **B. Burden on Plaintiff States' resources due to increased rates of vaccine-**
13 **preventable diseases.**

14 286. Regardless of the extent to which Plaintiff States' legal codes are tethered
15 to ACIP and the CDC—and regardless of Plaintiff States' responsive action—the
16 Kennedy Schedule will predictably lead to decreased vaccine uptake and increased rates
17 of vaccine-preventable diseases across all Plaintiff States by complicating the
18 administration of routine vaccinations and by spreading and reinforcing inaccurate
19 information about the safety and efficacy of the Demoted Vaccines.

20 287. The Kennedy Schedule imposes direct costs on Plaintiff States' health and
21 Medicaid agencies.

22 288. For example, while Arizona's Medicaid program, AHCCCS, reimburses
23 medical providers for vaccine counseling, doctors have generally not billed for counseling
24 when administering vaccines. In fomenting confusion and vaccine hesitancy, the
25 Kennedy Schedule will cause AHCCCS-enrolled providers to spend more time
26 counseling patients about vaccines, sometimes without ultimately administering any
27 vaccinations—imposing additional costs on the state for extended consultation sessions
28 without any commensurate public health benefit.

1 289. New Mexico’s Healthcare Authority (“HCA”), which administers the
2 state’s Medicaid program, likewise expects that the Kennedy Schedule will increase its
3 Medicaid costs associated with pediatrician visits for SCDM conversations. As vaccine
4 rates decrease, HCA also expects Medicaid costs will increase as a result of an increase
5 in pediatric hospital stays for immunization-preventable diseases.

6 290. In Pennsylvania, the state’s Medicaid program currently reimburses for
7 vaccine counseling for beneficiaries under twenty-one years of age, but it does not
8 reimburse for both vaccine counseling and an Early and Periodic Screening, Diagnosis
9 and Treatment (“EPSDT”) visit when the visit includes immunizations and related
10 counseling. Pennsylvania now faces an increased likelihood that providers may lobby for
11 payment for vaccine counseling visits in addition to the enhanced payment currently made
12 when all the required elements of the EPSDT visit are completed. The Medicaid program
13 potentially could also have providers lobby for vaccine counseling visits for adults. These
14 additional or enhanced payments would impose additional costs on the state.

15 291. MDHHS—which administers Michigan’s Medicaid program—expects that
16 Defendants’ actions will increase Michigan’s Medicaid costs. For example, MDHHS
17 anticipates additional reimbursement requests for vaccine counseling sessions and
18 increased costs for treatment of vaccine-preventable diseases, which will become more
19 prevalent as a result of decreased vaccine uptake.

20 292. The Kennedy Schedule will also result in more vaccine-preventable disease
21 cases and outbreaks, which will impose costs on and strain the resources of Plaintiff
22 States’ health agencies.

23 293. For example, in Arizona a single case of meningococcal disease detected
24 with a public exposure required public health staff in Arizona to undertake significant
25 contact tracing efforts and expend resources to determine possible exposures.
26 Additionally, treating meningococcal cases in the hospital setting requires immediate
27 precautions to isolate the patient and protect healthcare workers from the highly infectious
28 disease.

1 294. In Pennsylvania, a single case of meningococcal disease was detected in
2 2025 in an individual who had contact with school-aged children with additional
3 exposures in the home and health environments. This single case resulted in a complex
4 multi-day, multi-jurisdictional response involving a private company, hospital, school
5 district and family to determine potential close contact and need for postexposure
6 prophylaxis.

7 295. Additionally, as of September 30, 2026, Pennsylvania has responded to 943
8 measles cases in 2026, nearly all of which were domestically acquired. This is an increase
9 from 16 cases in the entire 2025 calendar year, including an outbreak in a child-care center
10 in which a single unvaccinated child acquired measles and introduced it into the center,
11 resulting in additional cases and lost work time for child-care staff and parents of ill or
12 exposed children. The single exposure generated more than 200 contacts requiring
13 intensive public health follow-up, including contact tracing, verification of immunization
14 status, and provision of post-exposure prophylaxis. In 2026, a single unvaccinated
15 resident who acquired measles resulted in four family members becoming ill and
16 exposures impacting three schools, two medical facilities, and one dental office. The
17 exposures resulted in approximately 1,500 individuals being notified of potential measles
18 exposure and many students missing in-person learning opportunities. In addition, there
19 were two exposures in neonatal intensive care units in Pennsylvania. These resulted in
20 the need for both large private and public notifications and at least 30 highly vulnerable
21 neonates requiring the administration of immunoglobulin to protect them from the most
22 severe outcomes from measles. Managing these preventable outbreaks in 2025 and 2026
23 has consumed substantial public health and health care resources. Wisconsin's
24 Department of Health Services has expended substantial resources responding to
25 confirmed cases of measles in 2025 and 2026. This includes identifying and notifying
26 people who may have been exposed to the measles virus, providing information about
27 potential exposure locations in public settings, and issuing health alerts.

296. In total, thirty-six confirmed cases of measles were reported in Wisconsin in the second half of 2025, all contracted by unvaccinated individuals. Responding to even a single confirmed case can require identification and notification of thousands of potentially exposed individuals. If the Kennedy Schedule remains in effect and Defendants' actions continue to cause vaccine hesitancy, Wisconsin's Department of Health Services will have to divert additional resources to monitor for, detect, and respond to outbreaks of vaccine-preventable illnesses.

297. Delaware has also experienced recent, real-life examples of the time and resource-intensive efforts required to investigate cases of vaccine-preventable diseases.

298. From 2024–2025, Delaware identified four confirmed hepatitis A cases. Although these cases were limited to household exposures and did not result in widespread community transmission, each case required extensive public health follow up. Epidemiologists conducted detailed investigations that included contact tracing, verification of immunization status, and infection source identification. Identified close contacts were then assessed and given appropriate post-exposure prophylaxis recommendations. In late 2024, Delaware coordinated sequencing of IgM-positive specimens with the CDC's Division of Viral Hepatitis. This process required formal approval prior to specimen submission, coordination with hospital partners, and shipment through the Delaware Public Health Laboratory to the CDC Division of Viral Hepatitis Laboratory Branch.

299. From 2024 to 2025, Delaware also identified three confirmed meningococcal disease cases, including two pediatric cases. Although no outbreaks occurred, each case required immediate and coordinated response efforts. The most recent pediatric case involved an inter-facility transfer, requiring Delaware to coordinate with infection prevention teams at two hospitals to closely assess potential healthcare exposures. The epidemiologist conducted thorough interviews with the child's parents and collaborated with the child's elementary school to monitor additional symptomatic individuals. While no additional cases were identified and no non-household contacts

1 required post-exposure prophylaxis, the investigation required multi-sector coordination
2 between healthcare facilities, elementary school personnel, and family members to ensure
3 rapid risk assessment and prevention of further transmission.

4 300. Even slight decreases in vaccine uptake can have significant consequences
5 on disease incidence. Defendants' inaccurate claims about vaccines are exacerbating
6 Michigan's already-declining vaccination rates. This, in turn, is resulting in increased
7 cases of vaccine-preventable diseases, including measles and pertussis. As a result,
8 MDHHS devoted significant resources to assist local health departments in responding to
9 recent outbreaks of infectious disease.

10 301. Maryland also anticipates that it will see decreased vaccination rates for the
11 Demoted Vaccines, and a corresponding increase in acute care needs for those diseases
12 in both pediatric and adult populations. And the burden on Maryland care delivery system
13 (primary care providers, urgent care, emergency departments and inpatient facilities) will
14 only further increase as vaccination rates for the respective diseases decrease. Maryland
15 anticipates that state funds and resources, such as increased billing claims to Medicaid,
16 CHIP, and the Maryland Children's Health Program by providers and hospitals, will be
17 strained by this foreseeable increase in acute care needs.

18 302. The Kennedy Schedule will also significantly increase the costs that
19 Plaintiff States' Medicaid programs must pay to treat vaccine-preventable diseases and
20 their long-term consequences.

21 303. For example, the universal hepatitis B birth dose is the most cost-effective
22 hepatitis B vaccination strategy—preventing the most infections among infants and
23 children and generating the greatest cost-savings to state health systems. Hall, et al, at
24 10. Decreases or delays in hepatitis B vaccine administration as a result of Defendants'
25 actions will substantially increase costs for Plaintiff States' health systems and Medicaid
26 programs.

27 304. Estimates show that delaying the initial hepatitis B vaccine dose by only
28 two months for infants whose mothers are not known to be infected with hepatitis B could

1 result in at least 1,400 new childhood hepatitis B infections annually nationwide. *Id.* at
2 8. Over time, those infections would result in nearly 300 new cases of liver cancer and
3 480 hepatitis B-related deaths, generating over \$222 million in healthcare costs. *Id.* This
4 is a conservative estimate. *Id.* at 10. While cancers due to hepatitis B do not manifest
5 immediately, they eventually occur at an annual rate of two to four percent, and that
6 cancer, along with cirrhotic liver disease, carries a lifetime risk of death of twenty-five
7 percent. *See* Hepatitis B Foundation (Updated Dec. 27, 2022),
8 [https://www.hepb.org/what-is-hepatitis-b/faqs/what-is-the-likelihood-that-someone-](https://www.hepb.org/what-is-hepatitis-b/faqs/what-is-the-likelihood-that-someone-infected-with-hepatitis-b-will-develop-liver-cancer/)
9 [infected-with-hepatitis-b-will-develop-liver-cancer/](https://www.hepb.org/what-is-hepatitis-b/faqs/what-is-the-likelihood-that-someone-infected-with-hepatitis-b-will-develop-liver-cancer/).

10 305. In discouraging the administration of hepatitis B vaccine as a matter of
11 policy, the Kennedy Schedule will cause these terrible harms to individuals to proliferate
12 and thereby cause further financial injury to Plaintiff States' Medicaid systems.

13 **C. Burden on State resources to combat misinformation and prevent**
14 **further harm.**

15 306. Plaintiff States are already expending resources to counter the impact of
16 increased vaccine hesitancy and the erosion of public trust in vaccines caused by
17 Defendants.

18 307. Health agencies in Plaintiff States, including the Arizona Department of
19 Health Services, the California Department of Public Health, the Connecticut Department
20 of Public Health, the Minnesota Department of Health, the New Mexico Department of
21 Health, and the Pennsylvania Department of Health have expended meaningful staff time
22 and resources creating and promulgating communications to the public and to healthcare
23 providers regarding the continued safety and efficacy of the previously routinely
24 recommended childhood vaccines. The health agencies have also expended meaningful
25 staff time and resources reviewing and modifying their guidelines, webpages, and other
26 relevant documents to address differences between state immunization requirements and
27 the federal recommendations now reflected in the Kennedy Schedule.

28 308. In New Mexico, the Department of Health has had to issue multiple Health
Action Network notices and public health orders to clarify state rules and ensure timely

1 access to routine immunizations. *See, e.g.,* N.M. Dep’t of Health, *Public Health Order*
2 *Ensuring Availability of COVID-19 Vaccine for the 2025-2026 Season* (Aug. 29, 2025),
3 nmhealth.org. The Board of Pharmacy also had to update the guidelines to its Vaccine
4 Protocol to remove its sole reliance on ACIP and ensure that pharmacists could continue
5 to administer the COVID vaccine. N.M. Reg. and Licensing Dep’t, *Protocol for*
6 *Pharmacist Prescribing of Vaccines*, nm.gov (last visited Feb. 8, 2026); *see also*
7 Goldberg, J., *NM health department announces new pharmacy protocol, easier COVID-*
8 *19 vaccine access*, Source NM (Sep. 5, 2025), [https://sourcenm.com/briefs/nm-health-](https://sourcenm.com/briefs/nm-health-department-issues-revised-covid-19-vaccine-guidance-for-easier-access/)
9 [department-issues-revised-covid-19-vaccine-guidance-for-easier-access/](https://sourcenm.com/briefs/nm-health-department-issues-revised-covid-19-vaccine-guidance-for-easier-access/).

10 309. In Michigan, MDHHS has diverted significant resources to respond to the
11 schedule changes and combat misinformation related to vaccine efficacy. For example,
12 as noted above, MDHHS historically looked to ACIP and CDC recommendations in
13 issuing guidance to providers and educating the public on vaccines. However, in response
14 to the activities of Defendants, MDHHS was forced to convene the Michigan Advisory
15 Committee on Immunizations (“MACI”) for several emergency sessions in 2025 to
16 consider the implications of the federal actions on vaccines. For the first time in recent
17 history, the medical and scientific advisors of MACI voted to deviate from ACIP and
18 CDC guidance in favor of the AAP and AAFP immunization schedules. MDHHS has
19 expended—and continues to expend—significant funds, staffing hours, and other
20 resources to effectuate this change, including in issuing standing recommendations,
21 developing guidance to providers, and educating the public. Since July 2025, MDHHS
22 estimates that it has dedicated several thousand staff hours responding to this issue.

23 310. In response to the widespread confusion and uncertainty created by
24 Defendants’ actions, Wisconsin Governor Tony Evers issued Executive Order #275
25 Relating to Interagency Cooperation to Urgently Safeguard Wisconsin’s Access to
26 Vaccinations on September 15, 2025. The Executive Order directs Wisconsin’s
27 Department of Health Services to review and continually monitor the available medical
28 evidence and guidance, to issue appropriate standing orders or protocols regarding access

1 to COVID-19 vaccines, and to consider whether additional measures may be necessary
2 to provide clarity and guidance on other routine vaccines. The Executive Order also
3 directs Wisconsin's Commissioner of Insurance to work with health plans to develop
4 guidance to insurers regarding vaccine access and costs.

5 311. Consistent with Executive Order #275, Wisconsin agencies including the
6 Department of Health Services have taken a number of steps to try to mitigate the harms
7 caused by Defendants, which has diverted and will continue to divert resources from other
8 public health work. These steps include, for example, conducting reviews of scientific
9 evidence regarding vaccines, issuing a standing order related to access to COVID-19
10 vaccines, and providing updated guidance relating to vaccines for health providers,
11 insurers, and others.

12 312. In Connecticut, the Department of Public Health has been required to
13 devote substantial communication resources to, among other things, clarify that the
14 underlying scientific evidence has not changed and that vaccines removed from routine
15 recommendations remain safe and effective; clarify the differences between state
16 immunization requirements and the new federal recommendations to ensure consistent
17 messaging for residents and clinicians in the State, including that Connecticut school and
18 childcare entry requirements remain in place; explain the "shared clinical decision-
19 making" designation; and address public confusion created when parents are told that
20 long-safe, effective vaccines are optional or negotiable.

21 313. To combat vaccine hesitancy caused by the federal schedule changes, the
22 Maryland Department of Health ("MDH") has devoted significantly increased time and
23 resources to public education on the safety and efficacy of vaccines, including through
24 social media, state websites, press events, and official statements.

25 314. MDH has already received questions from clinicians about whether and
26 how they are supposed to document SCDM for vaccine visits, and their concerns about
27 the need to dispel misinformation regarding vaccines. Indeed, MDH staff has also
28 engaged in increased communication with health provider groups, through email,

1 meetings, official Dear Clinician letters, and more, solely to address confusion caused by
2 the federal schedule changes. MDH anticipates expending significant time and resources
3 to coordinate with education agencies, districts, business owners, parents and educators,
4 and school-based health providers to encourage continued compliance with state school
5 and childcare entry immunization requirements.

6 315. Maryland has invested significant work in recent years to increase uptake
7 of RSV vaccine and monoclonal antibodies across the state, and has seen a corresponding
8 increase in immunizations, accompanied by a decrease in hospitalization of Maryland
9 infants for RSV. However, the sudden federal schedule changes, including with respect
10 to the RSV vaccine, threatens to undermine these hard-won gains. MDH now anticipates
11 requiring additional time and resources for infectious disease surveillance, detection, and
12 monitoring for and response to vaccine-preventable disease cases and outbreaks in
13 multiple bureaus.

14 316. These efforts have strained Plaintiff States' health agency resources amidst
15 other public health needs, such as responses to vaccine-preventable disease outbreaks—
16 which the agencies anticipate will only become more common as a result of the Kennedy
17 Schedule. Additionally, state health agencies will also now need to invest additional
18 resources to monitor for increased incidence of vaccine-preventable infections and
19 diseases, and to assess the Kennedy Schedule's impact on their public health systems.

20 317. The “absence of consistent, science-based federal leadership” has also led
21 several Plaintiff States, including California and Oregon, to form alliances to provide their
22 residents with “clear, evidence-based” public health guidance and immunization
23 recommendations by relying instead on the recommendations of medical professional
24 organizations. Press Release, Gov. Gavin Newsom, Hawaii to join West Coast Health
25 Alliance with California, Oregon, and Washington (Sep. 4, 2025),
26 [https://www.gov.ca.gov/2025/09/04/hawaii-to-join-west-coast-health-alliance-with-calif](https://www.gov.ca.gov/2025/09/04/hawaii-to-join-west-coast-health-alliance-with-california-oregon-and-washington/)
27 [ornia-oregon-and-washington/](https://www.gov.ca.gov/2025/09/04/hawaii-to-join-west-coast-health-alliance-with-california-oregon-and-washington/). The California Department of Public Health has
28 expended significant staff time and resources in the formation of the West Coast Health

1 Alliance, and in creating and promulgating communications to the public and to
2 healthcare providers regarding the West Coast Health Alliance's shared, collective
3 recommendations.

4 318. The schism between federal guidance and the scientific consensus on
5 vaccines is harmful in ways that Plaintiff States cannot plausibly rectify on their own.
6 That disparity can only be rectified by the CDC's adherence to scientific rigor and
7 evidence, consistent with the mandates of its Charter and Policies and Procedures.

8 319. ACIP and the CDC are the only bodies in the U.S. that have the ability and
9 stature to make vaccine recommendations across populations nationwide. ACIP has
10 historically synthesized the best available science and evidence across all population
11 groups. Even with Herculean, expensive effort, Plaintiff States will be hard-pressed to
12 fill the void left by formerly trustworthy federal bodies no longer providing reliable
13 guidance.

14 320. Additionally, "[w]hen states must route around federal guidance, when
15 different regions of the country operate under different recommendations, when the
16 message to parents varies by zip code, confusion multiplies and confidence erodes."
17 Scott, J., *Quiet Dismantling*.

18 321. In addition to the West Coast Health Alliance, California has expanded
19 funding to lead the Public Health for All Californians Together to bring together a
20 network of multi-sectoral partners across the state of California to provide timely,
21 evidence-based guidelines and culturally-appropriate health messaging to protect the
22 health and advance the well-being of all Californians.

23 322. The New Mexico Department of Health anticipates it will need to develop
24 SCDM guidance and frequently asked questions for providers and parents.

25 323. The Pennsylvania Department of Health has implemented plans due to the
26 uncertainties created by Defendants' decision-making in anticipation of needing to create
27 and manage a Pennsylvania-based program in the event the VFC Program stops providing
28 access to necessary vaccines without cost sharing. In addition to continuing the work of

1 safeguarding immunization access to families in accordance with Governor Shapiro's
2 Executive Order 2025-02 ("Protecting Pennsylvanians' Health and Freedom by Ensuring
3 Access to Safe and Effective Vaccines"), [https://www.pa.gov/content/dam/copapwp-](https://www.pa.gov/content/dam/copapwp-pagov/en/governor/documents/Executive_Order_2025_02_Governor_Shapiro_Vaccines_Access.pdf)
4 [pagov/en/governor/documents/Executive Order 2025 02 Governor Shapiro Vaccines](https://www.pa.gov/content/dam/copapwp-pagov/en/governor/documents/Executive_Order_2025_02_Governor_Shapiro_Vaccines_Access.pdf)
5 [Access.pdf](https://www.pa.gov/content/dam/copapwp-pagov/en/governor/documents/Executive_Order_2025_02_Governor_Shapiro_Vaccines_Access.pdf), the state department of health will continue to release evidence-based
6 information on vaccines to the public.

7 324. The new federal schedule has required Connecticut to engage in increased
8 efforts to bolster infectious disease surveillance, detection, and monitoring. Declines in
9 vaccination rates in other states will increase the risk of pathogens entering Connecticut
10 through unvaccinated persons. And given the likelihood of increased transmission from
11 decreased vaccination rates across the country, Connecticut will be compelled to expend
12 significant resources to address outbreak prevention, including surveillance and
13 monitoring through testing and contact tracing, which in turn requires increased staff,
14 improved data collection procedures, and improved coordination with healthcare facilities
15 and laboratories.

16 325. Further, Connecticut will need to increase resources to respond to future
17 vaccine-preventable outbreaks, including increasing outbreak investigation capacity,
18 ensuring vaccine availability for rapid response, improving communication
19 infrastructure, and coordinating with healthcare systems for surge capacity.

20 326. MDHHS also expects to expend further resources as a result of Defendants'
21 actions. Current CDC and ACIP guidance is creating confusion in Michigan about
22 vaccine safety, availability, and the definition of SCDM. MDHHS continues to receive
23 questions and outreach from providers regarding the interpretation of SCDM. It also
24 anticipates dedicating additional funds to develop specific forecasting algorithms for its
25 immunization information systems vendor.

26 327. Collectively, these additional demands will continue to strain state health
27 agencies' already limited resources.

28

1 328. Defendants and the heads of the NIH, CMS, and the FDA claim that all
2 vaccines, including the Demoted Vaccines, will remain available for free through private
3 insurance, Medicaid, and the VFC Program.

4 329. While Plaintiff States are presently unaware of an impact on the coverage
5 or availability of the vaccines through these programs, Defendants' thin assurances lay
6 the groundwork for future disruptions to critical programs on which Plaintiff States rely.

7 330. The VFC Program is the most significant source of federal funding for
8 States' immunization efforts. All states and the District of Columbia, as well as several
9 local and territorial jurisdictions, participate in the VFC Program. Ctrs. for Disease
10 Control and Prevention, *About the Vaccines for Children (VFC) Program* (Sep. 30, 2025),
11 <https://www.cdc.gov/vaccines-for-children/about/index.html>.

12 331. For example, in fiscal year 2023, Arizona received \$112,521,081 in VFC
13 funding, with approximately \$110 million allocated for vaccine purchases and the
14 remaining \$2 million for program administration. Ctrs. for Disease Control and
15 Prevention, FISCAL YEAR 2023 GRANTS SUMMARY PROFILE REPORT FOR ARIZONA 3
16 (2023).

17 332. In fiscal year 2025, California ordered more than \$600 million in VFC
18 vaccines to help protect more than four million children in the state.

19 333. In state fiscal year 2023–24, Pennsylvania received \$182,039,279 in VFC
20 funding, with approximately \$176 million allocated for vaccine purchase and the
21 remaining \$6 million for program administration. These funds were tied to 2.1 million
22 doses of vaccines ordered for use in vaccinating VFC-eligible children in the
23 Commonwealth.

24 334. Defendants' assurances that all vaccines on the Kennedy Schedule will
25 remain covered by private insurance companies as required by the Affordable Care Act
26 are similarly open to suspicion.

27 335. Coverage for vaccines under the Affordable Care Act and through VFC are
28 statutorily based on ACIP, not CDC, recommendations. *See* 42 U.S.C. § 1396s(c)(2)(b),

(e) (VFC), 42 U.S.C. § 300gg-13(a)(2) (ACA). Accordingly, Defendants' unilateral decision to issue the Kennedy Schedule is directly at odds with the statutory framework that actually safeguards and ensures coverage under the Affordable Care Act and through the VFC.

336. And, to the extent that Defendants claim they have authority to unilaterally alter the vaccine schedule, those decisions have the potential to destabilize other aspects of vaccine policy that safeguard the continued availability of vaccines in the U.S. *See* 42 U.S.C. § 300aa-14(e)(2).

337. In sum, Defendants have senselessly imperiled public health and thereby imposed ongoing costs and burdens on Plaintiff States that will grow worse and more unpredictable over time if Defendants' destruction of ACIP and imposition of the Kennedy Schedule is allowed to stand.

D. Defendants' unlawful reconstitution of ACIP injures Plaintiffs by causing them to incur administrative costs to change laws and policies that reasonably relied on ACIP's recommendations.

338. Prior to the reconstitution of ACIP in June 2025, many States had spent decades designing their legal and public health infrastructure governing immunization in reliance on ACIP and CDC's independent and evidence-based recommendations.

339. For example, many States' school entry immunization requirements and insurance coverage requirements have incorporated ACIP's immunization recommendations. *See, e.g.*, 6 CCR 1009-2; 216 R.I. Code R. 30-05-3.5.2(A)(4), (6)(a).

340. The same is true of some States' insurance coverage requirements. For example, Pennsylvania's Childhood Immunization Insurance Act requires health insurance policies to cover childhood immunizations that "conform with the standards of the Advisory Committee on Immunization Practices of the Center for Disease Control." 40 P.S. § 3502.

341. States have also incorporated ACIP recommendations into their data systems. Like New Mexico, *see* ¶ 267, Wisconsin has used ACIP recommendations to inform its vaccine forecasting model in the Wisconsin Immunization Registry. The

1 Wisconsin Immunization Registry is a statewide, centralized repository of vaccinations
2 and the forecasting is used by vaccinators to determine what vaccines are needed for an
3 individual and when they should be given. The system is also used by the state program
4 and health providers to measure vaccination rates for children and adolescents through
5 the use of benchmark reports, which were based on ACIP recommendations. Going
6 forward, the forecast and reports will be based on the professional organizations'
7 schedules (e.g., AAP).

8 342. In addition to the state laws that incorporate ACIP's immunization
9 recommendations, other state laws expressly incorporate the CDC's adoption of ACIP's
10 immunization recommendations.

11 343. For example, Minnesota law requires health insurance plans to cover
12 preventative items and services at participating providers without imposing cost-sharing
13 requirements, such as deductibles or co-payments. Minn. Stat. § 62Q.46, subd.1(b). The
14 definition of preventative items and services includes immunizations recommended by
15 ACIP that have been adopted by the CDC Director. *Id.* subd. 1(a)(2) (using language that
16 mirrors 45 C.F.R. § 147.130(a)(1)(ii)).

17 344. Arizona law requires the State's Medicaid agency to track and report the
18 number of children who, by age two and while enrolled in the State's Medicaid program,
19 have received immunizations recommended by the CDC. A.R.S. § 36-2904(N).

20 345. Historically, it has not made a material difference whether a state law
21 incorporated by reference (1) the ACIP recommendations or (2) the ACIP
22 recommendations once approved by the CDC Director. That is because the CDC Director
23 has almost always approved ACIP's recommendations, which reflected careful
24 deliberations by experts using well-accepted methodologies.

25 346. Since ACIP was established in 1964, the CDC Director has only deviated
26 from ACIP's recommendations two or three times.

1 347. In addition to the fact that ACIP recommendations and CDC
2 recommendations are largely synonymous, there are also other legal, practical and
3 historical reasons for states to specifically reference ACIP in their statutes.

4 348. First, ACIP's obligations under FACA and its Charter produced
5 recommendations that were reliably independent—the product of reasoned and
6 transparent decision-making by a body of qualified experts with fairly balanced
7 viewpoints who served overlapping terms and followed established procedures. These
8 legal and structural factors established ACIP as the nation's preeminent vaccine
9 policymaking body and imbued its recommendations with credibility on which the States
10 reasonably relied for decades. *See* Smith, et al., MMWR Morb. Mortal. Wkly. Rep.
11 (2014) (recounting, since the 1960s, the need for “expert technical advice . . . to address
12 national immunization policy” due to “the licensure of additional new vaccines” and
13 “increased federal investment of resources in vaccines and immunization programs”).

14 349. The ACIP Charter itself reinforces this reliance. It provides that ACIP's
15 primary objective is to advise the CDC on “the use of vaccines and related agents for
16 effective control of vaccine-preventable diseases in the civilian population of the United
17 States,” pursuant to HHS and CDC's statutory obligations “to assist *states* and their
18 political subdivisions in the prevention and control of communicable diseases; to advise
19 the *states* on matters relating to the preservation and improvement of the public's health;
20 and to make grants to *states* . . . to assist in meeting the costs of communicable disease
21 control programs.” *Charter* at 1 (emphasis added).

22 350. Second, historically ACIP's recommendations have been succinct, clear,
23 and accessible. *See, e.g., ACIP Recommendations*, Ctrs. for Disease Control and
24 Prevention, [https://www.cdc.gov/acip/vaccine-recommendations/index.html#cdc_toolkit](https://www.cdc.gov/acip/vaccine-recommendations/index.html#cdc_toolkit_main_toolkit_cat_1-recent-meeting-recommendations)
25 [_main_toolkit_cat_1-recent-meeting-recommendations](https://www.cdc.gov/acip/vaccine-recommendations/index.html#cdc_toolkit_main_toolkit_cat_1-recent-meeting-recommendations) (Aug. 8, 2025). After the CDC
26 adopts an ACIP recommendation, the recommendation is then published in a subsequent
27 edition of the *Morbidity and Mortality Weekly Report (MMWR)*, as one section in a
28 lengthy academic article that lays out the evidentiary basis for ACIP's recommendation

1 and details about its clinical use, among other information. There is typically a time lag
2 between when ACIP issues a recommendation and when the recommendation is
3 published in the *MMWR*. For example, an October 2024 meningococcal recommendation
4 was published in December 2024. *See* Schillie, et al., *New Dosing Interval and Schedule*
5 *for the Bexsero MenB-4C Vaccine: Updated Recommendations of the Advisory*
6 *Committee on Immunization Practices — United States, October 2024*, *MMWR Morb.*
7 *Mortal. Wkly. Rep.* 2024; 73(49), [https://www.cdc.gov/mmwr/volumes/73/wr/mm](https://www.cdc.gov/mmwr/volumes/73/wr/mm7349a3.htm)
8 [7349a3.htm](https://www.cdc.gov/mmwr/volumes/73/wr/mm7349a3.htm).

9 351. The incorporation of ACIP recommendations into state law therefore
10 ensures the incorporation of concise, actionable recommendations promulgated on a date
11 certain. By contrast, incorporation of a CDC recommendation may be understood to
12 encompass a lengthy *MMWR* publication that is intended to provide the
13 recommendation's underlying science and clinical use. While that information is
14 important, relying instead on the ACIP recommendation provides States with a clear,
15 efficient, and timely reference point for purposes of implementing their immunization
16 laws—avoiding potential ambiguity and uncertainty.

17 352. Third, national medical organizations have historically served as liaisons to
18 ACIP and endorsed the ACIP immunization recommendations. Referencing ACIP
19 guidance therefore effectively captured the scientific consensus across those
20 organizations. That alignment meant that ACIP's recommendations concisely conveyed
21 unified clinical guidance before ultimate publication in the *MMWR*.

22 353. Using ACIP as the reference point also offered practical advantages. Since
23 ACIP has historically operated in close coordination with both the CDC and the FDA,
24 States could previously reliably access detailed clinical guidance, supporting documents,
25 and implementation materials in a timely and consistent way. This made ACIP an
26 efficient anchor for state statutes, especially when harmonized with other nationally
27 recognized, consensus-based recommendations.

1 354. Further, ACIP recommendations determine the information that healthcare
2 providers are legally obligated to provide through the CDC’s Vaccine Information
3 Statements before administering certain vaccines. *See* 42 U.S. Code § 300aa-26; *VIS*
4 *Frequently Asked Questions*, Ctrs. for Disease Control and Prevention,
5 <https://www.cdc.gov/vaccines/hcp/about-vis/faq.html> (June 18, 2024).

6 355. And ACIP immunization decisions have direct legal impact on their own,
7 by determining which vaccines are covered under the VFC program. 42 U.S.C. §
8 1396s(e). The VFC statute reinforces federal-state partnership in promoting public health
9 by directing States receiving federal funds (i.e., *all* States) to “establish a pediatric vaccine
10 distribution program,” consistent with the requirements of that statute. 42 U.S.C. §
11 1396s(a)(1). “Pediatric vaccine” is defined as a vaccine that is on “the list established . .
12 . by [ACIP].” *See id.* § 1396s(e), (h)(6). And participating health care providers must
13 agree to “comply with the schedule . . . applicable to pediatric vaccines that is established
14 . . . by [ACIP].” *Id.* § 1396s(c)(2)(B)(i).

15 356. Said differently, “HHS regulations require that all grants for childhood
16 immunizations are subject to the states’ implementation of procedures to ensure routine
17 vaccination.” Comm. on Government Reform, *Conflicts of Interest in Vaccine Policy*
18 *Making*, U.S. House of Representatives at 24 (Aug. 21, 2000). “To receive federal
19 funding the states must, among other things, require a plan to systematically immunize
20 susceptible children at school entry through vigorous enforcement of school
21 immunization laws.” *Id.*

22 357. And, when Congress established VFC, it emphasized that “ACIP be
23 allowed to conduct its work in an objective manner, concerned only with issues of public
24 health and medicine” in making decisions under the program. H.R. Rep. No. 103-111, at
25 175 (1993).

26 358. Congress has similarly embedded references and tied immunization
27 coverage and cost-sharing benefits to ACIP and its recommendations across various
28 statutes. *See, e.g.*, 8 U.S.C. § 1182(a)(1)(A)(ii) (requiring ACIP-recommended vaccines

1 for alien admissibility); 38 U.S.C. § 1701(9)(G), (10) (defining immunization coverage
2 for veterans' preventative health services according to "the schedule established . . . by
3 [ACIP]"); 42 U.S.C. § 300u-12(a)(5) (providing for a "prevention and health promotion
4 outreach and education campaign" that includes information from ACIP); 42 U.S.C. §
5 1395w-102(b)(8) (providing for cost-sharing of adult vaccines recommended by ACIP).

6 359. It was therefore reasonable and foreseeable that Plaintiff States would base
7 their state laws on ACIP recommendations.

8 360. But when Secretary Kennedy unlawfully reconstituted the ACIP with a
9 majority of unqualified members, Plaintiff States could no longer rely on ACIP's
10 immunization recommendations (with or without CDC approval).

11 361. Documents shared by the HELP Committee and published by the *New York*
12 *Times* show that Secretary Kennedy sought to populate the ACIP with individuals aligned
13 with his agenda on vaccines, regardless of whether they had subject-matter expertise, and
14 without following ACIP's governing procedures for appointing new members. *See* HELP
15 Comm., Docs. A17-13–A17-19. For example, a senior CDC official's notes from a call
16 on May 19, 2025 state that the "Secretary wants to replace 10 members on the ACIP
17 committee. He has a bench of 10 ready to replace. . . . Didn't ask us for help. They
18 know who they want to put on." Help Comm., Doc. A17-19. The senior CDC official
19 also noted that "Stuart Burns [a senior adviser to Secretary Kennedy] will be writing a
20 memo to support this plan. Stated objective was to 'depoliticize' the committee by
21 installing more people aligned to the Secretary's agenda." *Id.* And HHS's Office of
22 General Counsel told CDC staff that candidates could be appointed to ACIP even "if
23 candidates actively promoted disinformation," or "do not have expertise for ACIP."
24 HELP Comm., Doc. A17-17.

25 362. Given the lack of qualifications and expertise on vaccines from the majority
26 of the new ACIP members, Plaintiff States therefore had to either (1) change their laws
27 that incorporated ACIP or CDC immunization recommendations or (2) allow those laws
28 to cause harm to public health.

1 363. The logical result was that some States began decoupling their
2 immunization laws and policies from ACIP and CDC.

3 364. Immediately following Secretary Kennedy's termination of all 17 existing
4 ACIP members on June 9, 2025, staff within the Colorado Department of Public Health
5 and Environment's (CDPHE) Division of Disease Control and Public Health Response
6 assessed the potential impacts of the termination and subsequent appointments. CDPHE
7 acknowledged that the new ACIP appointees included known vaccine skeptics with no
8 background in immunology, health policy, or vaccine science. They ultimately
9 determined that these composition changes were a strong signal that future vaccine
10 recommendations from ACIP would diverge from evidence-based practice and could
11 negatively impact vaccine access, coverage, and choice.

12 365. As a result, CDPHE took the following actions: (1) researched concerns
13 around provider liability should providers give vaccines according to a schedule other
14 than that approved by ACIP, especially as it applies to pharmacist liability; (2) initiated
15 rulemaking activities to incorporate the AAP immunization schedule by reference into
16 Colorado's school entry immunization rule that defines what vaccines are required to
17 attend school; and (3) developed news releases and provider communications that clearly
18 stated CDPHE's commitment to evidenced-based vaccine policies and decision-making.

19 366. After the ACIP reconstitution, New York enacted two laws to untether its
20 vaccine recommendations and reimbursements from ACIP's recommendations because
21 it recognized that while ACIP had "long agreed with the scientific and medical consensus
22 that immunizations are critical to protecting public health and safety," that was no longer
23 the case. See New York Senate Bill 2025-S9599, Sponsor Memo,
24 <https://www.nysenate.gov/legislation/bills/2025/S9599> (section entitled "Justification").
25 The sponsor further explained that Senate Bill 2025-S9599 was needed because "the
26 current federal administration does not share in this consensus and has replaced many of
27 the medical experts on [ACIP] with immunization skeptics that appear unwilling to
28

1 maintain evidence-based immunization recommendations that prioritize public health.”

2 *Id.*

3 367. The first law New York enacted requires that in addition to the vaccines
4 recommended by ACIP, health insurers also cover vaccines recommended by New
5 York’s Commissioner of Health to the Superintendent of Financial Services, utilizing
6 generally accepted medical standards and taking into consideration recommendations by
7 nationally or internationally recognized scientific organizations. 2026 N.Y. Laws Ch.
8 114.

9 368. The second law removes references to ACIP in the Public Health Law
10 (relating to school immunization requirements and recommended immunization schedule
11 for newborns), Education Law (relating to the immunizations that physicians and nurse
12 practitioners are authorized to prescribe or order and that pharmacists are authorized to
13 administer), and Social Services Law (relating to Medicaid coverage). 2026 N.Y. Laws
14 Ch. 115.

15 369. In response to the changes to ACIP membership and meetings, the
16 Minnesota Department of Health assigned one staff member from the Vaccine
17 Preventable Disease section to conduct an initial assessment of potential risks to program
18 activities and statutory requirements. This work required approximately 0.2 full-time
19 equivalent employees (FTE) over several months and provided early insight into the
20 potential operational impacts of ACIP membership changes.

21 370. In late fall of 2025, the Department established an internal workgroup to
22 monitor ACIP activities as well as other vaccine-related federal developments. The
23 workgroup included nine Department staff, with one staff member designated as the
24 coordinator. Meeting frequency varied based on federal activity, ranging from twice
25 weekly during periods of rapid change to twice monthly when updates were less frequent.
26 The coordinator dedicated approximately 0.1 FTE to supporting the workgroup, though
27 this fluctuated depending on workload. Other members contributed an estimated 0.05
28 FTE each to workgroup tasks, including reviewing federal updates, preparing summaries,

1 and coordinating internal communication. The absence of timely agendas and clearly
2 articulated recommendations from the newly restructured ACIP significantly increased
3 workload for the Department. Immunization program leadership, along with staff
4 specializing in clinical guidance, school and childcare immunization requirements,
5 immunization information system operations, and the VFC program, spent substantial
6 time assessing the potential implications of evolving ACIP actions. Staff also devoted
7 considerable effort responding to questions from partners, the public, and the media who
8 were seeking clarity on anticipated recommendation changes.

9 371. As ACIP reduced its use of established evidentiary frameworks
10 (specifically the GRADE and EtR frameworks), and its processes otherwise became less
11 reliable, the Department also initiated policy and statutory review to ensure Minnesota's
12 laws continued to reflect evidence-based immunization standards. The Department
13 proposed updates to several existing statutes, including Minnesota Statutes, sections
14 121A.15, 135A.14, and 62Q.46, to shift language away from relying solely on ACIP as a
15 proxy for evidence-based recommendations. This work required substantial effort from
16 Department staff engaged in policy development, legislative coordination, immunization
17 program leadership, and school and childcare immunization policy. The Department also
18 dedicated staff time to drafting statutory language, revising guidance materials, and
19 preparing for implementation. The statutory review and revision process required
20 collaboration across multiple Minnesota state agencies to ensure alignment and
21 operational feasibility. Staff from these agencies contributed time to legislative review,
22 drafting, program alignment, and stakeholder communication.

23 372. In Pennsylvania, the Department of Health ("PA DOH") and other
24 Commonwealth agencies recognized that ACIP's membership changes signaled a
25 departure from evidence-based recommendations and accordingly researched various
26 relevant topics, including (1) how non-evidence-based changes to ACIP's vaccine
27 schedules may impact vaccine hesitancy and the rise of vaccine preventable diseases; (2)
28 how non-evidence based changes to ACIP's vaccine schedule may impact insurance

1 coverage of immunizations; and (3) whether the Commonwealth should create its own
2 evidence-based vaccine schedules and guidance or otherwise find alternative reliable
3 schedules and guidance.

4 373. On October 1, 2025, as a result of this work, Governor Shapiro issued
5 Executive Order 2025-02 (“Protecting Pennsylvanians’ Health and Freedom by Ensuring
6 Access to Safe and Effective Vaccines”). Among numerous other actions, the Executive
7 Order (1) required all Commonwealth agencies to ensure that state regulations, guidance,
8 website material, and public communications related to vaccines were consistent with
9 evidence-based recommendations; (2) required PA DOH to create a central website that
10 provides accurate, evidence-based information about vaccines; (3) required PA DOH to
11 convene an advisory vaccine education workgroup that included representatives from
12 external stakeholders; and (4) required the Pennsylvania Insurance Department to require,
13 to the fullest extent of its regulatory authority, that health insurers provider coverage for
14 evidence-based vaccine recommendations.

15 374. Thereafter, Pennsylvania broadly implemented the Executive Order to
16 promote adherence to evidence-based standards. This included creating a new state
17 program with a state-funded administrator, the PA Children’s Access to Routine &
18 Essential Shots Program, to be ready to provide necessary vaccines to children if ACIP
19 voted to remove necessary vaccines from the VFC Program. Pennsylvania also provided
20 workshops and other guidance, and issued direction on insurance and Medicaid coverage.

21 375. Likewise, New Jersey amended state law to decouple from ACIP
22 recommendations and incorporate guidance from AAP and other trusted professional
23 bodies for guidance on vaccines. In testimony supporting the bill, the New Jersey
24 Department of Health’s Acting Commissioners, quoting a letter penned by former CDC
25 Directors, observed that Secretary Kennedy had “‘replaced experts on federal health
26 advisory committees with unqualified individuals who share his dangerous and
27 unscientific views,’ including those on ACIP.”

376. In Arizona, Secretary Kennedy’s dismissal and replacement of ACIP members prompted the State’s Medicaid agency, AHCCCS, to undertake urgent policy changes to mitigate the impact of potential changes to immunization schedules on vaccine coverage. Conversations around this work began in July 2025. In September 2025, AHCCCS convened a vaccine policy work group comprised of agency staff with medical, legal, pediatric, policy and/or public health experts to update AHCCCS policies to ensure continued coverage for all vaccines on ACIP’s prior evidence-based schedule. The work required extensive collaboration across state agencies, outreach to the stakeholders and providers, and consultation with AHCCCS attorneys and outside legal counsel to ensure that those policy changes complied with state and federal law and with the agency’s State Plan.

377. AHCCCS published its changes to the AHCCCS Medical Policy Manual on October 10, 2025 (pertaining to coverage of childhood vaccines) and November 14, 2025 (pertaining to coverage of adult vaccines). The revised immunization policies previously defined AHCCCS covered vaccines as those recommended by ACIP, but those vaccines can now be covered based also on the recommendations of certain medical societies when a medical provider deems a vaccine as “medically necessary.” 430 - EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT SERVICES, AHCCCS Policy Manual, (latest effective date Oct. 1, 2026), <https://www.azahcccs.gov/shared/Downloads/MedicalPolicyManual/400/430.pdf>; 310-M – IMMUNIZATIONS, AHCCCS Policy Manual (latest effective date Nov. 14, 2025), <https://www.azahcccs.gov/shared/Downloads/MedicalPolicyManual/300/310-M.pdf>.

AHCCCS’s revised childhood immunization policy further provides that, for AHCCCS members under 21 years old, “immunizations not within or aligned with the ACIP recommendations are covered . . . when, in the provider’s medical judgment, compliance with the ACIP recommendations is medically inappropriate” and when a “health care practitioner determines the immunization to be medically necessary.” 430 - EARLY AND PERIODIC SCREENING, DIAGNOSTIC, AND TREATMENT SERVICES,

1 AHCCCS Policy Manual at 14. Revising an AHCCCS policy is a resource and time-
2 intensive process, typically taking approximately 220 days. Completing multiple policy
3 changes in a two-month timespan required AHCCCS to invest significant staff time and
4 agency resources, including setting aside other routine work.

5 378. In September 2025, California, Oregon, Washington, and Hawaii co-
6 founded the West Coast Health Alliance (WCHA) in response to actions including
7 Secretary’s Kennedy’s “removal of all 17 members of the CDC’s Advisory Committee
8 on Immunization Practices” and to mitigate against the resulting “absence of consistent,
9 science-based federal leadership” and “ensure that . . . public health strategies are based
10 on best available science.” See Press Release, California, Oregon, and Washington to
11 launch new West Coast Health Alliance to uphold scientific integrity in public health as
12 Trump destroys CDC’s credibility, Gov. Gavin Newsom (Sep. 3, 2025),
13 [https://www.gov.ca.gov/2025/09/03/california-oregon-and-washington-to-launch-new-](https://www.gov.ca.gov/2025/09/03/california-oregon-and-washington-to-launch-new-west-coast-health-alliance-to-uphold-scientific-integrity-in-public-health-as-trump-destroys-cdcs-credibility/)
14 [west-coast-health-alliance-to-uphold-scientific-integrity-in-public-health-as-trump-](https://www.gov.ca.gov/2025/09/03/california-oregon-and-washington-to-launch-new-west-coast-health-alliance-to-uphold-scientific-integrity-in-public-health-as-trump-destroys-cdcs-credibility/)
15 [destroys-cdcs-credibility/](https://www.gov.ca.gov/2025/09/03/california-oregon-and-washington-to-launch-new-west-coast-health-alliance-to-uphold-scientific-integrity-in-public-health-as-trump-destroys-cdcs-credibility/).

16 379. Also in September 2025, California enacted a law, AB 144, to base
17 California’s immunization guidance on “credible, independent medical organizations
18 rather than the CDC’s increasingly politicized Advisory Committee on Immunization
19 Practices.” Press Release, Governor Newsom issues statement on Trump
20 administration’s vaccine schedule endangering the lives of infants and children, Gov.
21 Gavin Newsom (Jan. 5, 2026), [https://www.gov.ca.gov/2026/01/05/governor-newsom-](https://www.gov.ca.gov/2026/01/05/governor-newsom-issues-statement-on-trump-administrations-vaccine-schedule-endangering-the-lives-of-infants-and-children/)
22 [issues-statement-on-trump-administrations-vaccine-schedule-endangering-the-lives-of-](https://www.gov.ca.gov/2026/01/05/governor-newsom-issues-statement-on-trump-administrations-vaccine-schedule-endangering-the-lives-of-infants-and-children/)
23 [infants-and-children/](https://www.gov.ca.gov/2026/01/05/governor-newsom-issues-statement-on-trump-administrations-vaccine-schedule-endangering-the-lives-of-infants-and-children/). AB 144 establishes a baseline for vaccine coverage as the
24 immunization schedule recommended by the U.S. Preventive Services Task Force
25 (USPSTF), ACIP, and the Health Resources and Services Administration (HRSA) on
26 January 1, 2025. It also authorizes the California Department of Public Health to modify
27 or supplement these recommendations, considering guidance from independent medical
28

1 organizations such as AAP, the American College of Obstetricians and Gynecologists,
2 and the American Academy of Family Physicians.

3 380. Anticipating changes to ACIP, the Maine Center for Disease Control and
4 Prevention proposed Committee Amendment A to L.D. 93, No. H-728 (132nd Legis.
5 2025), which would amend the statute to no longer direct the Maine Vaccine Board to
6 consider vaccines recommended by ACIP or require the Maine DHHS to base its
7 recommendations to the Maine Vaccine Board on ACIP recommendations. In May 2025,
8 during a legislative work session on the bill, the director of the Maine Immunization
9 Program explained that the proposed amendments removing reliance on ACIP were the
10 result of “indications from the federal government of changes on having [sic] that
11 advisory committee.” May 19, 2025 Work Session of the Maine Legislature Joint
12 Standing Comm. on Health and Hum. Servs, 132nd Legis. 2025, at 10:30:15 (Statement
13 of Jessica Shminski), available at [https://legislature.maine.gov/audio/#209?event=9513](https://legislature.maine.gov/audio/#209?event=95133&startDate=2025-05-19T10:00:00-04:00)
14 [3&startDate=2025-05-19T10:00:00-04:00](https://legislature.maine.gov/audio/#209?event=95133&startDate=2025-05-19T10:00:00-04:00). On July 1, 2025, Maine enacted the proposed
15 amendments. *See* Maine P.L. 2025, ch. 440, § 11(E)(1)-(2), available at
16 [https://www.mainelegislature.org/legis/bills/display_ps.asp?ld=93&PID=1456&snum=1](https://www.mainelegislature.org/legis/bills/display_ps.asp?ld=93&PID=1456&snum=132)
17 [32](https://www.mainelegislature.org/legis/bills/display_ps.asp?ld=93&PID=1456&snum=132).

18 381. Oregon considered ACIP’s reconstitution to be one of the earliest
19 indications that federal health recommendations may be influenced by unqualified
20 political appointees and advisers. In early 2026, the State enacted a law requiring certain
21 health benefit plans to provide coverage for immunizations recommended by the State
22 Public Health Officer and authorizing the State Public Health Officer, or a designated
23 physician, to issue a standing order for a prescription to control, prevent, mitigate or treat
24 any infectious or noninfectious disease or other significant public health concern.

25 382. In June 2025, the Connecticut Department of Public Health began an
26 assessment of the impact of the changes at ACIP and its role in state law. By mid-August,
27 2025, the Department was working on a draft set of revisions to state statutes that relied
28

1 upon ACIP recommendations. Those draft revisions ultimately formed the basis for the
2 changes enacted in the next regular session of the Connecticut legislature.

3 383. Connecticut enacted Public Act 26-3, which amended four statutes to
4 replace reliance on ACIP with a standard of care for immunization set by the
5 Commissioner of Public Health (the “Commissioner’s Standard”). These statutes address
6 (i) which vaccines would be included in the Connecticut Vaccines for Children Program;
7 (2) which vaccines would be used to calculate fees imposed to support said program; (3)
8 which respiratory viral disease vaccines would be provided to nursing home residents;
9 and (iv) the vaccines required for matriculating higher education students. Among other
10 significant changes, the Act removed the direct impact of ACIP actions in school
11 enrollment and day care enrollment vaccination requirements, and added the vaccines in
12 the Commissioner’s Standard to those that could be ordered and administered by
13 pharmacists.

14 384. In anticipation of changes to ACIP membership and vaccine
15 recommendations, in 2025 the Vermont Department of Health began working on draft
16 legislation to untether Vermont vaccine policy from ACIP’s recommendations. The June
17 2025 reconstitution heightened the Department’s concerns and the urgency of enacting
18 legislation to decouple from ACIP.

19 385. In early 2026, Vermont enacted Act 76, which, among other things,
20 authorizes the Commissioner of Health to issue Vermont’s own immunization
21 recommendations considering ACIP and professional organizations’ recommendations.
22 *See* Vermont Act 76, [https://legislature.vermont.gov/Documents/2026/Docs/ACTS](https://legislature.vermont.gov/Documents/2026/Docs/ACTS/ACT076/ACT076%20As%20Enacted.pdf)
23 [/ACT076/ACT076%20As%20Enacted.pdf](https://legislature.vermont.gov/Documents/2026/Docs/ACTS/ACT076/ACT076%20As%20Enacted.pdf); *see* Vt. Stat. Ann. tit. 18, § 1130a. Prior to
24 this change, Vermont law was based on ACIP’s recommendations. *See id.* Act 76 allows
25 the Commissioner to issue standing orders authorizing health care professionals to
26 prescribe, dispense and/or administer immunizations consistent with the Commissioner’s
27 recommendations rather than ACIP’s. *Id.* Act 76 also amended pharmacist and pharmacy
28 technician scopes of practice to permit them to prescribe, dispense, and/or administer the

1 Commissioner's recommended immunizations rather than relying on ACIP's
2 recommendations. *Id.* Act 76 also amended state insurance laws to require no-cost
3 coverage of Commissioner's recommended immunization schedule rather than ACIP's
4 recommendations. *Id.* Finally, the Act authorized the Department to purchase
5 recommended immunizations from vendors other than the CDC whereas previously the
6 Department was limited to purchasing from the CDC. *Id.* The Commissioner has
7 implemented this new process to make recommendations for respiratory virus
8 immunizations for the Fall and Winter of 2026/2027.

9 386. In April 2026, Maryland signed into law the Recommendations for
10 Immunizations, Screenings, and Preventive Services - Pharmacist Administration and
11 Required Health Insurance Coverage (The Vax Act) (HB 637/SB 385). It requires the
12 State to make recommendations in accordance with the authoritative guidance of the
13 AAP, the American Academy of Family Physicians, and the American Colleges of
14 Obstetricians and Gynecologists. The bill also ensures coverage without cost-sharing in
15 commercial insurance plans regulated by the Maryland Insurance Administration (MIA)
16 and authorizes pharmacists to administer recommended vaccines.

17 387. Additionally, the Maryland Department of Health recently issued statewide
18 2026-27 vaccine schedules and recommendations in advance of the respiratory virus
19 season that align with the latest evidence and guidance by leading medical associations.
20 The State anticipates issuing new or updated recommendations regularly. This project
21 required significant staff resources, creating from scratch at the state what had previously
22 been federal products and workstreams.

23 388. The work of decoupling from ACIP and CDC recommendations is
24 disruptive and administratively costly.

25 389. These injuries are cognizable. As the Fifth Circuit has recognized, a State
26 is harmed if a federal policy forces it to either incur costs or change its laws. *See Texas*
27 *v. United States*, 787 F.3d 733, 749 (5th Cir. 2015) ("Texas's forced choice between
28 incurring costs and changing its fee structure is itself an injury: A plaintiff suffers an

1 injury even if it can avoid that injury by incurring other costs. And being pressured to
2 change state law constitutes an injury.”).

3 390. Although the Supreme Court in *Pennsylvania v. New Jersey*, 426 U.S. 660,
4 664 (1976) rejected harms that were “self-inflicted,” that was an unusual case involving
5 the Supreme Court’s original jurisdiction, and the Ninth Circuit has “question[ed]
6 whether the holding of *Pennsylvania* applies outside the specific requirements for the
7 invocation of the Supreme Court’s original jurisdiction,” *California v. Azar*, 911 F.3d
8 558, 574 (9th Cir. 2018).

9 391. And here, the States’ incorporation of ACIP recommendations or CDC
10 decisions into their public health laws and infrastructure was a reasonable decision made
11 “for the administration of a state program, not to challenge federal law,” *Texas*, 787 F.3d
12 at 749, and is consistent with a federal statutory scheme that relies on federal-state
13 cooperation to prevent and suppress disease, *see* 42 U.S.C. § 243(a).

14 392. This injury is ongoing. Plaintiff States have not fully decoupled their laws
15 from ACIP and CDC and doing so is not easy. Many of the Plaintiff States still have laws
16 that incorporate ACIP or CDC immunization decisions. Those States have had to take
17 temporary and resource-intensive measures to mitigate the impact of ACIP’s loss of
18 scientific credibility, including by ensuring that they can provide consistent access to all
19 vaccines on ACIP’s prior evidence-based schedule.

20 393. Plaintiff States are injured by ACIP’s unlawful reconstitution and its loss
21 of scientific credibility irrespective of whether their statutes incorporate ACIP’s or CDC’s
22 recommendations. Because the CDC almost always approves ACIP’s recommendations,
23 and cannot lawfully make its own changes to the federal immunization schedule without
24 first receiving and considering a recommendation from ACIP, the unlawful reconstitution
25 of ACIP makes state laws that incorporate CDC’s recommendations similarly ineffective
26 to those that incorporate ACIP’s recommendations.

27 394. This injury is redressable. If the Kennedy Appointments are vacated, such
28 that Defendants are required to follow the law and their own policies regarding

1 appointments to ACIP, Plaintiff States may not need to further decouple their laws from
 2 ACIP and CDC. *See Ctr. for Biological Diversity v. Mattis*, 868 F.3d 803, 818 (9th Cir.
 3 2017) (“Plaintiffs alleging procedural injury can often establish redress[a]bility with little
 4 difficulty, because they need to show only that the relief requested—that the agency
 5 follow the correct procedures—may influence the agency’s ultimate decision of whether
 6 to take or refrain from taking a certain action.”) (citation omitted); *Day v. Henry*, 152
 7 F.4th 961, 967 (9th Cir. 2025), *cert. denied*, 224 L. Ed. 2d 831 (May 18, 2026) (“[A]
 8 plaintiff satisfies redressability when he shows that a favorable decision will relieve a
 9 discrete injury to himself, not that a favorable decision will relieve his every injury.”)
 10 (citations and quotation marks omitted).

11 **E. Defendants’ reconstitution of ACIP also injured Plaintiffs because it**
 12 **was a proximate cause of the hepatitis B decision.**

13 395. The Administrative Procedure Act itself recognizes that intermediate steps
 14 can be legally cognizable causes of a plaintiff’s injury. *See* 5 U.S.C. § 704 (“A
 15 preliminary, procedural, or intermediate agency action or ruling not directly reviewable
 16 is subject to review on the review of the final agency action.”).

17 396. Defendants’ reconstitution of ACIP also injured Plaintiffs because it was a
 18 direct and proximate cause of the new, unlawfully composed ACIP’s decision to deviate
 19 from established process and ignore the extensive evidence in favor of the universal
 20 hepatitis B birth dose—which had been ACIP policy for over thirty years—and arbitrarily
 21 change that policy, with no new evidence. *See* ¶¶ 68-105, 178-189, above.

22 397. The decision—and the CDC’s approval of the decision—would not have
 23 occurred without a drastic change in ACIP membership and is unlikely to have occurred
 24 with an ACIP composed of qualified members whose appointment followed FACA and
 25 the processes required by Defendants’ own policies. *See Ctr. for Biological Diversity*,
 26 868 F.3d at 818 (plaintiffs alleging a procedural injury “need to show only that the relief
 27 requested—that the agency follow the correct procedures—may influence the agency’s
 28 ultimate decision of whether to take or refrain from taking a certain action”) (citation
 omitted).

398. Elimination of the universal birth dose recommendation for hepatitis B will injure the Plaintiff States by increasing hepatitis B infections and resulting medical costs. *See* ¶¶ 303-305, above.

399. The unlawful reconstitution of ACIP contributed to that decision and is a basis for vacating the hepatitis B decision, just as an administrative law judge’s decision should be vacated if the judge was not lawfully appointed. *See, e.g., Lucia v. SEC*, 587 U.S. 237 (2018).

CLAIMS

Count I

Violation of the APA

Arbitrary and Capricious Action – Kennedy Schedule

5 U.S.C. § 706(2)(A)

400. Plaintiff States reallege and incorporate by reference the foregoing paragraphs as though fully set forth herein.

401. The APA directs a reviewing court to “hold unlawful and set aside agency action” that is “arbitrary [or] capricious.” 5 U.S.C. § 706(2)(A); *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

402. An agency action is arbitrary and capricious if the agency “has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Motor Vehicle Mfrs.*, 463 U.S. at 43. In short, an agency must provide “a satisfactory explanation for its action[,] including a rational connection between the facts found and the choice made.” *Id.*

403. “[A]n agency’s refusal to consider evidence bearing on the issue before it constitutes arbitrary agency action within the meaning of § 706.” *Butte Cnty., Cal. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010); *Morall v. Drug Enf’t Admin.*, 412 F.3d 165,

1 178 (D.C. Cir. 2005) (“DEA’s decision does not withstand review because the agency
2 decisionmaker entirely ignored relevant evidence.”).

3 404. Agencies must further evaluate “significant and viable” alternatives to their
4 chosen course of action and provide “a reasoned explanation for [their] rejection.” *Am.*
5 *Radio Relay League, Inc. v. FCC*, 524 F.3d 227, 242 (D.C. Cir. 2008); *see also DHS v.*
6 *Regents of the Univ. of California*, 591, U.S. 1, 30 (2020) (“[The agency’s] reasoned
7 analysis must consider the alternative[s] that are within the ambit of the existing
8 [policy].”).

9 405. An agency must also explain a change in its position by identifying the new
10 circumstances that support the change. *Regents*, 591 U.S. at 14 (“conclusory statements
11 [are] insufficient to explain [a] change in” course) (cleaned up). And an agency must
12 “assess” any “reliance interests” implicated by its policy change and “weigh any such
13 interests against competing policy concerns.” *Id.* at 33.

14 406. The Kennedy Schedule is arbitrary and capricious because Defendants cut
15 out ACIP—the designated advisory body for developing vaccine recommendations—
16 from the policy development process and thereby disregarded the voluminous scientific
17 evidence underlying ACIP’s recommendations prior to June 2025.

18 407. After circumventing ACIP, Defendants did not base the Kennedy Schedule
19 on requisite evidence or scientific analysis under the GRADE and EtR frameworks,
20 identify any reason to abandon those methodological frameworks, or identify any
21 changed circumstance whatsoever supporting the new recommendations.

22 408. Rather, Defendants adopted recommendations based on the Høeg-Kulldorff
23 Report, which consists of superficial comparisons to “peer countries,” cherry-picked
24 studies, and unsupported claims about the safety, efficacy, and risk-benefit profiles of the
25 Demoted Vaccines.

26 409. In relying solely on the Høeg-Kulldorff Report, Defendants failed to
27 consider well-established evidence on the benefits, efficacy, and safety of the Demoted
28 Vaccines—including the evidence that CDC and ACIP previously considered when

1 previously recommending the routine administration of vaccines on the childhood
2 immunization schedule.

3 410. Similarly, Defendants failed to consider the unique needs and
4 characteristics of the U.S. and its public health system, and thereby also disregarded
5 Plaintiff States', medical providers', and patients' significant reliance on reasoned,
6 reliable, and consistent CDC recommendations.

7 411. And Defendants either failed to consider—or affirmatively wished to
8 foment—the increased vaccine hesitancy and resulting increase in infectious disease that
9 follows when safe and effective vaccines are not universally recommended.

10 412. If Defendants had wished to conduct a legitimate review of vaccine policies
11 in other countries (at President Trump's request or otherwise), they should have routed
12 the request through proper ACIP channels and evaluated evidence from "peer countries"
13 in a systematic way that established a reasoned, scientific nexus between those countries'
14 vaccine policies and the policies appropriate for the U.S. Instead, Defendants provided
15 no explanation, let alone a "reasoned" one, to depart from their longstanding vaccine
16 policy development process.

17 413. Further, ACIP's policies require that "[a]t least 60 days prior to the meeting,
18 the meeting date, items to be discussed, and location are published in the Federal
19 Register," because public comment is "an essential aspect of the Committee's
20 deliberations." CDC, Advisory Comm. on Immunization Pracs. Policies and Procedures
21 at 7, 9 (June 2022). And when ACIP cannot meet that deadline, the notice must "include
22 the reasons for providing less than 60 days' notice, as provided under [General Services
23 Administration] regulations at 41 CFR § 102-3.150(b)." *Id.* at 7.

24 414. Public engagement and input are vital to ACIP's work. Members of the
25 public are invited to submit comments to ACIP either in writing or orally at ACIP
26 meetings. When submitted in writing, all relevant comments received are posted without
27 change to <https://www.regulations.gov>.

1 415. In circumventing ACIP and its procedures, Defendants failed to obtain vital
2 public input on their major changes to U.S. vaccine policy. Indeed, the public had no
3 notice or opportunity to weigh in on the Kennedy Schedule’s proposed and drastic
4 departure from the longstanding childhood immunization schedule.

5 416. Defendants further ignored the mountains of highly relevant scientific
6 evidence supporting the prior childhood immunization schedule and promulgated the
7 Kennedy Schedule based on the unscientific dictates of political officials and pretextual
8 rationales. *See, e.g., Tummino v. Torti*, 603 F. Supp. 2d 519, 547 (E.D.N.Y. 2009)
9 (issuing administrative decision “prior to the completion of the scientific reviews . . .
10 would certainly be evidence of a departure from the typical FDA decision-making
11 process” and reflect improper “pressure[] by the White House”).

12 417. The Kennedy Schedule marked the consummation of CDC’s decision-
13 making process, determined the rights and obligation of stakeholders, including Plaintiff
14 States, and caused legal consequences to flow to Plaintiff States, as alleged herein.
15 Among other things, the Kennedy Schedule immediately rendered state laws and policies
16 tethered to ACIP’s recommendations unreliable, while also causing Plaintiff States to
17 undertake expensive efforts to mitigate the confusion and the threat to public health
18 effected by the Kennedy Schedule. The Kennedy Schedule is, moreover, an “agency
19 statement . . . designed to implement, interpret, or prescribe law or policy.” *Biden v.*
20 *Texas*, 597 U.S. 785, 810 (2022) (quoting 5 U.S.C. § 551(4)). It is therefore final agency
21 action. *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997).

22 418. Defendants’ approval of the Kennedy Schedule violates the APA and must
23 be vacated.

COUNT II

Violation of the APA

Contrary to Law and to Procedure Required by Law – Kennedy Schedule

5 U.S.C. § 706(2)(A), (D)

419. Plaintiff States reallege and incorporate by reference the foregoing paragraphs as though fully set forth herein.

420. The Secretary created ACIP pursuant to 42 U.S.C. § 217a(a) for the purpose of advising him and the CDC in connection with their functions on the “use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States.” *Charter* at 1.

421. Once ACIP was established as a FACA-compliant committee and assigned various other statutory functions, it was contrary to law and to procedure required by law for Defendants to exclude ACIP from the process for which ACIP was established. 5 U.S.C. § 1008 (a), (b) (explaining that an established advisory committee is to be utilized for advisory functions).

422. ACIP’s role is to “provide advice and guidance to the Director of the CDC regarding use of vaccines.” *Charter* at 1. Under HHS regulations, “a recommendation from [ACIP] is considered in effect after it has been adopted by the Director of the [CDC].” 45 C.F.R. § 147.130(a)(l)(ii). CDC must then publish the recommendation in its Morbidity and Mortality Weekly Report. *Charter* at 1. The Director’s role is therefore to decide whether to “adopt” ACIP’s recommendation, not to originate a recommendation independently.

423. ACIP must further ensure that its recommendations are not “inappropriately influenced by the appointing authority,” 5 U.S.C. § 1004(b)(3), (c); 41 C.F.R. § 102-3.105(g), a safeguard that is rendered meaningless here if the appointing authority can simply circumvent the advisory process.

424. Courts, moreover, have an obligation to interpret related statutes and regulations as part of “a symmetrical and coherent regulatory scheme.” *Mellouli v.*

1 *Lynch*, 575 U.S. 798, 809–10 (2015) (quoting *FDA v. Brown & Williamson Tobacco*
2 *Corp.*, 529 U.S. 120, 133 (2000)). Congress has specifically designated ACIP—not the
3 CDC—as the body that establishes the immunization schedules triggering federal
4 obligations in a number of federal health statutes. This was a deliberate choice that
5 forecloses CDC-only action.

6 425. For example, the Affordable Care Act requires health plans to cover certain
7 preventive services without cost-sharing, and it specifically names ACIP as the body
8 whose immunization recommendations trigger the coverage obligations. Under the ACA,
9 a health plan's obligation to cover an immunization without cost-sharing arises only when
10 there is “a recommendation from [ACIP]” that is “in effect.” 42 U.S.C. § 300gg-13(a)(2).

11 426. Likewise, the Medicaid statute links coverage to “diagnostic, screening,
12 preventative, and rehabilitative services, including . . . with respect to an adult individual,
13 approved vaccines recommended by [ACIP].” 42 U.S.C. §§ 1396a(a)(10)(A) &
14 1396d(a)(13)(B). And under the VFC program, the HHS Secretary “shall use, for the
15 purpose of the purchase, delivery, and administration of pediatric vaccines under this
16 section, the list established (and periodically reviewed and as appropriate revised) by
17 [ACIP].” 42 U.S.C. § 1396s(e). The statutory language “shall use” is mandatory and
18 assigns ACIP—not the Secretary or CDC Director—the role of establishing the list and
19 revising it.

20 427. Similarly, the 21st Century Cures Act requires ACIP to issue
21 recommendations for vaccines newly licensed by the FDA or for any new indication
22 (symptom or medical condition) necessitating the use of a vaccine. P.L. 114-255, Subtitle
23 I, § 3091, 130 Stat. 1033, 1149–50.

24 428. In circumventing ACIP and unilaterally issuing the Kennedy Schedule
25 without the scientific analysis, deliberation, and public input that a properly constituted
26
27
28

1 ACIP would have been required to perform, Defendants acted contrary to law and to
2 procedure required by law.

3 429. Because the Kennedy Schedule was prepared and promulgated in a manner
4 that is contrary to law and to procedure required by law, it should be vacated. *See, e.g.,*
5 *Sierra Club v. United States Army Corps of Engineers*, 909 F.3d 635, 655 (4th Cir. 2018)
6 (“The Supreme Court has recognized that Section 706(2)(A) requires federal courts to set
7 aside federal agency action that is not in accordance with law.”) (cleaned up).

8 **COUNT III**

9 **Violation of the APA**

10 **Arbitrary and Capricious, Contrary to Law, and Contrary to Procedure Required** 11 **by Law – Kennedy Appointments**

12 **5 U.S.C. § 706(2)(A), (D)**

13 430. Plaintiff States reallege and incorporate by reference the foregoing
14 paragraphs as though fully set forth herein.

15 431. FACA requires that membership of advisory committees for federal
16 agencies be “fairly balanced in terms of the points of view represented and the functions
17 to be performed.” 5 U.S.C. § 1004(b)(2), (c); *see also* 41 C.F.R. § 102-3.60(b)(3) (May
18 20, 2024 ed.).³

19 432. FACA further requires that advisory committees abide by their procedures
20 to guard against recommendations that are “inappropriately influenced by the appointing
21 authority.” 5 U.S.C. § 1004(b)(3), (c); 41 C.F.R. § 102-3.105(i) (May 20, 2024 ed.).
22 Pursuant to 5 U.S.C. § 1008(c)(1), advisory committees must maintain a charter that
23 specifies the “expertise or experience required” of its members. 41 C.F.R. § 102-3.75(l).
24 Advisory committees requiring “technical expertise,” in particular, “should include
25 persons with demonstrated professional or personal qualifications and experience

26
27 ³ On December 16, 2025, without formal rulemaking or any apparent notice or comment
28 period, the Trump Administration amended the General Services Administration’s
regulations implementing FACA. Citations with a date notation indicate the regulation
in place at the time that Defendants reconstituted ACIP.

relevant to the functions and tasks to be performed by the committee.” *Id.* § 102-3.60(b)(3)(i) (May 20, 2024 ed.).

433. FACA’s regulations further specify how agencies must select advisory committee members, including “as membership vacancies occur.” *Id.* § 102-3.60(b)(3)(i), (iii) (May 20, 2024 ed.). Agencies must conduct “broad outreach” to “interested parties and stakeholder groups likely to possess [the required balanced] points of view.” *Id.* § 102-3.60(b)(3)(ii) (May 20, 2024 ed.).

434. FACA further requires that all agency heads “establish uniform administrative guidelines and management controls for [their] advisory committees” and “maintain systematic information on the . . . operations of each advisory committee within its jurisdiction.” 5 U.S.C. § 1007(a). Any advisory committee guidelines and management controls must be “consistent with directives of the [General Services Administration] Administrator,” *id.*, pursuant to their authority to “prescribe administrative guidelines and management controls applicable to advisory committees,” *id.* § 1006(c).

435. Accordingly, agency heads must “issue administrative guidelines and management controls” detailing how staff must operate the agency’s federal advisory committees. 41 C.F.R. § 102-3.105(b) (May 20, 2024 ed.).

436. All agency heads, including the HHS Secretary, are required to comply with FACA, the General Services Administration’s federal advisory committee management regulations, and any other applicable laws and regulations. *Id.* § 102-3.105(a) (May 20, 2024 ed.). This includes appointing a Designated Federal Officer to ensure continued compliance with FACA, its implementing regulations, agency procedures, and any other applicable laws and regulations. *Id.* §§ 102-3.105(d), 102-3.120(a)(1) (May 20, 2024 ed.). These requirements are “procedure[s] required by law” within the meaning of the APA. *See* 5 U.S.C. § 706(2)(D).

437. ACIP’s Charter, Membership Balance Plan, and Policies and Procedures provide the required administrative guidelines and management controls needed to

1 operate ACIP in compliance with FACA and its “fairly balanced” membership
2 requirement. 5 U.S.C. § 1004(b)(2), (c); 41 C.F.R. § 102-3.60(b)(3) (May 20, 2024 ed.).

3 438. The ACIP Charter directs that its members “shall be selected from
4 authorities who are knowledgeable in the fields of immunization practices and public
5 health, have expertise in the use of vaccines and other immunobiologic agents in clinical
6 practice or preventive medicine, have expertise with clinical or laboratory vaccine
7 research, or have expertise in assessment of vaccine efficacy and safety.” *Charter* at 4.

8 439. ACIP’s Steering Committee must select at least two potential nominees per
9 vacancy based on the “quality of [their] technical expertise” and “balance of specialty
10 areas” required on the committee. *MBP* at 3.

11 440. Accordingly, the Secretary must appoint members with “expertise in the
12 field of immunization practices,” “multi-disciplinary expertise in public health,”
13 “expertise in the use of vaccines and immunologic agents,” and “knowledge of vaccine
14 development, evaluation, safety and delivery.” *MBP* at 2.

15 441. These requirements are rooted in ACIP’s foundational purpose. *See* U.S.
16 Gen. Servs. Admin., *Preparing Membership Balanced Plans* (October 17, 2024) (“[B]est
17 practice guidance in achieving fairly balanced committee membership includes
18 considering the . . . committee’s mission”) and *MBP* at 1 (discussing the ACIP’s mission).
19 The Charter frames the ACIP’s mission as an extension of HHS’s statutory duty to “assist
20 states . . . in the prevention and control of communicable diseases” and to “advise the
21 states on matters relating to the preservation and improvement of the public’s health.”
22 *Charter* at 1.

23 442. Consistent with this federal-state partnership, ACIP’s Membership Balance
24 Plan provides that a “state and local health department perspective” should be considered
25 when selecting voting members.

26 443. Defendants failed to appoint any ACIP member who represents the
27 perspective of state and local health departments who adhere to the scientific consensus
28

1 on vaccine safety and efficacy, thereby unlawfully denying Plaintiff States a
2 representational voice on the committee.

3 444. Additionally, ACIP's Policies and Procedures prescribe specific procedures
4 for selecting voting members consistent with FACA requirements and ACIP's Charter
5 and MBP.

6 445. Defendants failed to comply with these legally required procedures in
7 selecting the Kennedy Appointees to fill the vacancies resulting from the Secretary's
8 dismissal of the previous ACIP members:

9 a. Defendants violated the requirements that, in selecting ACIP's members,
10 they must "conduct broad outreach, using a variety of means and methods, to ensure that
11 the call for nominees reaches the interested parties and stakeholder groups likely to
12 possess [the required balanced] points of view." 41 C.F.R. § 102-3.60(b)(3)(ii) (May 20,
13 2024 ed.). Upon information and belief, Defendants conducted only limited outreach
14 targeted at individuals holding particular views shared by the Secretary and did not
15 conduct broad outreach to individuals called for in FACA's implementing regulation or
16 ACIP's Membership Balance Plan. *Id.*; *MBP* at 3.

17 b. Defendants failed to issue a Federal Register notice and ignored the year-
18 round online application process as required by ACIP's Membership Balance Plan and
19 Policies and Procedures. *MBP* at 3; *Policies and Procedures* at 16.

20 c. Upon information and belief, the Kennedy Appointees did not submit the
21 application materials required by ACIP's Membership Balance Plan and its membership
22 application page. *MBP* at 3; *Apply for ACIP Membership*, <https://www.cdc.gov/acip/apply-for-membership/index.html>.
23

24 d. Upon information and belief, Defendants circumvented the Executive
25 Secretary, ACIP, and Steering Committee's review, selection, and ranking of nominees
26 based on the qualifications and expertise needed on the Committee, as outlined in the
27 ACIP's Membership Balance Plan and Policies and Procedures. *MBP* at 3; *Policies and*
28

1 *Procedures* at 16. This includes “select[ing] two proposed candidates for each vacant
2 position” based on the criteria in the Membership Balance Plan. *MBP* at 3.

3 446. The Secretary violated these procedures required by law in service of
4 stacking ACIP with members who share scientifically unfounded, outlier views on
5 vaccine efficacy and safety that the medical and public health community rejects. A
6 committee that makes population-level recommendations on the use of vaccines is not
7 fairly balanced under FACA where its membership has a history of being unscientifically
8 hostile to or skeptical of vaccines and/or lacks the basic expertise and/or qualifications
9 required by the ACIP’s Charter and Membership Balance Plan.

10 447. At least twelve of the fourteen current ACIP members (Biss, Blackburn,
11 Downing, Farella Griffin, Hibbeln, Levi, Milhoan, Pagano, Pollak, Stein, and Urato) lack
12 the basic expertise and/or professional qualifications required by ACIP’s Charter. And
13 nine of the current ACIP members (Biss, Griffin, Farella, Malone, Meissner, Milhoan,
14 Pebsworth, Stein, and Urato) have stated views on vaccines that align with the Secretary’s
15 own minority anti-vaccination views or are generally skeptical about the safety and
16 efficacy of vaccines in a way that does not align with scientific consensus or evidence.

17 448. Defendants appointed unqualified, ideologically aligned members of ACIP
18 for the purpose of exerting inappropriate influence over ACIP.

19 449. Historically, Plaintiff States relied on ACIP’s highly-qualified and balanced
20 composition to ensure that vaccine policy would emerge from a body of independent and
21 multi-disciplinary experts guided by evidence-based decision-making. Kennedy’s
22 appointment of the current ACIP members circumvented established processes and
23 procedures that aligned with FACA’s requirements and thereby eviscerated Plaintiff
24 States’ ability to rely on ACIP’s recommendations.

25 450. Defendants’ failure to follow their own procedures and account for Plaintiff
26 States’ reliance interests in appointing the Kennedy Appointees further renders them
27 arbitrary and capricious.
28

1 451. The appointment of unqualified ACIP members in violation of procedures
2 required by law, and without considering relevant factors bearing on their qualifications,
3 was final agency action in violation of the APA.

4 452. Irrespective of whether the Kennedy Appointees' appointment is itself final
5 agency action, "[a] preliminary, procedural, or intermediate agency action or ruling not
6 directly reviewable is subject to review on the review of the final agency action." 5 U.S.C.
7 § 704. As Defendants have admitted in other litigation, their adoption of the hepatitis B
8 recommendation is a downstream consequence of the ACIP's reconstitution. Thus, the
9 ACIP reconstitution is reviewable even if deemed to be intermediate action preceding the
10 final hepatitis B decision.

11 453. As alleged herein, the Kennedy Appointees' appointment caused Plaintiffs
12 concrete and imminent harm to legally protectable interests.

13 454. Plaintiffs' injuries were the foreseeable and predictable consequence of
14 Defendants' action.

15 455. As ACIP's Charter recognizes, "ACIP has been given statutory roles" under
16 various provisions of federal law. *Charter* at 1.

17 456. It was therefore reasonable and foreseeable that states would likewise rely
18 on ACIP's recommendations in state laws, as many Plaintiff States have done.

19 457. While Plaintiff States may rely on either ACIP or CDC recommendations,
20 incorporating ACIP recommendations into state laws promotes alignment with federal
21 laws that incorporate ACIP's recommendations and ensures that state vaccine programs
22 are consistent with requirements tied to federal vaccine funding, including through the
23 VFC program.

24 458. As alleged previously, the incorporation of ACIP recommendations into
25 state law also ensures the incorporation of specific recommendations promulgated on a
26 date certain, avoiding potential delay and ambiguity in relying on the CDC's later lengthy
27 publication of the recommendation's evidentiary basis and clinical use in the *MMWR*.
28 The historically independent nature of ACIP, consistent with its status as a FACA-

1 compliant committee, made it reasonable for Plaintiff States to rely specifically on ACIP
2 as an authoritative scientific body.

3 459. 45 CFR § 147.130(a)(ii)’s provision that “a recommendation from [ACIP]
4 is considered in effect after it has been adopted by the Director of the [CDC]” does not
5 negate the foreseeability of State injuries arising out of their reliance on ACIP.

6 460. This provision expressly applies “for th[e] purpose” of § 147.130—a
7 regulation that establishes the parameters of mandatory health insurance—not for all
8 purposes.

9 461. Further, because ACIP lawfully performed its expert function for decades,
10 it was exceedingly rare for the CDC Director to reject an ACIP recommendation. Thus,
11 it has always been reasonable for Plaintiff States to incorporate ACIP’s evidence-based
12 recommendations into their legal codes, with the longstanding expectation that references
13 to ACIP and CDC would effectively be synonymous.

14 462. However, Secretary Kennedy reconstituted ACIP for the purpose of
15 exerting inappropriate influence over members who are willing to eschew independent
16 scientific reasoning in favor of predetermined conclusions, causing the injuries alleged
17 herein.

18 463. Thus, after reasonably and foreseeably relying on ACIP’s recommendations
19 for decades, Plaintiffs suffered direct injuries when Defendants’ actions rendered ACIP
20 untrustworthy and unreliable.

21 464. This stands in contrast to the facts in *Pennsylvania v. New Jersey*, where
22 the defendant states’ taxation of out-of-state residents had no impact on the plaintiff states
23 until the plaintiffs voluntarily decided to issue tax credits to their residents. 426 U.S. at
24 664.

25 465. Vacating the unlawful ACIP appointments would, at a minimum, obviate
26 the need for further emergency actions by States to decouple from ACIP. This would
27 afford partial relief and satisfy the constitutional standard for redressability. *See, e.g.,*
28 *Larson v. Valente*, 456 U.S. 228, 243 n.15 (1982) (“a plaintiff satisfies the redressability

1 requirement when he shows that a favorable decision will relieve a discrete injury to
2 himself”; “[h]e need not show that a favorable decision will relieve his *every* injury”); *see*
3 *also, e.g., NAACP Legal Def. & Educ. Fund*, 496 F. Supp. 3d at 130 (“Even if [plaintiff]
4 cannot secure complete relief, these “potential gains are undoubtedly sufficient to give
5 [plaintiff] standing.”).

6 466. For the foregoing reasons, Plaintiff States request that this court declare the
7 Kennedy Appointees’ appointment arbitrary and capricious, unlawful, and contrary to
8 procedure required by law, vacate their appointments, and vacate their hepatitis B
9 recommendation.

10 467. Plaintiffs further request that the Court enjoin ACIP from taking further
11 actions tainted by its unlawful composition. *NAACP Legal Def. & Educ. Fund*, 496 F.
12 Supp. 3d at 130 (ordering “defendants to refrain from publishing any report produced by
13 the Commission until the requirements of FACA are satisfied”).

14 468. Additionally, Plaintiffs request that the Court order Defendants to
15 undertake good faith efforts to restore ACIP to a composition that is fairly balanced and
16 not subject to inappropriate influence. *Nat. Res. Def. Council v. Dep’t of Interior*, 410 F.
17 Supp. 3d 582, 602–03 (S.D.N.Y. 2019) (“no reason why the Court” cannot order ‘good
18 faith effort[s]’ to appoint a ‘properly qualified ... representative’”) (citing *Nw. Ecosystem*
19 *All. v. Off. of the U.S. Trade Representative*, No. C99-1165R, 1999 WL 33526001, at *8
20 (W.D. Wash. Nov. 9, 1999)).

COUNT IV**Violation of the APA****Arbitrary and Capricious – Hepatitis B Decisions****5 U.S.C. § 706(2)(A)**

469. Plaintiff States reallege and incorporate by reference the foregoing paragraphs as though fully set forth herein.

470. To begin with, the Hepatitis B Decisions were unlawful because the ACIP that made the recommendations was unlawfully appointed and composed. *See* Count III, above.

471. Furthermore, the hepatitis B decisions—as recommended by the Kennedy Appointees, adopted by the CDC, and promulgated by Defendants—resulted from a decision-making process that was arbitrary and capricious.

472. In voting for the hepatitis B recommendations, the Kennedy Appointees failed to engage in reasoned decision-making or to adequately account for the scientific consensus showing the hepatitis B vaccine is safe and effective in its standard three-dose series, starting with a birth dose.

473. The Kennedy Appointees ignored the required GRADE and EtR frameworks to evaluate the best available scientific evidence, cherry-picked and misinterpreted studies, and suppressed available facts. This decision-making process reflected the Kennedy Appointees’ determination to eliminate the ACIP hepatitis B birth dose recommendation regardless of the available evidence.

474. Indeed, the Kennedy Appointees failed to account for any of the scientific data establishing that a change in recommendation was not necessary or justified. This evidence included the scientific consensus that the initial dose of the hepatitis B vaccine poses no increased risk of any adverse events, including serious adverse events, when given shortly after birth, compared with administration at a later point. Further, the FDA-approved course is three doses, and this is what was tested in clinical trials.

1 475. In making hepatitis B recommendations, the Kennedy Appointees also
2 entirely failed to consider important aspects of the consequences of their votes,
3 disregarding input from commenters and hepatitis experts.

4 476. For example, the Kennedy Appointees failed to adequately consider the
5 impact of their decision in the context of the U.S. and its healthcare system, including its
6 practical challenges, risks, costs, and access to care and continuity of care considerations,
7 among others.

8 477. The Kennedy Appointees also failed to consider whether their hepatitis B
9 recommendations would likely result in increased vaccine hesitancy, leading to a decrease
10 in vaccination rates and an increase in rates of hepatitis B infection. The Kennedy
11 Appointees' recommendation for serology testing, for example, failed to consider
12 whether parents would therefore be inclined to delay subsequent doses of the vaccine due
13 to the challenges associated with infant blood draws.

14 478. The Kennedy Appointees also failed to adequately examine the likelihood
15 of inaccuracies in testing and in interpreting test results that may ultimately prevent a
16 child from completing the full immunization series required to achieve lifelong hepatitis
17 B immunity.

18 479. The Kennedy Appointees failed to adequately consider how the hepatitis B
19 recommendations may undermine immunization programs, including those implemented
20 by Plaintiff States, leading to increases in overall healthcare costs, undermining the
21 efficient administration of vaccine programs, and generally causing harm to Plaintiff
22 States' economic and propriety interests.

23 480. In ignoring the evidence supporting the ACIP's longstanding hepatitis B
24 recommendation, the Kennedy Appointees primarily cited stakeholder "dissatisfaction"
25 as the impetus for the change in vaccine policy. However, relying on anecdotes about
26 stakeholder dissatisfaction runs directly counter to ACIP's role and function as
27
28

1 established by FACA and reinforced by its Charter—to provide technical and
2 scientifically sound advice and recommendations.

3 481. In sum, Defendants adopted hepatitis B recommendations that were
4 inconsistent with ACIP's statutory mandates, ACIP's role and function in setting U.S.
5 vaccine policy, and ACIP's Charter and Policies & Procedures.

6 482. Plaintiff States are therefore entitled to a declaration that the Kennedy
7 Appointees' recommendations were arbitrary and capricious and should be vacated.

8 PRAYER FOR RELIEF

9 WHEREFORE, Plaintiff States pray that the Court:

10 i. Declare that the Kennedy Schedule is arbitrary and capricious and contrary
11 to law;

12 ii. Declare that the Secretary's appointment of the Kennedy Appointees was
13 arbitrary and capricious and contrary to law;

14 iii. Declare that ACIP's Hepatitis B Decisions were arbitrary and capricious.

15 iv. Enjoin, vacate, and set aside the appointment of the Kennedy Appointees
16 and the Kennedy Schedule and any implementation of these actions or any other actions
17 tainted by ACIP's unlawful constitution;

18 v. Order Defendants to undertake good faith efforts to restore ACIP to a
19 composition that is fairly balanced and not subject to inappropriate influence; and

20 vi. Award Plaintiff States such further relief as the Court deems just and
21 proper.

22
23 RESPECTFULLY SUBMITTED this 2nd day of October, 2026.

24
25 **KRISTIN K. MAYES**

26 Attorney General for the State of Arizona

27 /s/ Joshua D. Bendor

28 Joshua D. Bendor*

Solicitor General

Clinton N. Garrett*

ROB BONTA

Attorney General for the State of
California

/s/ Katherine Milton

Katherine Milton

Deputy Attorney General

1 Syreeta A. Tyrell*
 2 Alexa G. Salas*
Assistant Attorneys General
 3 Office of the Arizona Attorney General
 2005 N. Central Ave.
 4 Phoenix, Arizona 85004

5 *Attorneys for the State of Arizona*

Neli Palma
 Senior Assistant Attorney General
 Kathleen Boergers
 Nimrod Pitsker Elias
 Supervising Deputy Attorneys General
 Marnie G. Ganotis
 Deputy Attorney General
 455 Golden Gate Avenue
 San Francisco, CA 94102-7004
 (415) 229-0118
 katherine.milton@doj.ca.gov_
 Neli.Palma@doj.ca.gov
 Kathleen.Boergers@doj.ca.gov
 Nimrod.Elias@doj.ca.gov
 Marnie.Ganotis@doj.ca.gov

Counsel for the State of California

13 **PHILIP J. WEISER**
 Attorney General for the State of Colorado

15 /s/ David Moskowitz
 David Moskowitz*
 Deputy Solicitor General
 Nora Passamaneck*
 Senior Assistant Attorney General
 Colorado Department of Law
 1300 Broadway, #10
 Denver, CO 80203
 (720) 508-6000
 david.moskowitz@coag.gov

Attorneys for the State of Colorado

24 **KATHLEEN JENNINGS**
 Attorney General of the State of Delaware

26 /s/ Vanessa L. Kassab
 Ian R. Liston*
 Director of Impact Litigation
 Vanessa L. Kassab*
 Deputy Attorney General
 Delaware Department of Justice

WILLIAM TONG
 Attorney General of Connecticut

15 /s/ Shawn L. Rutchick
 Shawn L. Rutchick*
 Assistant Attorney General
 165 Capitol Ave
 Hartford, CT 06106
 (860) 808-5210
 Shawn.Rutchick@ct.gov

Attorneys for Plaintiff State of Connecticut

AARON M. FREY
 Maine Attorney General

26 /s/ Kendall R. Schutzer
 Kendall R. Schutzer*
 Assistant Attorney General
 Office of the Attorney General
 6 State House Station
 Augusta, ME 04333

820 N. French Street
 Wilmington, DE 19801
 (302) 683-8899
 vanessa.kassab@delaware.gov

Attorneys for Plaintiff State of Delaware

ANTHONY G. BROWN
 Attorney General of Maryland

/s/ Michael Drezner
 Michael Drezner*
 Senior Assistant Attorney General
 Office of the Attorney General
 200 Saint Paul Place
 Baltimore, Maryland 21202
 (410) 576-6959
 mdrezner@oag.state.gov

Counsel for the State of Maryland

KEITH ELLISON
 Attorney General for the State of Minnesota

/s/ Jennifer Moreau
 Jennifer Moreau*
 Brian S. Carter**
 Assistant Attorneys General
 445 Minnesota Street, Suite 600
 St. Paul, Minnesota, 55101
 (651) 757-1195
 jennifer.moreau@ag.state.mn.us
 brian.carter@ag.state.mn.us

Attorneys for Plaintiff State of Minnesota

RAÚL TORREZ
 Attorney General for the State of
 New Mexico

Tel.: 207-626-8452
 Fax: 207-287-3145
 Kendall.Schutzer@Maine.gov

Attorneys for Plaintiff State of Maine

DANA NESSEL
 Attorney General of Michigan

/s/ Neil Giovanatti
 Neil Giovanatti*
 Assistant Attorney General
 Michigan Department of Attorney
 General
 525 W. Ottawa
 Lansing, MI 48909
 (517) 335-7603
 GiovanattiN@michigan.gov

Attorney for the State of Michigan

JENNIFER DAVENPORT
 Attorney General of New Jersey

/s/ Joshua P. Bohn
 Joshua P. Bohn*
 Kevin Bui*
 Amanda McElfresh*
 Deputy Attorneys General
 Office of the Attorney General
 25 Market Street
 Trenton, NJ 08625
 (609) 696-5366
 Joshua.Bohn@law.njoag.gov
 Kevin.Bui@law.njoag.gov
 Amanda.McElfresh@law.njoag.gov

Counsel for the State of New Jersey

LETITIA JAMES
 Attorney General of New York

/s/ Ben Osborn
Ben Osborn*
Senior Counsel
New Mexico Department of Justice
201 3rd St NW #300
Albuquerque, NM 87102
bosborn@nmjoj.gov

Attorney for State of New Mexico

/s/ Mark Ladov
Mark Ladov**
Special Counsel
Rabia Muqaddam**
Chief Counsel for Federal Initiatives
Andres Ivan Navedo
Assistant Attorney General
28 Liberty St.
New York, NY 10005
(212) 416-8240
mark.ladov@ag.ny.gov
rabia.muqaddam@ag.ny.gov
ivan.navedo@ag.ny.gov

Attorneys for the State of New York

DAN RAYFIELD
Attorney General of Oregon

/s/ Scott P. Kennedy
Scott P. Kennedy*
Senior Assistant Attorney General
Oregon Department of Justice
100 SW Market Street
Portland, OR 97201
Tel (971) 673-1880
Fax (971) 673-5000
Scott.Kennedy@doj.oregon.gov

Attorneys for Plaintiff State of Oregon

PETER F. NERONHA
Attorney General of Rhode Island

/s/ Kathryn T. Gradowski
Kathryn T. Gradowski*
Special Assistant Attorney General
150 South Main Street
Providence, RI 02903
(401) 274-4400, Ext. 2810
kgradowski@riag.ri.gov
Rhode Island Bar No. 10871

Counsel for the State of Rhode Island

JOSHUA L. KAUL
Attorney General of Wisconsin

/s/ Amanda Quester
Amanda Quester*
Assistant Attorney General
Wisconsin Department of Justice
Post Office Box 7857
Madison, WI 53707-7857
(608) 266-8690
amanda.quester@wisdoj.gov

CHARITY R. CLARK
Attorney General for the State of
Vermont

/s/ Ryan Patrick Kane
Ryan Patrick Kane**
Deputy Solicitor General
109 State Street
Montpelier, VT 05609
(802) 828-3171
Ryan.Kane@vermont.gov

1 *Counsel for the State of Wisconsin*

2
3 **JOSH SHAPIRO**

4 *in his official capacity as Governor of the*
5 *Commonwealth of Pennsylvania*

6 Jennifer Selber
7 *General Counsel*

8 /s/ Aimee D. Thomson

9 Aimee D. Thomson*

10 Deputy General Counsel

11 Pennsylvania Office of the Governor

12 30 N. 3rd St., Suite 200

13 Harrisburg, PA 17101

14 (223) 234-4986

15 aimeethomson@pa.gov

16 *Counsel for Governor Josh Shapiro*

17
18
19
20
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22
23
24
25
26
27
28
*Admitted Pro Hac Vice

** Pro Hac Vice application forthcoming

CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

October 2nd, 2026

/s/ Joshua D. Bendor