

**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](mailto:Joshua.Bendor@azag.gov)

[Clinton.Garrett@azag.gov](mailto:Clinton.Garrett@azag.gov)

[Syreeta.Tyrell@azag.gov](mailto:Syreeta.Tyrell@azag.gov)

[Alexa.Salas@azag.gov](mailto:Alexa.Salas@azag.gov)

[ACL@azag.gov](mailto: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](mailto:Neli.Palma@doj.ca.gov)

[Kathleen.Boergers@doj.ca.gov](mailto:Kathleen.Boergers@doj.ca.gov)

[Nimrod.Elias@doj.ca.gov](mailto:Nimrod.Elias@doj.ca.gov)

[Katherine.Milton@doj.ca.gov](mailto:Katherine.Milton@doj.ca.gov)

[Marnie.Ganotis@doj.ca.gov](mailto: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 OREGON;  
STATE OF RHODE ISLAND; STATE OF  
WISCONSIN; JOSH SHAPIRO, in his  
official capacity as Governor of the  
Commonwealth of Pennsylvania,

Case No. \_\_\_\_\_

**COMPLAINT FOR  
DECLARATORY AND  
INJUNCTIVE RELIEF**

Date:

Time:

Dept:

Judge:

Trial Date:

Action Filed:

Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his  
official capacity as Secretary of the  
DEPARTMENT OF HEALTH AND  
HUMAN SERVICES; U.S.  
DEPARTMENT OF HEALTH AND  
HUMAN SERVICES; JAYANTA  
BHATTACHARYA, in his capacity as  
acting Director of the CENTERS FOR  
DISEASE CONTROL AND  
PREVENTION; CENTERS FOR  
DISEASE CONTROL AND  
PREVENTION,

Defendants.

## 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  
28

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.<sup>1</sup>

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  
25

---

26  
27 <sup>1</sup> 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](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.”<sup>2</sup>

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  
26

---

27 <sup>2</sup> 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 Oregon is a sovereign state of the United States. Oregon  
18 is represented by Attorney General Dan Rayfield. The Attorney General is the chief legal  
19 officer of Oregon and is authorized to institute this action.

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

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

27           40. Plaintiff Josh Shapiro brings this suit in his official capacity as Governor of  
28 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**

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

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

43. 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).

44. Defendant Jayanta Bhattacharya is the Acting Director of the CDC. He is charged with the supervision and management of all decisions and actions of that agency. He is sued in his official capacity. Bhattacharya replaced O’Neill as Acting Director of the CDC in February 2026.

## **ALLEGATIONS**

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

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

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

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

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

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

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

51. 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.

52. 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*”).

53. 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).

54. 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.”

55. 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.

56. 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.

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

58. If the Director disagrees with an ACIP recommendation, he must state his concerns in an internal decision memo back to ACIP. *Id.* ACIP may then revise its recommendation or further brief the Director through a second internal memo. *Id.* If the CDC Director still disagrees with ACIP’s recommendation, the ACIP Secretariat must

1 publish a notice in the Federal Register “that articulates the Director’s views and proposed  
2 decision” and provides a thirty-day comment period. *Id.*

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

10 60. ACIP’s work is aided by Work Groups that analyze data and develop  
11 evidence-based recommendation options to present to ACIP using the GRADE  
12 framework. *Id.* at 4.

13 61. The GRADE framework consists of five tables that contain “a clear  
14 description of the outcomes assessed (benefits and harms), the results of a comprehensive  
15 search of relevant databases, a list describing all of the data included in the review, an  
16 assessment of potential biases of each study, a meta-analysis of all included studies with  
17 quantification of observed benefits and harms, and an overall rating of the quality of the  
18 evidence.” *Id.*

19 62. The GRADE assessment has historically been completed by CDC staff who  
20 present their findings to the ACIP Work Groups for review and consideration. *Id.* The  
21 Work Groups subsequently present the information derived from the GRADE assessment  
22 to the entire ACIP prior to a vote. *Id.*

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

26 64. Since approximately 2019, ACIP has used the Evidence to  
27 Recommendations (“EtR”) framework to consider several additional variables beyond  
28 GRADE’s assessment on vaccine efficacy and safety. *Id.* These variables include “the

1 magnitude of the public health problem being addressed, costs vs benefits, feasibility of  
2 the intervention, views of community stakeholders, and effects on equity.” *Id.*

3 65. The addition of EtR was intended to improve transparency in ACIP’s  
4 decision-making process. The ACIP EtR User’s Guide explains that “[t]he purpose of  
5 EtR framework is to help panels making recommendations move from evidence to  
6 decisions, and to provide transparency around the impact of additional factors on  
7 deliberations when considering a recommendation.” Ctrs. for Disease Control and  
8 Prevention, *ACIP Evidence to Recommendation User’s Guide* at 3 (Oct. 1, 2020),  
9 [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)  
10 [.pdf](https://www.cdc.gov/acip/media/pdfs/2024/09/ACIP-EtR-Users-Guide_October-1-2020.pdf).

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

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

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

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

69. ACIP's Charter provides that "[m]embers shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety." *Charter* at 4.

70. ACIP's Membership Balance Plan requires members to possess "expertise in the field of immunization practices; multi-disciplinary expertise in public health; expertise in the use of vaccines and immunologic agents; knowledge of vaccine development, evaluation, safety and delivery; or, in the case of the consumer representative, knowledge about consumer perspectives and/or social and community aspects of immunization programs." *MBP* at 2.

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

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

73. Indeed, prior to the Kennedy Appointments, the overwhelming majority of ACIP voting members had prolific experience studying and/or administering vaccines

1 and almost invariably had contributed to the understanding of vaccines and their  
2 administration through original research reports in peer-reviewed medical, scientific, and  
3 public health journals. For example, of the seventeen ACIP members dismissed by  
4 Secretary Kennedy, fifteen had extensive records of conducting and publishing the results  
5 of vaccine-related research in peer-reviewed medical, public health, and scientific  
6 journals and one had an extensive track record overseeing public health immunization  
7 programs. The seventeenth member was a highly respected medical school faculty  
8 member with experience in pediatrics, internal medicine, and primary care, the settings  
9 in which most routinely administered vaccines are provided in the U.S.

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

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

20 76. Indeed, Defendants purposefully populated ACIP with unqualified  
21 individuals whose minority anti-vaccine views align with Kennedy’s views, and over  
22 whom Defendants can exert inappropriate influence, in violation of FACA.

23 77. At least nine of the thirteen current ACIP members—Hillary Blackburn,  
24 Evelyn Griffin, Joseph Hibbeln, Retsef Levi, Robert Malone, Kirk Milhoan, James  
25 Pagano, Raymond Pollak, and Catherine Stein—lack the experience and/or professional  
26 qualifications required by ACIP’s Charter.

27 78. 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 79. Based on searches of PubMed and other publicly available databases and  
4 sources, six of the current Kennedy Appointees—Blackburn, Griffin, Hibbeln, Milhoan,  
5 Pagano, and Pollak—have no documented prior experience conducting research on  
6 vaccines, vaccination, vaccine safety, or vaccine policy and have not held positions  
7 relating to the administration or distribution of vaccines. Three of the current Kennedy  
8 Appointees—Levi, Malone, and Stein—have only a very small number of publications  
9 or any prior experience in one or more of these areas, in no way comparable to the  
10 extensive experience and documented expertise previously deemed a pre-requisite for  
11 appointment as a voting member of ACIP.

12 80. At least nine of the current ACIP members—Biss, Griffin, Levi, Malone,  
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 81. 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 82. 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 83. Likewise, the current chair of ACIP, Kirk Milhoan, stated during a break at  
4 the December 5, 2025 ACIP meeting that the committee felt “a little bit like puppets on a  
5 string as opposed to really being [an] independent advisory panel.” *See* Declaration of  
6 Jason M. Goldman, MD, MACP, 1:25-cv-11916-BEM, Dkt. 162.

7 84. Previously, CDC relied on the advice of a lawfully constituted ACIP,  
8 comprised of qualified experts, to recommend for over thirty years that all children  
9 receive a dose of the hepatitis B vaccine at birth, followed by two more doses of the  
10 vaccine.

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

17 86. The CDC adopted this recommendation on December 16, 2025.

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

25 88. Unlike the prior recommendations, no scientific study has ever assessed this  
26 approach, let alone supported its efficacy.

1           89. 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           90. 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           91. Likewise, the Kennedy Appointees presented no evidence establishing that  
13 a departure from the current recommended dosing is effective.

14           92. 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           93. 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           94. 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           95. 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 96. 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 97. 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 **V. The acting CDC Director bypassed ACIP and purported to radically alter the**  
 15 **childhood immunization schedule via the Decision Memo.**

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

19 99. On January 5, 2026, CMS’s Dr. Mehmet Oz, NIH’s Dr. Jayanta  
 20 Bhattacharya, and FDA’s Dr. Martin Makary—none of whom were affiliated with  
 21 CDC—sent then-acting CDC director Jim O’Neill a “Decision Memo” recommending  
 22 that he review and approve “a revised childhood and adolescent immunization schedule.”  
 23 O’Neill—who has two Humanities degrees, but no medical or scientific background—  
 24 approved and signed the Decision Memo the same day, misdating it “January 5, 2025.”

25 100. Ignoring federal law that requires vaccine recommendations to originate  
 26 from a properly constituted ACIP following an evidence-based decision-making process,  
 27 the Decision Memo fragments the formerly unified childhood immunization schedule into  
 28 three confusing and partially-overlapping tiers: (1) “immunizations recommended for all  
 children,” (2) “immunizations recommended for certain high-risk groups or populations,”

1 and (3) “immunizations based on [SCDM].” Høeg-Kulldorff Rep. at 2–3; *see also*  
2 Decision Memo at 8.

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

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

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

18 104. In demoting certain vaccines to SCDM or risk-based recommendations, the  
19 Decision Memo implies that the long-established schedule recommended by ACIP poses  
20 a potential risk to public health.

21 105. The Decision Memo, however, does not provide a scintilla of scientific  
22 evidence to support its unscientific insinuation. Instead, it relies on specious assertions  
23 and non-scientific rationales.

24 106. The Decision Memo first suggests that its recommendations will ameliorate  
25 “decreased vaccine uptake and trust” that has led to falling childhood vaccinations rates  
26 in recent years. But the Decision Memo cites zero evidence that its recommendations  
27 will have this effect. Instead, the effect—and likely intent—of demoting numerous  
28

1 vaccines from being routinely recommended to SCDM is to reduce uptake of the  
2 vaccines.

3 107. Kennedy is among the most prominent anti-vaccine activists in the country  
4 and has significantly contributed to eroding trust in vaccines long established as safe and  
5 effective.

6 108. In 2019, Kennedy spread misinformation about the measles vaccine in the  
7 country of Samoa that experts believe contributed directly to the deaths of over eighty  
8 people. See T. Yang, *The perils of RFK Junior's anti-vaccine leadership for public*  
9 *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)  
10 [/article/PIIS0140-6736\(24\)02603-5/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(24)02603-5/fulltext).

11 109. In a 2023 interview, Kennedy falsely stated that “[t]here’s no vaccine that  
12 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)  
13 [171/issue-29/senate-section/article/S903-1](https://www.congress.gov/congressional-record/volume-171/issue-29/senate-section/article/S903-1).

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

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

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

27 113. The two-paragraph presidential memorandum asserted that the U.S. is a  
28 “high outlier in the number of vaccinations recommended for all children,” compared to

1 “[p]eer, developed countries” like Denmark, Japan, and Germany. It also stated without  
 2 elaboration that “[o]ther current [U.S.] childhood vaccine recommendations also depart  
 3 from policies in the majority of developed countries.” *Aligning United States Core*  
 4 *Childhood Vaccine Recommendations with Best Practices from Peer, Developed*  
 5 *Countries*, Presidential Memoranda (Dec. 5, 2025),  
 6 [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)  
 7 [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);  
 8 Decision Memo at 1.

9 114. President Trump is not a medical expert, and his political directive gave  
 10 Defendants no legal basis to bypass ACIP and flout statutory and procedural requirements  
 11 to make a consequential public health determination.

12 115. The Decision Memo also incorporates an “Assessment of the U.S.  
 13 Childhood and Adolescent Immunization Schedule Compared to Other Countries,”  
 14 authored by Høeg and Kulldorff, a current HHS official and a former ACIP Kennedy  
 15 Appointee.

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

21 117. On information and belief, CDC vaccine experts delivered a presentation  
 22 on vaccine schedule comparisons by country to Defendants on or around December 18,  
 23 2025. The presentation advised that, “Across the U.S., Germany, Denmark, Japan,  
 24 Canada, and Australia, most childhood vaccines are recommended in all countries,” and  
 25 that small differences “reflect public health strategy not disagreement about [vaccine]  
 26 safety.”

27 118. Defendants disregarded the presentation’s findings and pushed through the  
 28 Kennedy Schedule by unlawfully bypassing ACIP.

1           119. Defendants’ unilateral decision to issue the Kennedy Schedule even  
2 blindsided vaccine experts at the CDC, who were cut out of the agency’s decision-making  
3 process.

4           120. By law, any recommendation should have originated with a properly  
5 constituted ACIP, and Defendants should have meaningfully considered input from CDC  
6 scientists, outside experts, and the public, before overturning decades of evidence-based  
7 vaccine recommendations. Indeed, CDC’s preparation for changes to the immunization  
8 schedule, including consultation with ACIP Work Groups, often began years before any  
9 ACIP votes took place.

10           121. Instead, Defendants took unilateral and unprecedented action to undermine  
11 the childhood immunization schedule, in furtherance of their ideological hostility to  
12 vaccines.

13           122. Relying on the Høeg-Kulldorff Report, Defendants recommended that six  
14 childhood vaccines be stripped of their routinely recommended status and instead be  
15 subject to SCDM.

16           123. Defendants also created unnecessary and dangerous confusion around the  
17 recommendation for a seventh immunization, RSV, by nominally moving it from the  
18 universally recommended routine status to an immunization recommended for certain  
19 high-risk groups or populations, without actually changing the substantive  
20 recommendation that infants should get the immunized if their mothers were not  
21 vaccinated during pregnancy.

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

27           125. Contrary to Defendants’ assertions, SCDM is intended for situations in  
28 which “individual factors meaningfully shift the risk-benefit assessment and population-

level benefit is uncertain.” Scott, J., *CIDRAP Op-Ed: Quiet dismantling: How ‘shared decision-making’ weakens vaccine policy and harms kids*, CIDRAP (Jan. 6, 2026), <https://www.cidrap.umn.edu/childhood-vaccines/cidrap-op-ed-quiet-dismantling-how-shared-decision-making-weakens-vaccine-policy>.

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

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

128. Because SCDM recommendations mean that there are no clear recommendations for a specific group of people, they have historically been reserved for vaccines about which, after considering all available evidence, true uncertainty exists at a population level about whether the risks outweigh the benefits.

129. Prior to the Kennedy Schedule, the CDC had used SCDM sparingly. In the past, SCDM was used for hepatitis B vaccination among certain adults sixty years of age or older, serogroup B meningococcal vaccination in adolescents and young adults, human papillomavirus (“HPV”) vaccination for adults aged twenty-seven to forty-five, and a particular pneumococcal vaccine in patients sixty-five years or older. Kempe, A., et al., *Shared Clinical Decision-Making Recommendations for Adult Immunization: What Do*

1 *Physicians Think?* Journal of general internal medicine. 2021;36(8):2283–91.  
2 doi:10.1007/s11606-020-06456-z.

3 130. Most recently, ACIP recommended adult RSV vaccines based on SCDM  
4 for a specific age group, but that recommendation was changed after one year to a risk-  
5 based recommendation.

6 131. In these instances, there were specific nuances to each vaccine that made  
7 SCDM appropriate. Melgar M, et al., *Use of Respiratory Syncytial Virus Vaccines in*  
8 *Older Adults: Recommendations of the Advisory Committee on Immunization Practices -*  
9 *United States, 2023.* MMWR Morb. Mortal. Wkly. Rep. Jul 21, 2023; 72(29):793–801.  
10 doi:10.15585/mmwr.mm7229a4; Britton A., et al., *Use of Respiratory Syncytial Virus*  
11 *Vaccines in Adults Aged  $\geq 60$  Years: Updated Recommendations of the Advisory*  
12 *Committee on Immunization Practices - United States, 2024.* MMWR Morb. Mortal.  
13 Wkly. Rep. Aug 15, 2024; 73(32):696–702. doi:10.15585/mmwr.mm7332e1.

14 132. In recommending that safe and effective vaccines be subject to SCDM  
15 absent any new evidence to support that shift, Defendants have distorted scientific  
16 evidence and sown doubt and confusion about these vaccines, without even providing  
17 clear guidance to clinicians about what this decision-making process should entail. *See,*  
18 *e.g.,* CDC Urges ‘Shared Decision-Making’ on Some Childhood Vaccines; Many Unclear  
19 About What That Means. *Annenberg Science Knowledge Surveys.* Annenberg Public  
20 Policy Center, University of Pennsylvania (Jan. 5, 2026), [https://www.annenbergpublic](https://www.annenbergpublicpolicycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/)  
21 [policycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-](https://www.annenbergpublicpolicycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/)  
22 [unclear-about-what-that-means/](https://www.annenbergpublicpolicycenter.org/cdc-urges-shared-decision-making-on-some-childhood-vaccines-many-unclear-about-what-that-means/).

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

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

1           134. As of the time of this complaint’s filing, the Kennedy Schedule conflicts  
2 with ACIP’s recommendations for each of the Demoted Vaccines—including even the  
3 unscientific hepatitis B recommendation from the Kennedy Appointees—infusing further  
4 confusion into national vaccine policy.

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

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

21           137. The Kennedy Schedule contradicts, or needlessly casts doubt on, decades  
22 of scientific evidence demonstrating the safety and efficacy of the Demoted Vaccines that  
23 were removed from the “consensus” list:

24           **Rotavirus**

25           138. Rotavirus is a viral infection of the gut that can cause severe diarrhea,  
26 dehydration, or death. See Childhood Immunization Schedule by Recommendation  
27 Group (“*CDC Imm. Sched. Index*”), Ctrs. for Disease Control and Prevention (last visited  
28 Feb. 24, 2025), <https://www.hhs.gov/childhood-immunization-schedule/index.html>. By

1 1980, rotavirus was the most common cause of severe gastroenteritis in infants and young  
2 children in the U.S. Cortese, M.M. & Penina, H., *Epidemiology and Prevention of*  
3 *Vaccine-Preventable Diseases, Chapter 19: Rotavirus*, Ctrs. for Disease Control and  
4 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)  
5 [contents/chapter-19-rotavirus.html](https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-19-rotavirus.html).

6 139. In 2006, after one of the currently available rotavirus vaccines was licensed  
7 in the U.S., the CDC recommended immunizing all babies against the disease starting at  
8 two months. Yandell, K. & McDonald, J., *The Facts on the Vaccines the CDC No Longer*  
9 *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/)  
10 [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/).

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

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

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

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

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

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

19           146. The report also gives a misleadingly low estimate of pre-vaccine deaths that  
20 directly conflicts with CDC’s own estimate of twenty to sixty deaths annually in children  
21 younger than five before routine immunization. *See* Høeg-Kulldorff Rep. at 20.  
22 Specifically, the report contends that “among all U.S. children [under fifteen], there were  
23 an average of 3.3 deaths per year” which, after the implementation of routine vaccination,  
24 was reduced to 1.6 deaths per year from 2009 to 2020. *Id.* at 20-21. The report then  
25 surmises that “[t]here may be many reasons for this very small decrease in mortality that  
26 are unrelated to the vaccine, including improved medical care, changes in diagnostic  
27 practices or random fluctuations.” *Id.*

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

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

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

### **Meningococcal**

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

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

1 two types to provide coverage against serogroups A, B, C, W, and Y (MenABCWY  
2 vaccine).

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

7 153. Prior to the Kennedy Schedule, ACIP routinely recommended the  
8 MenACWY vaccine for all adolescents aged eleven and twelve, with a booster at age  
9 sixteen due to waning protection and increased risk in later adolescence. ACIP also  
10 recommended the MenB vaccine based on SCDM for healthy persons aged sixteen to  
11 twenty-three (with sixteen to eighteen framed as the preferred age window) and separately  
12 recommended the MenB vaccine routinely for persons at increased risk.

13 154. The difference in vaccine uptake based on recommendation type (routine  
14 vs. SCDM) is evident. U.S. adolescent coverage for MenACWY is high, with  
15 approximately ninety percent receiving at least one dose and sixty percent receiving the  
16 recommended booster dose. On the other hand, MenB vaccine uptake has been  
17 substantially lower under SCDM, with approximately thirty-two percent of adolescents  
18 receiving at least one dose and only fourteen percent completing the two-dose MenB  
19 series.

20 155. Without presenting any new evidence concerning vaccine efficacy or safety  
21 or demonstrating that the prior routine recommendation for MenACWY was  
22 inappropriate, the Kennedy Schedule moved the MenACWY vaccine into the SCDM  
23 category with the MenB vaccine.

24 156. Instead of addressing any existing and relevant evidence, the Høeg-  
25 Kulldorff Report makes various unsupported assertions and irrelevant comparisons to  
26 justify its conclusion.

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

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

159. But the report’s reliance on the WHO threshold is misplaced. WHO vaccine position papers provide “global vaccine and immunization recommendations for diseases that have an international public health impact” and are therefore developed for a global audience and do not consider unique U.S. public health needs, as CDC must do when formulating domestic vaccine policy. *See Strategic Advisory Group of Experts on Immunization (SAGE)*, World Health Organization (last visited Feb. 20, 2026), <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 designed for reactive mass campaigns during epidemics in the African Meningitis Belt, not for routine preventative care in high-income nations.” Scott, J., *Quiet Dismantling*.

160. 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*.

1           **Hepatitis A**

2           161. Hepatitis A is a viral, highly contagious liver infection that can result in  
3 liver failure or death. *CDC Imm. Sched. Index*. The hepatitis A vaccine was first licensed  
4 as a two-dose vaccine for children twenty-four months or older in 1995. Ctrs. for Disease  
5 Control and Prevention, *Hepatitis A Vaccination Coverage Among U.S. Children Age 12-*  
6 *23 Months—Immunization Information System Sentinel Sites, 2006-2009*, MMWR Morb.  
7 Mortal. Wkly. Rep. (Jul. 2, 2010), [https://www.cdc.gov/mmwr/preview/mmwrhtml/mm](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5925a3.htm)  
8 [5925a3.htm](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5925a3.htm).

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

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

18           164. Hepatitis A vaccines have also been proven safe, with millions of doses  
19 administered since licensure in 1995. Ctrs. for Disease Control and Prevention, *Hepatitis*  
20 *A Vaccine* (Jan. 31, 2025), <https://www.cdc.gov/hepatitis-a/vaccination/index.html>. As  
21 recently as January 2025, the CDC confirmed that both types of hepatitis A vaccines  
22 (single antigen vaccines for solely hepatitis A and combination vaccines for both hepatitis  
23 A and B) are safe and highly effective, even for people with compromised immune  
24 systems. *Id.* Further, the CDC has stated that the “potential risks of hepatitis A are much  
25 higher than any risks associated with [the] hepatitis A vaccine.” *Id.*

26           165. The Høeg-Kulldorff Report asserts, without attribution, that “high [hepatitis  
27 A] endemic communities” in the U.S. had “disappeared” by the time the hepatitis A  
28 vaccine was universally recommended for all children in 2006, at which time the “annual

1 incidence rate . . . was very low.” Høeg-Kulldorff Rep. at 20. It further asserts that the  
2 incidence of hepatitis A “remains similarly low” and that the annual mortality rate is only  
3 “1 per 10 million, with the highest rate among older men.” *Id.* The report also claims  
4 that “reliable safety data is limited” due to a lack of “proper placebo-controlled  
5 randomized trial[s]” for the currently available FDA-approved hepatitis A vaccines. *Id.*  
6 Based on the purportedly “low U.S. incidence and mortality, and the lack of randomized  
7 placebo-controlled safety data,” the report sweepingly concludes that “the benefit-risk  
8 ratio is at best very low for most children” and the hepatitis A vaccine thus “should not  
9 be recommended for all children.” *Id.*

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

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

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

## **Hepatitis B**

169. 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.

170. 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/>.

171. 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.

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

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

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

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

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

25           177. At the December 4-5, 2025 ACIP meeting, the Kennedy Appointees  
26 acknowledged that there currently is no scientific evidence of harm in giving the hepatitis  
27 B vaccine to infants, or any difference in giving the initial dose of the vaccine at any point  
28 earlier than two months. One ACIP member—Hibbeln—specifically observed that

1 “there was no data presented that two months is an appropriate cut-off” for the hepatitis  
 2 B vaccine. Stobbe, M., *RFK Jr.’s chosen vaccine advisers say not all babies need a*  
 3 *hepatitis B shot at birth*, Associated Press (Dec. 5, 2025),  
 4 <https://www.pbs.org/newshour/health/rfk-jr-s-chosen-vaccine-advisers-say-not-all-babies-need-a-hepatitis-b-shot-at-birth>.  
 5

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

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

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

## 20 **Influenza**

21 181. Influenza is a viral respiratory infection that can cause pneumonia, sinus  
 22 and ear infections, worsen underlying heart or lung conditions, and lead to death. *CDC*  
 23 *Imm. Sched. Index*. The disease can trigger acute cardiac events. Woodruff, R.C., et al.,  
 24 *Acute Cardiac Events in Hospitalized Older Adults With Respiratory Syncytial Virus*  
 25 *Infection*, JAMA Internal Medicine (June 1, 2024),  
 26 <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2817609>. Influenza  
 27 typically causes a major epidemic in the U.S. annually, starting in late fall and early  
 28 winter, but often extending into early spring.

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

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

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

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

186. 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.

187. 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.

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

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

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

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

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

22           193. Rather than acknowledge this data, the Høeg-Kulldorff Report  
23 misleadingly relied on a study that “did not identify hospitalization or death benefits of  
24 flu vaccination . . . [and] did not include any trials with data on those outcomes. It did,  
25 notably, find evidence that flu shots worked to reduce influenza in children.” Yandell &  
26 McDonald.

## COVID-19

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

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

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

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

198. Infants less than six months are among the groups currently experiencing the highest hospitalization rates.

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

200. 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

1 averted approximately 107,000 hospitalizations, 18,000 admissions to the intensive care  
2 unit, and more than 6,700 deaths. Wiegand, R.E., et al., *Estimating COVID-19 associated*  
3 *hospitalizations, ICU admissions, and in-hospital deaths averted in the United States by*  
4 *2023-2024 COVID-19 vaccination: A conditional probability, causal inference, and*  
5 *multiplier-based approach*, Vaccine (Mar. 7, 2025), doi:10.1016/j.vaccine.2025.126808.  
6 This is comparable to the burden of disease prevented by influenza vaccination in a typical  
7 season.

8 201. Across nine states from August 29, 2024 to September 2, 2025, COVID-19  
9 vaccination reduced the risk of COVID-19–associated emergency department or urgent  
10 care visits among children aged nine months to four years by seventy-six percent and by  
11 an estimated fifty-six percent for children and adolescents aged five to seventeen,  
12 compared to those who did not receive a vaccine for that season. Irving, S.A., et al.,  
13 *Effectiveness of 2024-2025 COVID-19 Vaccines in Children in the United States -*  
14 *VISION, August 29, 2024-September 2, 2025*, MMWR Morb. Mortal. Wkly. Rep. (Dec.  
15 11, 2025), doi:10.15585/mmwr.mm7440a1. In addition, multiple studies have shown that  
16 COVID-19 vaccination was associated with lower risk of post-COVID-19 symptoms,  
17 including long COVID, in children. Scott J., et al., *Updated Evidence for Covid-19, RSV,*  
18 *and Influenza Vaccines for 2025-2026*, N. Engl. J. Med. (Dec. 4, 2025),  
19 doi:10.1056/NEJMsa2514268.

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

24 203. On April 15, 2025, at the last ACIP meeting before Defendants’ extensive  
25 interference and the appointment of the Kennedy Appointees, CDC staff and the COVID-  
26 19 Work Group presented multiple times on COVID-19 epidemiology and vaccine  
27 coverage and safety to prepare the committee for its June 2025 meeting.

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

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

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

24           207. On May 30, 2025, Defendants officially changed the publicly-available  
25 immunization schedule on CDC's website to indicate that COVID-19 vaccines were  
26 changed to SCDM for all children. Defendants also provided no guidance to clinicians  
27 or parents as to which groups were most at risk of severe disease or as to which groups  
28 the benefits of vaccination clearly outweighed the risks.

208. 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.

209. 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**

210. 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.

211. 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.

212. 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.

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

214. 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.

215. 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.

216. 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.*

217. 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.

218. 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.

219. 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=redirecintensed>. 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>.

220. 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.

221. 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.

222. 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

1 underlying comorbidities, unusual exposure to the disease, or the risk of disease  
2 transmission to others.” Decision Memo at 5. But, at the same time, a table in the Høeg-  
3 Kulldorff Report on RSV prevention products (monoclonal antibodies) is accompanied  
4 by a footnote stating that “[a]ll children” should receive one dose of monoclonal antibody  
5 if their mother was not vaccinated for RSV during pregnancy. Høeg-Kulldorff Rep. at 2.

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

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

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

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

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

23 227. Defendants’ decision to base the Kennedy Schedule on the vaccine policies  
24 of supposed “peer countries” is confounding and dangerous. For one thing, Defendants  
25 misrepresent those policies. And regardless, as Dr. Adam Langer stated at the December  
26 4-5, 2025 ACIP meeting, the U.S. has no true “peer” nations in terms of vaccine policy.

27 228. Defendants’ reliance on vaccine policies in Denmark and other dissimilar  
28 countries disregards the unique public health features that led the U.S., over many

1 decades, to adopt its prior childhood immunization schedule. These factors include  
2 demographic diversity, population size, disease risks and burden, and a lack of universal  
3 access to preventative and remedial care and other safety net services. *Id.*; Ulrich, A.K.,  
4 et al. at 13.

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

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

19 **VIII. Defendants' decision to change the routine immunization schedule will**  
20 **mislead and confuse patients and reduce vaccination rates.**

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

25 232. Historically, the CDC has placed a vaccine on the routine immunization  
26 schedule when the scientific evidence clearly shows that the vaccine is safe and effective,  
27 and that patients and the public benefit from routine immunization against a disease.

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

1           234. As noted, SCDM is appropriate when “individual factors meaningfully shift  
2 the risk-benefit assessment and [the] population-level benefit is uncertain.” Scott, J.,  
3 *Quiet Dismantling*.

4           235. That is not true of any of the Demoted Vaccines.

5           236. Defendants’ change to the immunization schedule therefore misleads  
6 patients about the safety and efficacy of the Demoted Vaccines.

7           237. By misleading patients in this way, Defendants’ change in official CDC  
8 policy will reduce vaccination rates for the diseases against which the Demoted Vaccines  
9 protect.

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

13           239. The vaccines historically placed on the routine immunization schedule were  
14 essentially the CDC’s recommended default decision, and for good reason—the scientific  
15 evidence clearly showed that they were safe, effective, and important to public health.

16           240. Providers and patients alike had therefore relied on the CDC’s routine  
17 recommendations, and the data supporting those recommendations, to inform their  
18 decision-making around immunization in an efficient and evidence-based manner. By  
19 changing the default in official CDC policy, Defendants’ actions will naturally and  
20 predictably reduce vaccination rates. Indeed, that is their intent.

21           241. Furthermore, unlike countries with universal healthcare, “[m]ore than 100  
22 million Americans lack usual access to primary care,” meaning that an “instruction to  
23 ‘discuss with your clinician’ is not neutral guidance,” but “a barrier” to getting vaccinated.  
24 Scott, J., *Quiet Dismantling*.

25           242. The Kennedy Schedule will therefore likely have a disproportionate impact  
26 on uninsured or underinsured populations and those with limited or no access to a primary  
27 care provider.

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

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

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

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

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

247. When CDC’s recommendations are science-based, objective, and 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.**

248. ACIP recommendations are inextricably linked with state legal codes. Until June 2025, nearly 600 statutes and regulations across forty-nine states, territories, and

1 Washington, D.C. incorporated ACIP recommendations by reference, often requiring  
2 states to use or consider ACIP recommendations to formulate and implement vaccine  
3 policies. *Impact of the Advisory Committee on Immunization Practices*  
4 *Recommendations on State Law*, Ass’n of State and Territorial Health Offs. (June 23,  
5 2025). ACIP’s recommendations are often incorporated into state scope of practice laws,  
6 school entry requirements, and insurance coverage requirements, among other places. *Id.*

7 249. This interdependence reflects the Secretary’s express statutory obligations  
8 to “assist States . . . in the prevention and suppression of communicable diseases,”  
9 “cooperate with and aid” states “in the enforcement of their quarantine and other health  
10 regulations,” and advise the States “on matters relating to the preservation and  
11 improvement of the public health.” 42 U.S.C. § 243(a).

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

16 251. As a measure of ACIP’s prestige—and of how it was previously  
17 unfathomable that ACIP would be politically compromised or wholly bypassed—state  
18 immunization laws often refer specifically to “ACIP’s recommendations.”

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

21 253. Defendants’ unlawful reconstitution of ACIP, followed by their unlawful  
22 bypass of it entirely, therefore injects immediate confusion and uncertainty into the  
23 administration of many of Plaintiff States’ public health laws and regulations. If CDC’s  
24 childhood immunization schedule is no longer a product of lawful ACIP  
25 recommendations—and if it does not reflect scientific consensus—then states must  
26 undertake the massive administrative burden and expense of untethering their laws from  
27 CDC and ACIP.

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

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

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

19           257. The Kennedy Schedule turns the previously simple assessment required by  
20 § 36-2904(N) into a morass of uncertainty and confusion. If the only vaccines now  
21 "recommended by the" CDC are the purported "consensus vaccines," then Arizona law  
22 no longer provides for the tracking of important diseases, several of which Arizona  
23 requires for childcare and school entry. On the other hand, if the "recommend[ation]" is  
24 contingent on an individualized assessment based on SCDM, then the director is suddenly  
25 encumbered by a complex data collection and reporting challenge. In either event, the  
26 action has senselessly harmed and burdened AHCCCS and compromised the collection  
27 and reliability of public health data.

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

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

260. Likewise, because of the changes in ACIP recommendations, Delaware Health and Social Services/the Delaware Division of Public Health updated Delaware’s Communicable Disease Regulations in Fall of 2025. *See* 27 Del. Reg. 863 (May 2024). These regulations previously referenced ACIP as the source for determining vaccines and vaccine schedules for children entering schools. The regulations had to be updated to include reference to the American Academy of Pediatrics (“AAP”), the American College of Obstetricians & Gynecologists, and the American Academy of Family Physicians

1 (“AAFP”). These updates required legal review, interagency coordination, and public  
2 notice. They are currently going through administrative processes and are scheduled for  
3 publication on May 11, 2026.

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

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

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

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

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

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

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

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

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

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

24           271. Similarly, to address concerns about the trustworthiness of ACIP's  
25 recommendations as incorporated in State regulations, the Colorado State Board of Health  
26 recently adopted, via an emergency rule, regulations incorporating the 2025 AAP  
27 Recommended Child and Adolescent Immunization Schedule. *See* 6 CCR 1009-2.  
28 Meanwhile, other statutory provisions still rely on ACIP. *See, e.g.,* C.R.S. § 25-4-2403

1 (providing that the Department of Public Health and Environment may address “the  
2 ability of the department of health care policy and financing to purchase vaccines  
3 recommended by ACIP through a purchasing system”); C.R.S. § 25-4-2403 (outlining  
4 that coverage for preventative health services must include “recommendations  
5 established by the ACIP”).

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

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

23 274. While Michigan law does not explicitly reference ACIP and CDC  
24 recommendations, the Michigan Department of Health and Human Services (“MDHHS”)  
25 has historically relied on ACIP and CDC recommendations in educating and issuing  
26 guidance to providers. For example, MDHHS previously used the CDC immunization  
27 schedule to advise providers enrolled in the VFC program which vaccines they should  
28 carry.

1           275. As a result of the Kennedy Schedule, Plaintiff States must now expend time  
2 and resources to ensure that the public has access to accurate information about vaccine  
3 safety and efficacy.

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

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

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

16          278. The Kennedy Schedule imposes direct costs on Plaintiff States' health and  
17 Medicaid agencies.

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

25          280. New Mexico's Healthcare Authority ("HCA"), which administers the  
26 state's Medicaid program, likewise expects that the Kennedy Schedule will increase its  
27 Medicaid costs associated with pediatrician visits for SCDM conversations. As vaccine  
28 rates decrease, HCA also expects Medicaid costs will increase as a result of an increase  
in pediatric hospital stays for immunization-preventable diseases.

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

10           282. MDHHS—which administers Michigan’s Medicaid program—expects that  
11 Defendants’ actions will increase Michigan’s Medicaid costs. For example, MDHHS  
12 anticipates additional reimbursement requests for vaccine counseling sessions and  
13 increased costs for treatment of vaccine-preventable diseases, which will become more  
14 prevalent as a result of decreased vaccine uptake.

15           283. The Kennedy Schedule will also result in more vaccine-preventable disease  
16 cases and outbreaks, which will impose costs on and strain the resources of Plaintiff  
17 States’ health agencies.

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

24           285. In Pennsylvania, a single case of meningococcal disease was detected in  
25 2025 in an individual who had contact with school-aged children with additional  
26 exposures in the home and health environments. This single case resulted in a complex  
27 multi-day, multi-jurisdictional response involving a private company, hospital, school  
28

1 district and family to determine potential close contact and need for postexposure  
2 prophylaxis.

3 286. Additionally, in 2025 Pennsylvania responded to sixteen domestically and  
4 internationally imported measles cases, including an outbreak in a child-care center in  
5 which a single unvaccinated child acquired measles and introduced it into the center,  
6 resulting in additional cases. The single exposure generated more than 200 contacts  
7 requiring intensive public health follow-up, including contact tracing, verification of  
8 immunization status, and provision of post-exposure prophylaxis. Managing and  
9 containing this preventable outbreak consumed substantial public health resources,  
10 requiring coordination between two public health departments, and resulted in lost work  
11 time for child-care staff and parents of ill or exposed children, as child-care services were  
12 disrupted or unavailable.

13 287. Wisconsin's Department of Health Services has expended substantial  
14 resources responding to confirmed cases of measles in 2025 and 2026. This includes  
15 identifying and notifying people who may have been exposed to the measles virus,  
16 providing information about potential exposure locations in public settings, and issuing  
17 health alerts.

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

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

27 290. From 2024–2025, Delaware identified four confirmed hepatitis A cases.  
28 Although these cases were limited to household exposures and did not result in

1 widespread community transmission, each case required extensive public health follow  
2 up. Epidemiologists conducted detailed investigations that included contact tracing,  
3 verification of immunization status, and infection source identification. Identified close  
4 contacts were then assessed and given appropriate post-exposure prophylaxis  
5 recommendations. In late 2024, Delaware coordinated sequencing of IgM-positive  
6 specimens with the CDC's Division of Viral Hepatitis. This process required formal  
7 approval prior to specimen submission, coordination with hospital partners, and shipment  
8 through the Delaware Public Health Laboratory to the CDC Division of Viral Hepatitis  
9 Laboratory Branch.

10 291. From 2024 to 2025, Delaware also identified three confirmed  
11 meningococcal disease cases, including two pediatric cases. Although no outbreaks  
12 occurred, each case required immediate and coordinated response efforts. The most  
13 recent pediatric case involved an inter-facility transfer, requiring Delaware to coordinate  
14 with infection prevention teams at two hospitals to closely assess potential healthcare  
15 exposures. The epidemiologist conducted thorough interviews with the child's parents  
16 and collaborated with the child's elementary school to monitor additional symptomatic  
17 individuals. While no additional cases were identified and no non-household contacts  
18 required post-exposure prophylaxis, the investigation required multi-sector coordination  
19 between healthcare facilities, elementary school personnel, and family members to ensure  
20 rapid risk assessment and prevention of further transmission.

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

27 293. Maryland also anticipates that it will see decreased vaccination rates for the  
28 Demoted Vaccines, and a corresponding increase in acute care needs for those diseases

1 in both pediatric and adult populations. And the burden on Maryland care delivery system  
2 (primary care providers, urgent care, emergency departments and inpatient facilities) will  
3 only further increase as vaccination rates for the respective diseases decrease. Maryland  
4 anticipates that state funds and resources, such as increased billing claims to Medicaid,  
5 CHIP, and the Maryland Children's Health Program by providers and hospitals, will be  
6 strained by this foreseeable increase in acute care needs.

7 294. The Kennedy Schedule will also significantly increase the costs that  
8 Plaintiff States' Medicaid programs must pay to treat vaccine-preventable diseases and  
9 their long-term consequences.

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

16 296. Estimates show that delaying the initial hepatitis B vaccine dose by only  
17 two months for infants whose mothers are not known to be infected with hepatitis B could  
18 result in at least 1,400 new childhood hepatitis B infections annually nationwide. *Id.* at  
19 8. Over time, those infections would result in nearly 300 new cases of liver cancer and  
20 480 hepatitis B-related deaths, generating over \$222 million in healthcare costs. *Id.* This  
21 is a conservative estimate. *Id.* at 10. While cancers due to hepatitis B do not manifest  
22 immediately, they eventually occur at an annual rate of two to four percent, and that  
23 cancer, along with cirrhotic liver disease, carries a lifetime risk of death of twenty-five  
24 percent. *See* Hepatitis B Foundation (Updated Dec. 27, 2022), **Error! Hyperlink reference**  
25 **not valid..**

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

1           **C. Burden on State resources to combat misinformation and prevent**  
 2           **further harm.**

3           298. Plaintiff States are already expending resources to counter the impact of  
 4 increased vaccine hesitancy and the erosion of public trust in vaccines caused by  
 5 Defendants.

6           299. Health agencies in Plaintiff States, including the Arizona Department of  
 7 Health Services, the California Department of Public Health, the Connecticut Department  
 8 of Public Health, the Minnesota Department of Health, the New Mexico Department of  
 9 Health, and the Pennsylvania Department of Health have expended meaningful staff time  
 10 and resources creating and promulgating communications to the public and to healthcare  
 11 providers regarding the continued safety and efficacy of the previously routinely  
 12 recommended childhood vaccines. The health agencies have also expended meaningful  
 13 staff time and resources reviewing and modifying their guidelines, webpages, and other  
 14 relevant documents to address differences between state immunization requirements and  
 15 the federal recommendations now reflected in the Kennedy Schedule.

16           300. In New Mexico, the Department of Health has had to issue multiple Health  
 17 Action Network notices and public health orders to clarify state rules and ensure timely  
 18 access to routine immunizations. *See, e.g.,* N.M. Dep't of Health, *Public Health Order*  
 19 *Ensuring Availability of COVID-19 Vaccine for the 2025-2026 Season* (Aug. 29, 2025),  
 20 nmhealth.org. The Board of Pharmacy also had to update the guidelines to its Vaccine  
 21 Protocol to remove its sole reliance on ACIP and ensure that pharmacists could continue  
 22 to administer the COVID vaccine. N.M. Reg. and Licensing Dep't, *Protocol for*  
 23 *Pharmacist Prescribing of Vaccines*, [nm.gov](https://nm.gov) (last visited Feb. 8, 2026); *see also*  
 24 Goldberg, J., *NM health department announces new pharmacy protocol, easier COVID-*  
 25 *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/)  
 26 [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/).

27           301. In Michigan, MDHHS has diverted significant resources to respond to the  
 28 schedule changes and combat misinformation related to vaccine efficacy. For example,  
 as noted above, MDHHS historically looked to ACIP and CDC recommendations in

1 issuing guidance to providers and educating the public on vaccines. However, in response  
2 to the activities of Defendants, MDHHS was forced to convene the Michigan Advisory  
3 Committee on Immunizations (“MACI”) for several emergency sessions in 2025 to  
4 consider the implications of the federal actions on vaccines. For the first time in recent  
5 history, the medical and scientific advisors of MACI voted to deviate from ACIP and  
6 CDC guidance in favor of the AAP and AAFP immunization schedules. MDHHS has  
7 expended—and continues to expend—significant funds, staffing hours, and other  
8 resources to effectuate this change, including in issuing standing recommendations,  
9 developing guidance to providers, and educating the public. Since July 2025, MDHHS  
10 estimates that it has dedicated several thousand staff hours responding to this issue.

11       302. In response to the widespread confusion and uncertainty created by  
12 Defendants’ actions, Wisconsin Governor Tony Evers issued Executive Order #275  
13 Relating to Interagency Cooperation to Urgently Safeguard Wisconsin’s Access to  
14 Vaccinations on September 15, 2025. The Executive Order directs Wisconsin’s  
15 Department of Health Services to review and continually monitor the available medical  
16 evidence and guidance, to issue appropriate standing orders or protocols regarding access  
17 to COVID-19 vaccines, and to consider whether additional measures may be necessary  
18 to provide clarity and guidance on other routine vaccines. The Executive Order also  
19 directs Wisconsin’s Commissioner of Insurance to work with health plans to develop  
20 guidance to insurers regarding vaccine access and costs.

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

1           304. In Connecticut, the Department of Public Health has been required to  
2 devote substantial communication resources to, among other things, clarify that the  
3 underlying scientific evidence has not changed and that vaccines removed from routine  
4 recommendations remain safe and effective; clarify the differences between state  
5 immunization requirements and the new federal recommendations to ensure consistent  
6 messaging for residents and clinicians in the State, including that Connecticut school and  
7 childcare entry requirements remain in place; explain the “shared clinical decision-  
8 making” designation; and address public confusion created when parents are told that  
9 long-safe, effective vaccines are optional or negotiable.

10           305. To combat vaccine hesitancy caused by the federal schedule changes, the  
11 Maryland Department of Health (“MDH”) has devoted significantly increased time and  
12 resources to public education on the safety and efficacy of vaccines, including through  
13 social media, state websites, press events, and official statements.

14           306. MDH has already received questions from clinicians about whether and  
15 how they are supposed to document SCDM for vaccine visits, and their concerns about  
16 the need to dispel misinformation regarding vaccines. Indeed, MDH staff has also  
17 engaged in increased communication with health provider groups, through email,  
18 meetings, official Dear Clinician letters, and more, solely to address confusion caused by  
19 the federal schedule changes. MDH anticipates expending significant time and resources  
20 to coordinate with education agencies, districts, business owners, parents and educators,  
21 and school-based health providers to encourage continued compliance with state school  
22 and childcare entry immunization requirements.

23           307. Maryland has invested significant work in recent years to increase uptake  
24 of RSV vaccine and monoclonal antibodies across the state, and has seen a corresponding  
25 increase in immunizations, accompanied by a decrease in hospitalization of Maryland  
26 infants for RSV. However, the sudden federal schedule changes, including with respect  
27 to the RSV vaccine, threatens to undermine these hard-won gains. MDH now anticipates  
28 requiring additional time and resources for infectious disease surveillance, detection, and

1 monitoring for and response to vaccine-preventable disease cases and outbreaks in  
2 multiple bureaus.

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

9 309. The “absence of consistent, science-based federal leadership” has also led  
10 several Plaintiff States, including California and Oregon, to form alliances to provide their  
11 residents with “clear, evidence-based” public health guidance and immunization  
12 recommendations by relying instead on the recommendations of medical professional  
13 organizations. Press Release, Gov. Gavin Newsom, Hawaii to join West Coast Health  
14 Alliance with California, Oregon, and Washington (Sep. 4, 2025),  
15 [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/)  
16 [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  
17 expended significant staff time and resources in the formation of the West Coast Health  
18 Alliance, and in creating and promulgating communications to the public and to  
19 healthcare providers regarding the West Coast Health Alliance's shared, collective  
20 recommendations.

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

25 311. ACIP and the CDC are the only bodies in the U.S. that have the ability and  
26 stature to make vaccine recommendations across populations nationwide. ACIP has  
27 historically synthesized the best available science and evidence across all population  
28 groups. Even with Herculean, expensive effort, Plaintiff States will be hard-pressed to

1 fill the void left by formerly trustworthy federal bodies no longer providing reliable  
2 guidance.

3 312. Additionally, “[w]hen states must route around federal guidance, when  
4 different regions of the country operate under different recommendations, when the  
5 message to parents varies by zip code, confusion multiplies and confidence erodes.”  
6 Scott, J., *Quiet Dismantling*.

7 313. In addition to the West Coast Health Alliance, California has expanded  
8 funding to lead the Public Health for All Californians Together to bring together a  
9 network of multi-sectoral partners across the state of California to provide timely,  
10 evidence-based guidelines and culturally-appropriate health messaging to protect the  
11 health and advance the well-being of all Californians.

12 314. The New Mexico Department of Health anticipates it will need to develop  
13 SCDM guidance and frequently asked questions for providers and parents.

14 315. The Pennsylvania Department of Health has implemented plans due to the  
15 uncertainties created by Defendants’ decision-making in anticipation of needing to create  
16 and manage a Pennsylvania-based program in the event the VFC Program stops providing  
17 access to necessary vaccines without cost sharing. In addition to continuing the work of  
18 safeguarding immunization access to families in accordance with Governor Shapiro’s  
19 Executive Order 2025-02 – [Protecting Pennsylvanians’ Health and Freedom by Ensuring](#)  
20 [Access to Safe and Effective Vaccine](#), the state department of health will continue to  
21 release evidence-based information on vaccines to the public.

22 316. The new federal schedule has required Connecticut to engage in increased  
23 efforts to bolster infectious disease surveillance, detection, and monitoring. Declines in  
24 vaccination rates in other states will increase the risk of pathogens entering Connecticut  
25 through unvaccinated persons. And given the likelihood of increased transmission from  
26 decreased vaccination rates across the country, Connecticut will be compelled to expend  
27 significant resources to address outbreak prevention, including surveillance and  
28 monitoring through testing and contact tracing, which in turn requires increased staff,

1 improved data collection procedures, and improved coordination with healthcare facilities  
2 and laboratories.

3 317. Further, Connecticut will need to increase resources to respond to future  
4 vaccine-preventable outbreaks, including increasing outbreak investigation capacity,  
5 ensuring vaccine availability for rapid response, improving communication  
6 infrastructure, and coordinating with healthcare systems for surge capacity.

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

13 319. Collectively, these additional demands will continue to strain state health  
14 agencies' already limited resources.

15 320. Defendants and the heads of the NIH, CMS, and the FDA claim that all  
16 vaccines, including the Demoted Vaccines, will remain available for free through private  
17 insurance, Medicaid, and the VFC Program.

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

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

26 323. For example, in fiscal year 2023, Arizona received \$112,521,081 in VFC  
27 funding, with approximately \$110 million allocated for vaccine purchases and the  
28 remaining \$2 million for program administration. Ctrs. for Disease Control and

1 Prevention, FISCAL YEAR 2023 GRANTS SUMMARY PROFILE REPORT FOR ARIZONA 3  
2 (2023).

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

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

10 326. Defendants’ assurances that all vaccines on the Kennedy Schedule will  
11 remain covered by private insurance companies as required by the Affordable Care Act  
12 are similarly open to suspicion.

13 327. Coverage for vaccines under the Affordable Care Act and through VFC are  
14 statutorily based on ACIP, not CDC, recommendations. *See* 42 U.S.C. § 1396s(c)(2)(b),  
15 (e) (VFC), 42 U.S.C. § 300gg-13(a)(2) (ACA). Accordingly, Defendants’ unilateral  
16 decision to issue the Kennedy Schedule is directly at odds with the statutory framework  
17 that actually safeguards and ensures coverage under the Affordable Care Act and through  
18 the VFC.

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

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

**CLAIMS****Count I****Violation of the APA****Arbitrary and Capricious Action – Kennedy Schedule****5 U.S.C. § 706(2)(A)**

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

331. 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).

332. 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.*

333. “[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, 178 (D.C. Cir. 2005) (“DEA’s decision does not withstand review because the agency decisionmaker entirely ignored relevant evidence.”).

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

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

6           336. The Kennedy Schedule is arbitrary and capricious because Defendants cut  
7 out ACIP—the designated advisory body for developing vaccine recommendations—  
8 from the policy development process and thereby disregarded the voluminous scientific  
9 evidence underlying ACIP’s recommendations prior to June 2025.

10           337. After circumventing ACIP, Defendants did not base the Kennedy Schedule  
11 on requisite evidence or scientific analysis under the GRADE and EtR frameworks,  
12 identify any reason to abandon those methodological frameworks, or identify any  
13 changed circumstance whatsoever supporting the new recommendations.

14           338. Rather, Defendants adopted recommendations based on the Høeg-Kulldorff  
15 Report, which consists of superficial comparisons to “peer countries,” cherry-picked  
16 studies, and unsupported claims about the safety, efficacy, and risk-benefit profiles of the  
17 Demoted Vaccines.

18           339. In relying solely on the Høeg-Kulldorff Report, Defendants failed to  
19 consider well-established evidence on the benefits, efficacy, and safety of the Demoted  
20 Vaccines—including the evidence that CDC and ACIP previously considered when  
21 previously recommending the routine administration of vaccines on the childhood  
22 immunization schedule.

23           340. Similarly, Defendants failed to consider the unique needs and  
24 characteristics of the U.S. and its public health system, and thereby also disregarded  
25 Plaintiff States’, medical providers’, and patients’ significant reliance on reasoned,  
26 reliable, and consistent CDC recommendations.

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

4           342. If Defendants had wished to conduct a legitimate review of vaccine policies  
5 in other countries (at President Trump’s request or otherwise), they should have routed  
6 the request through proper ACIP channels and evaluated evidence from “peer countries”  
7 in a systematic way that established a reasoned, scientific nexus between those countries’  
8 vaccine policies and the policies appropriate for the U.S. Instead, Defendants provided  
9 no explanation, let alone a “reasoned” one, to depart from their longstanding vaccine  
10 policy development process.

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

18           344. Public engagement and input are vital to ACIP’s work. Members of the  
19 public are invited to submit comments to ACIP either in writing or orally at ACIP  
20 meetings. When submitted in writing, all relevant comments received are posted without  
21 change to <https://www.regulations.gov>.

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

26           346. Defendants further ignored the mountains of highly relevant scientific  
27 evidence supporting the prior childhood immunization schedule and promulgated the  
28 Kennedy Schedule based on the unscientific dictates of political officials and pretextual

rationales. *See, e.g., Tummino v. Torti*, 603 F. Supp. 2d 519, 547 (E.D.N.Y. 2009) (issuing administrative decision “prior to the completion of the scientific reviews . . . would certainly be evidence of a departure from the typical FDA decision-making process” and reflect improper “pressure[] by the White House”).

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

348. Defendants’ approval of the Kennedy Schedule violates the APA and must 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)

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

350. 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.

351. 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

1 for Defendants to exclude ACIP from the process for which ACIP was established. 5  
2 U.S.C. § 1008 (a), (b) (explaining that an established advisory committee is to be utilized  
3 for advisory functions).

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

11 353. ACIP must further ensure that its recommendations are not “inappropriately  
12 influenced by the appointing authority,” 5 U.S.C. § 1004(b)(3), (c); 41 C.F.R. § 102-  
13 3.105(g), a safeguard that is rendered meaningless here if the appointing authority can  
14 simply circumvent the advisory process.

15 354. Courts, moreover, have an obligation to interpret related statutes and  
16 regulations as part of “a symmetrical and coherent regulatory scheme.” *Mellouli v.*  
17 *Lynch*, 575 U.S. 798, 809–10 (2015) (quoting *FDA v. Brown & Williamson Tobacco*  
18 *Corp.*, 529 U.S. 120, 133 (2000)). Congress has specifically designated ACIP—not the  
19 CDC—as the body that establishes the immunization schedules triggering federal  
20 obligations in a number of federal health statutes. This was a deliberate choice that  
21 forecloses CDC-only action.

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

27 356. Likewise, the Medicaid statute links coverage to “diagnostic, screening,  
28 preventative, and rehabilitative services, including . . . with respect to an adult individual,

1 approved vaccines recommended by [ACIP].” 42 U.S.C. §§ 1396a(a)(10)(A) &  
 2 1396d(a)(13)(B). And under the VFC program, the HHS Secretary “shall use, for the  
 3 purpose of the purchase, delivery, and administration of pediatric vaccines under this  
 4 section, the list established (and periodically reviewed and as appropriate revised) by  
 5 [ACIP].” 42 U.S.C. § 1396s(e). The statutory language “shall use” is mandatory and  
 6 assigns ACIP—not the Secretary or CDC Director—the role of establishing the list and  
 7 revising it.

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

12 358. In circumventing ACIP and unilaterally issuing the Kennedy Schedule  
 13 without the scientific analysis, deliberation, and public input that a properly constituted  
 14 ACIP would have been required to perform, Defendants acted contrary to law and to  
 15 procedure required by law.

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

### 21 **COUNT III**

#### 22 **Violation of the APA**

#### 23 **Arbitrary and Capricious, Contrary to Law, and Contrary to Procedure Required** 24 **by Law – Kennedy Appointments**

#### 25 **5 U.S.C. § 706(2)(A), (D)**

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

361. FACA requires that membership of advisory committees for federal agencies 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); *see also* 41 C.F.R. § 102-3.60(b)(3) (May 20, 2024 ed.).<sup>3</sup>

362. FACA further requires that advisory committees abide by their procedures to guard against recommendations that are “inappropriately influenced by the appointing authority.” 5 U.S.C. § 1004(b)(3), (c); 41 C.F.R. § 102-3.105(i) (May 20, 2024 ed.). Pursuant to 5 U.S.C. § 1008(c)(1), advisory committees must maintain a charter that specifies the “expertise or experience required” of its members. 41 C.F.R. § 102-3.75(l). Advisory committees requiring “technical expertise,” in particular, “should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed by the committee.” *Id.* § 102-3.60(b)(3)(i) (May 20, 2024 ed.).

363. 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.).

364. 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

---

<sup>3</sup> On December 16, 2025, without formal rulemaking or any apparent notice or comment 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.

1 administrative guidelines and management controls applicable to advisory committees,”  
2 *id.* § 1006(c).

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

6 366. All agency heads, including the HHS Secretary, are required to comply with  
7 FACA, the General Services Administration’s federal advisory committee management  
8 regulations, and any other applicable laws and regulations. *Id.* § 102-3.105(a) (May 20,  
9 2024 ed.). This includes appointing a Designated Federal Officer to ensure continued  
10 compliance with FACA, its implementing regulations, agency procedures, and any other  
11 applicable laws and regulations. *Id.* §§ 102-3.105(d), 102-3.120(a)(1) (May 20, 2024  
12 ed.). These requirements are “procedure[s] required by law” within the meaning of the  
13 APA. *See* 5 U.S.C. § 706(2)(D).

14 367. ACIP’s Charter, Membership Balance Plan, and Policies and Procedures  
15 provide the required administrative guidelines and management controls needed to  
16 operate ACIP in compliance with FACA and its “fairly balanced” membership  
17 requirement. 5 U.S.C. § 1004(b)(2), (c); 41 C.F.R. § 102-3.60(b)(3) (May 20, 2024 ed.).

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

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

26 370. Accordingly, the Secretary must appoint members with “expertise in the  
27 field of immunization practices,” “multi-disciplinary expertise in public health,”  
28

1 “expertise in the use of vaccines and immunologic agents,” and “knowledge of vaccine  
2 development, evaluation, safety and delivery.” *MBP* at 2.

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

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

14 373. Defendants failed to appoint any ACIP member who represents the  
15 perspective of state and local health departments who adhere to the scientific consensus  
16 on vaccine safety and efficacy, thereby unlawfully denying Plaintiff States a  
17 representational voice on the committee.

18 374. Additionally, ACIP’s Policies and Procedures prescribe specific procedures  
19 for selecting voting members consistent with FACA requirements and ACIP’s Charter  
20 and MBP.

21 375. Defendants failed to comply with these legally required procedures in  
22 selecting the Kennedy Appointees to fill the vacancies resulting from the Secretary’s  
23 dismissal of the previous ACIP members:

24 a. Defendants violated the requirements that, in selecting ACIP’s members,  
25 they must “conduct broad outreach, using a variety of means and methods, to ensure that  
26 the call for nominees reaches the interested parties and stakeholder groups likely to  
27 possess [the required balanced] points of view.” 41 C.F.R. § 102-3.60(b)(3)(ii) (May 20,  
28 2024 ed.). Upon information and belief, Defendants conducted only limited outreach

1 targeted at individuals holding particular views shared by the Secretary and did not  
2 conduct broad outreach to individuals called for in FACA's implementing regulation or  
3 ACIP's Membership Balance Plan. *Id.*; *MBP* at 3.

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

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

11 d. Upon information and belief, Defendants circumvented the Executive  
12 Secretary, ACIP, and Steering Committee's review, selection, and ranking of nominees  
13 based on the qualifications and expertise needed on the Committee, as outlined in the  
14 ACIP's Membership Balance Plan and Policies and Procedures. *MBP* at 3; *Policies and*  
15 *Procedures* at 16. This includes "select[ing] two proposed candidates for each vacant  
16 position" based on the criteria in the Membership Balance Plan. *MBP* at 3.

17 376. The Secretary violated these procedures required by law in service of  
18 stacking ACIP with members who share scientifically unfounded, outlier views on  
19 vaccine efficacy and safety that the medical and public health community rejects. A  
20 committee that makes population-level recommendations on the use of vaccines is not  
21 fairly balanced under FACA where nearly its entire membership has a history of being  
22 unscientifically hostile to or skeptical of vaccines and/or lacks the basic expertise and/or  
23 qualifications required by the ACIP's Charter and Membership Balance Plan.

24 377. At least nine of the thirteen current ACIP members (Blackburn, Griffin,  
25 Hibbeln, Levi, Malone, Milhoan, Pagano, Pollak, and Stein) lack the basic expertise  
26 and/or professional qualifications required by ACIP's Charter. And eight of the current  
27 ACIP members (Biss, Griffin, Malone, Meissner, Milhoan, Pebsworth, Stein, and Urato)  
28 have stated views on vaccines that align with the Secretary's own minority anti-

1 vaccination views or are generally skeptical about the safety and efficacy of vaccines in  
2 a way that does not align with scientific consensus or evidence.

3 378. Defendants appointed unqualified, ideologically aligned members of ACIP  
4 for the purpose of exerting inappropriate influence over ACIP.

5 379. Historically, Plaintiff States relied on ACIP's highly-qualified and balanced  
6 composition to ensure that vaccine policy would emerge from a body of independent and  
7 multi-disciplinary experts guided by evidence-based decision-making. Kennedy's  
8 appointment of the current ACIP members circumvented established processes and  
9 procedures that aligned with FACA's requirements and thereby eviscerated Plaintiff  
10 States' ability to rely on ACIP's recommendations.

11 380. Defendants' failure to follow their own procedures and account for Plaintiff  
12 States' reliance interests in appointing the Kennedy Appointees further renders them  
13 arbitrary and capricious.

14 381. The appointment of unqualified ACIP members in violation of procedures  
15 required by law, and without considering relevant factors bearing on their qualifications,  
16 was final agency action in violation of the APA.

17 382. For the foregoing reasons, Plaintiff States request that this court declare the  
18 Kennedy Appointees' appointment arbitrary and capricious, unlawful, and contrary to  
19 procedure required by law, and vacate their appointments and their hepatitis B  
20 recommendation.

**COUNT IV**

**Violation of the APA**

**Arbitrary and Capricious – Hepatitis B Decisions**

**5 U.S.C. § 706(2)(A)**

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

384. 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.

385. 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.

386. 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.

387. 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.

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

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

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

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

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

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

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

3 394. 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.

6 395. 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;

17 v. Award Plaintiff States such further relief as the Court deems just and  
18 proper.

19  
20 RESPECTFULLY SUBMITTED this 24th day of February, 2026.

21 **KRISTIN K. MAYES**

22 Attorney General for the State of Arizona

23 /s/ Joshua D. Bendor

24 Joshua D. Bendor\*

25 Clinton N. Garrett\*

26 Syreeta A. Tyrell\*

Alexa G. Salas\*

Office of the Arizona Attorney General

27 2005 N. Central Ave.

28 Phoenix, Arizona 85004

**ROB BONTA**

Attorney General for the State of California

/s/ Katherine Milton

Katherine Milton

Deputy Attorney General

Neli Palma

Senior Assistant Attorney General

Kathleen Boergers

Nimrod Pitsker Elias

Supervising Deputy Attorneys General

Marnie G. Ganotis

*Attorneys for the State of Arizona*

Deputy Attorney General  
455 Golden Gate Avenue  
San Francisco, CA 94102-7004

*Counsel for the State of California*

**PHILIP J. WEISER**

Attorney General for the State of  
Colorado

**WILLIAM TONG**

Attorney General of Connecticut

/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](mailto:david.moskowitz@coag.gov)

/s/ Elizabeth Bannon

Elizabeth Bannon\*  
Assistant Attorney General  
165 Capitol Ave  
Hartford, CT 06106  
(860) 808-5210  
[Elizabeth.Bannon@ct.gov](mailto:Elizabeth.Bannon@ct.gov)

*Attorneys for Plaintiff State of Connecticut*

*Attorneys for the State of Colorado*

**KATHLEEN JENNINGS**

Attorney General of the State of Delaware

**AARON M. FREY**

Maine Attorney General

/s/ Vanessa L. Kassab

IAN R. LISTON\*  
Director of Impact Litigation  
VANESSA L. KASSAB\*  
Deputy Attorney General  
Delaware Department of Justice  
820 N. French Street  
Wilmington, DE 19801  
(302) 683-8899  
[vanessa.kassab@delaware.gov](mailto:vanessa.kassab@delaware.gov)

/s/ Kendall R. Schutzer

Kendall R. Schutzer\*  
Assistant Attorney General  
Office of the Attorney General  
6 State House Station  
Augusta, ME 04333  
Tel.: 207-626-8452  
Fax: 207-287-3145  
[Kendall.Schutzer@Maine.gov](mailto:Kendall.Schutzer@Maine.gov)

*Attorneys for Plaintiff State of Maine*

*Attorneys for Plaintiff State of Delaware*

**ANTHONY G. BROWN**

Attorney General of Maryland

**DANA NESSEL**

Attorney General of Michigan

/s/ Michael Drezner

Michael Drezner\*  
Senior Assistant Attorney General

/s/ Neil Giovanatti

Neil Giovanatti\*  
Assistant Attorney General

Office of the Attorney General  
200 Saint Paul Place  
Baltimore, Maryland 21202  
(410) 576-6959  
[mdrezner@oag.state.gov](mailto: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](mailto:jennifer.moreau@ag.state.mn.us)

[brian.carter@ag.state.mn.us](mailto:brian.carter@ag.state.mn.us)

*Attorneys for Plaintiff State of Delaware*

**RAÚL TORREZ**

New Mexico Attorney General

*/s/ Justin McCarthy*

Justin McCarthy\*

Assistant Solicitor General

New Mexico Department of Justice

408 Galisteo Street

Santa Fe, NM 87501

(505) 629-7741

[jmccarthy@nmjoj.gov](mailto:jmccarthy@nmjoj.gov)

*Attorney for State of New Mexico*

**PETER F. NERONHA**

Attorney General of Rhode Island

*/s/ Kathryn T. Gradowski*

Michigan Department of Attorney General  
525 W. Ottawa  
Lansing, MI 48909  
(517) 335-7603

[GiovanattiN@michigan.gov](mailto: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](mailto:Joshua.Bohn@law.njoag.gov)

[Kevin.Bui@law.njoag.gov](mailto:Kevin.Bui@law.njoag.gov)

[Amanda.McElfresh@law.njoag.gov](mailto:Amanda.McElfresh@law.njoag.gov)

*Counsel for the State of New Jersey*

**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](mailto:Scott.Kennedy@doj.oregon.gov)

*Attorneys for Plaintiff State of Oregon*

**JOSHUA L. KAUL**

Attorney General of Wisconsin

*/s/ Amanda Quester*

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

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

*Counsel for the State of Rhode Island*

*Counsel for the State of Wisconsin*

**JOSH SHAPIRO**

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

Jennifer Selber  
*General Counsel*

/s/ Aimee D. Thomson

Aimee D. Thomson\*

Deputy General Counsel  
Pennsylvania Office of the Governor  
30 N. 3rd St., Suite 200  
Harrisburg, PA 17101  
(223) 234-4986  
[aimeethomson@pa.gov](mailto:aimeethomson@pa.gov)

*Counsel for Governor Josh Shapiro*

\* pro hac vice application forthcoming