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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

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

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

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

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

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

10. In unilaterally promulgating and approving this radical change to the science-based childhood immunization schedule, Defendants disregarded the extensive and well-established evidence supporting ACIP's and CDC's pre-Kennedy recommendations. Defendants did not utilize established scientific decision-making frameworks, they identified no changed circumstances, and they ignored the clear risk to

public health posed by downgrading routine vaccinations without notice or public comment.

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

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

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

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

15. While Denmark and other countries are free to pursue vaccine policies based on their unique demographics and health profiles, the CDC's previous vaccine recommendations have been transformative life-saving interventions in the U.S. Among children born in the U.S. between 1994 and 2023 alone, researchers have estimated that "routine childhood vaccinations will have prevented approximately 508 million cases of

[1] *See* Mandavilli, A., *R.F.K. Jr. Likely to Swap U.S. Childhood Vaccine Schedule for 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.

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

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

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

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

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

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

21. In appointing unqualified ACIP members who issued a dangerous hepatitis B recommendation without requisite deliberation, analysis, or process—and then by

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[2] Zhou F., et al., *Health and Economic Benefits of Routine Childhood Immunizations in 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.

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

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

JURISDICTION

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

VENUE

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

DIVISIONAL ASSIGNMENT

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

PARTIES

I. Plaintiffs

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

40. Plaintiff Josh Shapiro brings this suit in his official capacity as Governor of the Commonwealth of Pennsylvania. The Pennsylvania Constitution vests "[t]he

supreme executive power" in the Governor, who "shall take care that the laws be faithfully executed." Pa. Const. art. IV, § 2. The Governor oversees all executive agencies in Pennsylvania and is authorized to bring suit on their behalf. 71 P.S. §§ 732-204(c), 732-301(6), 732-303.

II. Defendants

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. S*ee* 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

publish a notice in the Federal Register "that articulates the Director's views and proposed decision" and provides a thirty-day comment period. *Id*.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

89. In justifying their rogue recommendations, the Kennedy Appointees relied on vague anecdotes about purported stakeholder "dissatisfaction" and other explanations that disregarded, downplayed, or contradicted well-established scientific evidence.

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

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

92. Reflecting their unscientific approach, the Kennedy Appointees and Dr. Tracy Beth Høeg—the Acting Director of the Food and Drug Administration's ("FDA") Center for Drug Evaluation and Research—repeatedly cited and relied on Denmark's immunization practices at the December 4-5, 2025 meeting.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

109. In a 2023 interview, Kennedy falsely stated that "[t]here's no vaccine that is safe and effective." *See* https://www.congress.gov/congressional-record/volume-171/issue-29/senate-section/article/S903-1.

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

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

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

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

"[p]eer, developed countries" like Denmark, Japan, and Germany. It also stated without elaboration that "[o]ther current [U.S.] childhood vaccine recommendations also depart from policies in the majority of developed countries." *Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries,* Presidential Memoranda (Dec. 5, 2025), https://www.whitehouse.gov/presidential-actions/2025/12/aligning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries; Decision Memo at 1.

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

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

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

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

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

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

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

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

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

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

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

125. Contrary to Defendants' assertions, SCDM is intended for situations in 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*

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

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

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

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

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

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

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

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

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

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

Rotavirus

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

1980, rotavirus was the most common cause of severe gastroenteritis in infants and young children in the U.S. Cortese, M.M. & Penina, H., *Epidemiology and Prevention of Vaccine-Preventable Diseases, Chapter 19: Rotavirus*, Ctrs. for Disease Control and Prevention (Apr. 25, 2025), https://www.cdc.gov/pinkbook/hcp/table-of-contents/chapter-19-rotavirus.html.

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

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

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

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

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

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

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

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

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

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

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

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

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

156. Instead of addressing any existing and relevant evidence, the Høeg-Kulldorff Report makes various unsupported assertions and irrelevant comparisons to 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*.

Hepatitis A

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

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

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

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

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

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

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

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

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

Hepatitis B

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.*

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

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

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

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

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

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

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

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

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

Influenza

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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=redirecintensted. It also reduced pediatric RSV-associated intensive care unit ("ICU") admissions as well as acute respiratory failure among infants admitted to with respiratory symptoms during RSV season. Zambrano, L.D., et al., *Nirsevimab Effectiveness Against Intensive Care Unit Admission for Respiratory Syncytial Virus in Infants – 24 States, December 2024–April 2025*, MMWR Morb. Mortal. Wkly. Rep. (Nov. 20, 2025), Ctrs. For Disease Control and Prevention, https://www.cdc.gov/mmwr/volumes/74/wr/mm7437a1.htm.

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

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

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

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

VII. Reliance on purported "peer countries" lacks any reasoned basis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

300. In New Mexico, the Department of Health has had to issue multiple Health Action Network notices and public health orders to clarify state rules and ensure timely access to routine immunizations. *See, e.g.*, N.M. Dep't of Health, *Public Health Order Ensuring Availability of COVID-19 Vaccine for the 2025-2026 Season* (Aug. 29, 2025), nmhealth.org. The Board of Pharmacy also had to update the guidelines to its Vaccine Protocol to remove its sole reliance on ACIP and ensure that pharmacists could continue to administer the COVID vaccine. N.M. Reg. and Licensing Dep't, *Protocol for Pharmacist Prescribing of Vaccines*, nm.gov (last visited Feb. 8, 2026); *see also* Goldberg, J., *NM health department announces new pharmacy protocol, easier COVID-19 vaccine access*, Source NM (Sep. 5, 2025), https://sourcenm.com/briefs/nm-health-department-issues-revised-covid-19-vaccine-guidance-for-easier-access/.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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].").

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

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

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

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

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

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

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

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

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

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

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

346. Defendants further ignored the mountains of highly relevant scientific evidence supporting the prior childhood immunization schedule and promulgated the 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

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

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

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

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

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

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

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

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

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

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

COUNT III

Violation of the APA

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

5 U.S.C. § 706(2)(A), (D)

360. Plaintiff States reallege and incorporate by reference the foregoing 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.).[3]

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

[3] 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.

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

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

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

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

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

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

370. Accordingly, the Secretary must appoint members with "expertise in the field of immunization practices," "multi-disciplinary expertise in public health,"

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

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

372. Consistent with this federal-state partnership, ACIP's Membership Balance Plan provides that a "state and local health department perspective" should be considered when selecting voting members.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff States pray that the Court:

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

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

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

iv. Enjoin, vacate, and set aside the appointment of the Kennedy Appointees and the Kennedy Schedule and any implementation of these actions;

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

RESPECTFULLY SUBMITTED this 24th day of February, 2026.

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