

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF PEDIATRICS,  
AMERICAN COLLEGE OF PHYSICIANS,  
INC., AMERICAN PUBLIC HEALTH  
ASSOCIATION, INFECTIOUS DISEASES  
SOCIETY OF AMERICA, MASSACHUSETTS  
PUBLIC HEALTH ASSOCIATION D/B/A  
MASSACHUSETTS PUBLIC HEALTH  
ALLIANCE, SOCIETY FOR MATERNAL-  
FETAL MEDICINE, and JANE DOE,

*Plaintiffs,*

vs.

ROBERT F. KENNEDY, JR., in his official  
capacity as Secretary of the Department of Health  
and Human Services; UNITED STATES  
DEPARTMENT OF HEALTH AND HUMAN  
SERVICES; MARTY MAKARY, in his official  
capacity as Commissioner of the Food and Drug  
Administration; FOOD AND DRUG  
ADMINISTRATION; JAY BHATTACHARYA,  
in his official capacity as Director of the National  
Institutes of Health; NATIONAL INSTITUTES  
OF HEALTH; MATTHEW BUZZELLI, in his  
official capacity as Acting Director of Centers for  
Disease Control and Prevention; CENTERS FOR  
DISEASE CONTROL AND PREVENTION; and  
DOES 1–50, inclusive,

*Defendants.*

Case No. 1:25-cv-11916

**COMPLAINT FOR DECLARATORY  
AND INJUNCTIVE RELIEF**

**INTRODUCTION**

1. On May 27, 2025, Defendant, the Secretary of the United States Department of Health and Human Services, Robert F. Kennedy, Jr. (the “Secretary” or “Mr. Kennedy”), announced in a post on social media site X that he “couldn’t be more pleased that, as of today, the Covid vaccine for healthy children and healthy pregnant women has been **removed** from the CDC recommended immunization schedules.”<sup>1</sup> Unless the Secretary’s baseless and uninformed policy decision is vacated, pregnant women, their unborn children, and, in fact, all children remain at grave and immediate risk of contracting a preventable disease. This decision immediately exposes these vulnerable populations to a serious illness with potentially irreversible long-term effects and, in some cases, death. This is not a hypothetical concern, but a pressing public health emergency that demands immediate legal action and correction.

2. This announcement, from the person who leads the agency charged with “enhanc[ing] the health and well-being of all Americans,”<sup>2</sup> stands in stark contrast to his sworn testimony only two weeks prior before Congress that “I don’t think people should be taking medical advice from me,”<sup>3</sup> and “what I would say is my opinions about vaccines are irrelevant.”<sup>4</sup>

3. The Secretary promised multiple times during his Senate confirmation process that: “If confirmed, I will do nothing as HHS Secretary that makes it difficult or discourages people from taking vaccines.”<sup>5</sup> The final agency action that he announced on X on May 27 is documented in a “Secretarial Directive” that bears the Secretary’s signature and is dated May 19, 2025 (the “Directive”). The Directive breaks the promise that the Secretary made to the Senate and the

<sup>1</sup> Robert F. Kennedy, Jr. (@SecKennedy), X (May 27, 2025, 10:16 AM), <https://x.com/SecKennedy/status/1927368440811008138> (emphasis added).

<sup>2</sup> *About HHS*, U.S. Department of Health and Human Services, <https://www.hhs.gov/about/index.html> (last visited July 5, 2025).

<sup>3</sup> Cecelia Smith-Schoenwalder, *RFK Jr. Gets Grilled on Capitol Hill: 4 Takeaways*, US. News, (May 14, 2025, at 5:23 p.m.) <https://www.usnews.com/news/health-news/articles/2025-05-14/rfk-jr-defends-trumps-budget-plan-addresses-vaccines-on-capitol-hill>.

<sup>4</sup> *Id.*

<sup>5</sup> *Hearing to Consider the Nomination of Robert F. Kennedy, Jr., of California, to be Secretary of Health and Human Services Before the United States Senate Comm. on Finance, Responses to Questions for the Record to Robert F. Kennedy, Jr., Part 2*, 119th Cong., at 26–42 (2025).

American people not to make it difficult to get vaccines or discourage them. The Directive, unless vacated, will result in preventable deaths, including the unborn and newborns under six months old.

4. The Directive is but one example of the Secretary's agenda to dismantle the longstanding, Congressionally-authorized, science- and evidence-based vaccine infrastructure that has prevented the deaths of untold millions of Americans.

5. The Secretary's dismantling of the vaccine infrastructure must end, and halting this effort begins with vacating the Directive.

6. The Directive was a final agency action justiciable under the Administrative Procedure Act, was arbitrary and capricious, and has caused irreparable harm to the Plaintiffs in this action. That final agency action must be vacated.

### **JURISDICTION AND VENUE**

7. The Court has jurisdiction under 28 U.S.C. §§ 1331 and 1346. This Court has further remedial authority under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 *et seq.* Pursuant to 5 U.S.C. § 702, sovereign immunity is waived for the United States.

8. Pursuant to 28 U.S.C. § 1391(c) and (e), venue properly lies within the District of Massachusetts.

### **PARTIES**

#### **Plaintiffs**

9. Plaintiff, the American Academy of Pediatrics ("AAP"), is the nation's premier professional organization for pediatric medicine and serves as an independent forum for addressing children's health. The AAP's membership includes 67,000 pediatricians nationwide, many of whom are currently providing direct care to infants, children, adolescents, and young adults in both hospital and outpatient settings.

10. Plaintiff, the American College of Physicians, Inc. ("ACP"), is a professional organization comprised of 161,000 internal medicine specialists, related subspecialists, and medical students who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and

compassionate care of adults worldwide. The ACP's mission is to enhance the quality and effectiveness of health care by fostering excellence and professionalism in the practice of medicine.

11. Plaintiff, the American Public Health Association ("APHA"), has promoted the health of all U.S. residents since its founding in 1872. APHA members include more than 23,000 individual public health professional members, state and local health departments, organizations interested in health, and health-related businesses. APHA members work in every discipline of public health, in every state, and in countries across the globe.

12. Plaintiff, the Infectious Diseases Society of America ("IDSA"), is a professional nonprofit society comprised of over 13,000 members, including practicing clinicians, scientists and researchers in the academic setting, public health officials, hospital epidemiologists, and infectious disease specialists working in a variety of settings nationwide. Many IDSA members are currently providing direct care to pregnant women, newborns, and children in both hospital and outpatient settings. IDSA's mission is to bring together the curiosity, compassion and knowledge of its members and strengthen the field of infectious diseases, advance science, and advocate for health equity.

13. Plaintiff, the Massachusetts Public Health Association d/b/a Massachusetts Public Health Alliance ("MPHA"), is a nonprofit organization dedicated to advocating for health equity and strong public health systems across the Commonwealth of Massachusetts. MPHA's membership is comprised of both individual and organizational public health leaders, including physicians, nurses, community health center leaders, academic public health professionals, nonprofit executives, and other frontline practitioners.

14. Plaintiff, the Society for Maternal-Fetal Medicine ("SMFM"), is a professional organization dedicated to advancing optimal and equitable perinatal outcomes for all people who desire or experience pregnancy. SMFM represents the interests of over 6,500 members, comprised primarily of maternal-fetal medicine subspecialists, as well as physicians in related disciplines, scientists, nurses, genetic counselors, and ultrasound technicians. At its core, SMFM is committed

to leading the evidence-based practice of high-risk pregnancy care to optimize maternal and fetal outcomes and assure medically appropriate treatment options are available to all patients.

15. Plaintiff, Jane Doe, is a physician working in a hospital where she puts herself at risk of infectious diseases every day to care for patients and save lives. Jane Doe is also more than 20 weeks pregnant. Although she was vaccinated against Covid before becoming pregnant, her doctors have advised her to get another dose of the vaccine later in pregnancy to better protect herself and her baby from contracting this deadly disease. Pregnancy increases the risk of severe illness and complications from infectious disease, including preterm birth and stillbirth. However, the Directive creates barriers to access to the vaccine and has left Jane and her husband overwhelmed with stress and uncertainty. Her worries are not just for herself, but also for the health and safety of her unborn child.

### **Defendants**

16. Defendant Robert F. Kennedy, Jr. is the Secretary of the United States Department of Health and Human Services and that agency's highest ranking official. He is charged with the supervision and management of all decisions and actions of that agency. 42 U.S.C. § 300u. He is sued in his official capacity.

17. Defendant the United States Department of Health and Human Services ("HHS") is an agency of the United States.

18. Defendant Marty Makary is Commissioner of the Food and Drug Administration and is sued in his official capacity ("FDA Commissioner Makary").

19. Defendant Food and Drug Administration is an agency that is housed within HHS.

20. Defendant Jay Bhattacharya is Director of the National Institutes of Health ("NIH") and is sued in his official capacity ("NIH Director Bhattacharya").

21. Defendant NIH is an agency that is housed within HHS.

22. Defendant Matthew Buzzelli, upon information and belief, is the Acting Director Centers for Disease Control and Prevention ("CDC") and is sued in his official capacity.

23. CDC is an agency that is housed within HHS.

24. The names and capacities of defendants sued herein as Does 1 through 50, inclusive, are presently not known to Plaintiffs, who therefore sue these Defendants by such fictitious names. Plaintiffs will seek to amend this Complaint and include these Doe Defendants' names and capacities when they are ascertained. Each of the fictitiously named Defendants is responsible in some manner for the conduct alleged here and for the injuries suffered by Plaintiffs.

## **FACTUAL ALLEGATIONS AND LEGAL BACKGROUND**

### **A. A Brief History Of Vaccines**

25. As early as the 15<sup>th</sup> century,<sup>6</sup> a process called variolation was utilized to provide immunity against smallpox. Variolation worked by blowing material from smallpox sores into the nostrils or by inserting the material into cuts on the skin.<sup>7</sup> Historical accounts indicate that it was used in regions such as India, China, and the Ottoman Empire before being introduced to Western Europe in 1721.<sup>8</sup> This practice became widespread, including in Boston and the colonies of New England.<sup>9</sup> For example, by 1777, George Washington required all soldiers to be variolated before new military operations.<sup>10</sup>

26. In 1796 England, Edward Jenner discovered that cowpox, a less harmful virus, could be used to protect against smallpox. He deliberately inoculated a young boy with material from a cowpox sore, and, lo and behold, he did not fall ill. Jenner named his discovery a “vaccine” after the Latin term for cowpox, vaccinia<sup>11</sup>. Decades later, Louis Pasteur posited that vaccines could be

<sup>6</sup> See *A Brief History of Vaccines*, WORLD HEALTH ORGANIZATION, <https://www.who.int/news-room/spotlight/history-of-vaccination/a-brief-history-of-vaccination> (last visited July 5, 2025).

<sup>7</sup> See *Smallpox: A Great and Terrible Scourge*, NATIONAL LIBRARY OF MEDICINE (Mar. 5, 2024), [https://www.nlm.nih.gov/exhibition/smallpox/sp\\_variolation.html](https://www.nlm.nih.gov/exhibition/smallpox/sp_variolation.html).

<sup>8</sup> See *History of smallpox vaccination*, WORLD HEALTH ORGANIZATION, <https://www.who.int/news-room/spotlight/history-of-vaccination/history-of-smallpox-vaccination> (last visited July 6, 2025).

<sup>9</sup> Stefan Riedel, *Edward Jenner and the History of Smallpox and Vaccination*, 18 BAYLOR UNIVERSITY MEDICAL CENTER PROCEEDINGS 21, 21–25 (2005).

<sup>10</sup> *Id.*

<sup>11</sup> *Id.*

discovered for other diseases than smallpox and introduced the concept of “attenuation,” using less virulent material to develop equally effective vaccines.<sup>12</sup>

27. In Massachusetts, near the turn of the last century, the Cambridge Board of Health ordered vaccination for all residents after an outbreak of smallpox. In a case that would reach the Supreme Court, a Cambridge resident argued that the mandate violated his personal liberty. In 1905, the Supreme Court held that States may limit individual freedoms when necessary to protect the public’s health, setting a precedent for the role of the government in managing communicable diseases. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).

28. The Influenza Pandemic of 1918, known as the “Spanish flu,” killed approximately 50 million people worldwide in about a year.<sup>13</sup> Roughly 675,000 people died in the United States alone.<sup>14</sup> About 500 million people, or a third of the world’s population at the time, were infected with Spanish flu.<sup>15</sup> Likely originating in Haskell, Kansas, the disease spread as soldiers moved from Kansas, through the United States, and into Europe for World War I.<sup>16</sup> At the time, Allied and Central powers censored reports of the disease to maintain morale.<sup>17</sup> Spain, however, remained a neutral country during the war and faced no restrictions. Accordingly, Spanish media freely reported on the illness and, as a result, the illness was nicknamed the “Spanish flu.”<sup>18</sup> There were no vaccines or antivirals to help slow the spread.<sup>19</sup> A version of H1N1 avian influenza virus, the ancestor of most of the flu viruses we see today, was the cause of the Spanish flu.<sup>20</sup> While it is impossible to quantify how many cases of severe illness, hospitalization, and deaths vaccines have prevented since

<sup>12</sup> Caroline Barranco, *The First Live Attenuated Vaccines*, NATURE MILESTONES (Sep. 28, 2020), <https://www.nature.com/articles/d42859-020-00008-5>.

<sup>13</sup> *1918 Influenza Pandemic (Spanish Flu)*, CLEVELAND CLINIC (Oct. 24, 2024), <https://my.clevelandclinic.org/health/diseases/21777-spanish-flu>.

<sup>14</sup> *Id.*

<sup>15</sup> *1918 Influenza Pandemic (Spanish Flu)*, CLEVELAND CLINIC (Oct. 24, 2024), <https://my.clevelandclinic.org/health/diseases/21777-spanish-flu>.

<sup>16</sup> John M. Barry, *The Site of Origin of the 1918 Influenza Pandemic and Its Public Health Implications*, 2 J. OF TRANSLATIONAL MED., 1–2 (2004).

<sup>17</sup> Evan Andrews, *Why Was It Called the ‘Spanish Flu?’*, HISTORY, <https://www.history.com/articles/why-was-it-called-the-spanish-flu> (last visited July 5, 2025).

<sup>18</sup> *Id.*

<sup>19</sup> *Id.*

<sup>20</sup> *Id.*

1796, in the last 50 years, global immunization has saved over 150 million lives.<sup>21</sup> Of those, over 100 million were infant lives.<sup>22</sup> In the year after their introduction, Covid vaccines prevented almost 20 million deaths worldwide.<sup>23</sup> In the Americas in their first year, Covid vaccines saved 3.8 million lives.<sup>24</sup>

29. The remainder of the 20th Century saw the development of vaccines for tetanus, diphtheria, pertussis, and other once-unpreventable illnesses.<sup>25</sup> Polio was a national crisis that caused paralysis in tens of thousands of children and the closure of public spaces.<sup>26</sup> When polio vaccines became available, they were rapidly administered across the country.<sup>27</sup>

30. By the 1960s, the country turned the tide on the battle against the infectious diseases of measles, mumps, and rubella with the invention of the measles, mumps, and rubella (“MMR”) vaccine.<sup>28</sup> By the end of the century, vaccines had eradicated smallpox and virtually eliminated polio and measles in this country.<sup>29</sup>

31. In 1964, the U.S. Surgeon General established the Advisory Committee on Immunization Practices (“ACIP”), which was tasked with recommending the most effective infectious disease preventive measures in public health. The ACIP was charged with assessing efficacy and safety of vaccines and advising on the practical implementation of vaccine measures nationwide.<sup>30</sup> See § B. *infra*.

<sup>21</sup> Andrew J. Shattock et al., *Contribution of Vaccination to Improved Survival and Health: Modelling 50 Years of the Expanded Programme on Immunization*, 403 THE LANCET 2307, 2311–12 (2024).

<sup>22</sup> *Id.*

<sup>23</sup> Oliver J. Watson, et al., *Global Impact of the First Year of COVID-19 Vaccination: A Mathematical Modelling Study*, 22 LANCET INFECTIOUS DISEASES 1923, 1926 (2022).

<sup>24</sup> *Id.*

<sup>25</sup> See *Vaccine History: Developments by Year*, CHILD.’S HOSP. OF PHILA., <https://www.chop.edu/vaccine-education-center/science-history/vaccine-history/developments-by-year> (last visited July 5, 2025).

<sup>26</sup> Linton Weeks, *Defeating Polio, The Disease That Paralyzed America*, NAT’L PUB. RADIO (Apr. 10, 2015), <https://www.npr.org/sections/npr-history-dept/2015/04/10/398515228/defeating-the-disease-that-paralyzed-america>.

<sup>27</sup> See 1954: Children Receive First Polio Vaccine, HISTORY (May 27, 2025), <https://www.history.com/this-day-in-history/february-23/children-receive-first-polio-vaccine>.

<sup>28</sup> See *Vaccine History: Developments by Year*, CHILD.’S HOSP. OF PHILA., <https://www.chop.edu/vaccine-education-center/science-history/vaccine-history/developments-by-year> (last visited July 5, 2025).

<sup>29</sup> See Ctrs. for Disease Control and Prevention, *Achievements in Public Health, 1900-1999 Impact of Vaccines Universally Recommended for Children—United States, 1990-1998*, 48 MORBIDITY AND MORTALITY WKLY REP. 243, 243 (1999).

<sup>30</sup> Jean Clare Smith, Alan R. Hinman, Larry K. Pickering, *History and Evolution of the Advisory Committee on Immunization Practices—United States, 1964–2014*, 63 MORBIDITY AND MORTALITY WKLY REP. 955, 956 (2014).



32. In the 1990s, Vaccines for Children (“VFC”) program expanded access to vaccines for low-income families. *See* Social Security Act § 1928, 42 U.S.C. § 1396s. The VFC program remains a key part of America’s immunization infrastructure; more than half of all children in the country are eligible for VFC.<sup>31</sup>

33. Progress was stalled when, in 1998, British physician, Andrew Wakefield, published a flawed study in *The Lancet* claiming a link between the rising number of autism diagnoses and increasing vaccination for MMR. He based his study, however, on only 12 children and anecdotal, parental reports.<sup>32</sup> Further, Wakefield failed to account for an increase in autism diagnoses due to expanded diagnostic criteria and school-based evaluations<sup>33</sup> that was concurrent with increased rates of MMR vaccination.<sup>34</sup> More egregiously, Wakefield failed to disclose that he had been paid hundreds of thousands of dollars by lawyers representing parents who were suing vaccine manufacturers.<sup>35</sup> Ultimately, *The Lancet* retracted the study and issued an apology. Wakefield was thoroughly discredited. However, the damage he wrought was devastating.<sup>36</sup>

34. Separately, during this time, concerns about mercury were heightened due to environmental disasters in prior decades, which led some to wrongly conflating thimerosal, which breaks down into ethylmercury, with harmful forms of mercury like methylmercury, which appear in fish.<sup>37</sup> In 1999, U.S. health officials recommended removing thimerosal from childhood vaccines

<sup>31</sup> *See* Cynthia G. Whitney et al., *Benefits from Immunization During the Vaccines for Children Program Era—United States, 1994–2013*, 63 MORBIDITY AND MORTALITY WKLY REP. 352–55 (2014).

<sup>32</sup> *See* Andrew J. Wakefield et al., *RETRACTED: Ileal-lymphoid-nodular Hyperplasia, Non-Specific Colitis, and Pervasive Developmental Disorder in Children*, 351 THE LANCET 637, 637–641 (1998).

<sup>33</sup> *Id.*; *see also* 20 U.S.C. § 1414(a)(1)(A) (“A State educational agency, other State agency, or local educational agency shall conduct a full and individual evaluation ... before the initial provision of special education and related services to a child with a disability”).

<sup>34</sup> *See* *Measles, Mumps and Rubella (MMR): The Diseases & Vaccines*, CHILD.’S HOSP. OF PHILA., <https://www.chop.edu/vaccine-education-center/vaccine-details/measles-mumps-and-rubella-vaccines> (last visited July 5, 2025).

<sup>35</sup> Arthur Gale, *Autism’s False Prophets*, 109 MO. MED. 108, 108 (reviewing Paul Offit’s *Autism’s False Prophets*) (“Later investigations revealed that Wakefield received not \$100,000 but \$800,000 from Barr to support his research. A number of other researchers, both in the U.K. and the U.S. who had supported Wakefield’s findings also received large stipends from Barr’s law firm.”).

<sup>36</sup> *See* T.S. Sathyanarayana Rao, Chittaranjan Andrade, *The MMR Vaccine and Autism: Sensation, Refutation, Retraction, and Fraud*, 53 INDIAN J. OF PSYCHIATRY 95, 95–96 (2011).

<sup>37</sup> Jeffrey P. Baker, *Mercury, Vaccines, and Autism*, 98 AM. J. OF PUB. HEALTH 244, 244–53 (2008).

out of an abundance of caution, even though thimerosal had never been shown to be harmful.<sup>38</sup> The decision, though well-intentioned, was misinterpreted as confirmation that thimerosal was unsafe.<sup>39</sup>

35. The Wakefield study ignited a wave of vaccine hesitancy and skepticism in the 21st century. In 2005, before he became Secretary, Mr. Kennedy published an article falsely linking thimerosal to autism<sup>40</sup> Like Wakefield's article, Mr. Kennedy's article contained numerous errors and was retracted.<sup>41</sup>

36. Because of his name and profile, Mr. Kennedy has been instrumental in increasing the levels of vaccine hesitancy and skepticism in this country. Before he was Secretary, Mr. Kennedy made opposing vaccines a central part of his public identity. During his confirmation hearing, Congress recognized Mr. Kennedy's outsized role in creating vaccine hesitancy and skepticism in this country as evidenced by the Committee's following question to him: "You advocate for medical practices that blatantly contradict scientific consensus and spread life-threatening information. Will you commit to decision-making based on credible, peer-reviewed research, and acknowledge the danger of promoting unfounded theories?" Although Mr. Kennedy answered "yes" to this question,<sup>42</sup> his actions as Secretary belie his answer. *See* §§ C-E, *infra*.

## **B. The American Academy Of Pediatrics And The Birth Of The Advisory Committee On Immunization Practices ("ACIP")**

37. For more than 25 years before the ACIP came into existence, the main body that made recommendations on vaccine use in the United States was the AAP's Committee on Infectious

<sup>38</sup> *Understanding Thimerosal, Mercury, and Vaccine Safety*, FOOD AND DRUG ADMIN. (Jan. 2011), <https://www.fda.gov/media/83535/download>.

<sup>39</sup> *See* Liza Gross, *A Broken Trust: Lessons from the Vaccine-Autism Wars*, 7 PLOS BIO. e1000114 (2009).

<sup>40</sup> Robert F. Kennedy, Jr., *Deadly Immunity*, Rolling Stone (July 14, 2005), <https://www.webcitation.org/5glaWmdym> (previously available here: [http://www.rollingstone.com/politics/story/7395411/deadly\\_immunity/](http://www.rollingstone.com/politics/story/7395411/deadly_immunity/)).

<sup>41</sup> Kerry Lauerman, *Correcting Our Record*, SALON (Jan. 16, 2011) [https://www.salon.com/2011/01/16/dangerous\\_immunity/](https://www.salon.com/2011/01/16/dangerous_immunity/).

<sup>42</sup> *Hearing to Consider the Nomination of Robert F. Kennedy, Jr., of California, to be Secretary of Health and Human Services Before the United States Senate Comm. on Finance, Responses to Questions for the Record to Robert F. Kennedy, Jr., Part 2*, 119TH CONG., at 24 (2025).

Diseases (“COID”)—called the Committee on Immunization Procedures at the time of its inception.<sup>43</sup>

38. “By the early 1960s, with the licensure of additional new vaccines (monovalent oral poliovirus vaccine, 1961; trivalent oral poliovirus vaccine, 1963; and measles vaccine, 1963) and increased federal investment of resources in vaccines and immunization programs, it was evident that decision making on use of vaccines required a greater degree of continuity of expert technical advice rather than formation of ad hoc committees to address national immunization policy.”<sup>44</sup> Therefore, the Surgeon General established ACIP in March 1964. The committee was “charged with the responsibility of advising the Surgeon General regarding the most effective application in public health practice of specific preventive agents which may be applied in communicable disease control.”<sup>45</sup> That mission has remained essentially unchanged since the ACIP’s inception.<sup>46</sup>

39. In 1972, the ACIP was designated a federal advisory committee under the Federal Advisory Committee Act, 5 U.S.C. § 1001, *et. seq* (“FACA”), which sets forth legal requirements for operations of federal advisory committees such as the ACIP.

### **C. The ACIP Is Embedded Into The Federal And State Vaccine Infrastructure**

40. For over 60 years, the ACIP has served as a global exemplar of sound prevention policy, providing evidence-based advice and guidance that forms the bedrock of U.S. vaccine policy. Its recommendations, including the routine immunization schedules for children and adults,

<sup>43</sup> L. Reed Walton, et al., *The History of the United States Advisory Committee on Immunization Practices (ACIP)*, 33 VACCINE 3, 405–14 (Jan. 2015).

<sup>44</sup> Jean Clare Smith, et al., *History and Evolution of the Advisory Committee on Immunization Practices – United States, 1964-2014*, CENTERS FOR DISEASE CONTROL AND PREVENTION’S MORBIDITY AND MORTALITY WEEKLY REPORT (MMWR), (Oct. 24, 2014) <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm>.

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

are developed through a transparent and rigorous scientific process and are relied upon by clinicians, public health departments, and patients as the “source of truth” for preventing infectious diseases.<sup>47</sup>

41. ACIP recommendations are foundational to U.S. vaccine policy. They form the basis of the official childhood and adult immunization schedules, which are considered the standard of care by clinicians nationwide.

42. ACIP’s centrality to the nation’s health is not merely a matter of scientific custom but is deeply woven into the fabric of federal and state law. Both federal and state statutes deliberately and repeatedly tie essential public health programs and insurance coverage mandates directly to ACIP’s recommendations. This statutory scheme that embeds ACIP recommendations into federal and state laws underscores the reliance of the entire U.S. healthcare ecosystem on the committee’s stability, scientific integrity, and trustworthiness. For example:

a. The Affordable Care Act (“ACA”): Section 2713 of the Public Health Service Act requires most private health plans to cover, without cost-sharing, immunizations recommended by the ACIP (42 U.S.C. § 300gg-13).

b. The VFC Program: This federal entitlement, which provides free vaccines to millions of eligible children, is statutorily required to include all vaccines recommended by the ACIP (42 U.S.C. § 1396s).

c. Medicare Part D: The law prohibits beneficiary cost-sharing for ACIP-recommended vaccines (42 U.S.C. § 1395w-114).

d. The Immigration and Nationality Act: This act establishes immunization requirements for individuals seeking entry into the United States based on ACIP recommendations (8 U.S.C. § 1182).

e. Veterans’ Health Administration (“VHA”): The VHA defines veterans’ health benefits to include ACIP-recommended immunizations (38 U.S.C. § 1701).

<sup>47</sup> See *General Committee-Related Information*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/acip/about/index.html> (last visited July 5, 2025).

f. TRICARE: Health benefits for well-child care must include immunizations as recommended by CDC (32 CFR 199.4(c)(3)(xi)(A)(2)(iv)).

43. Furthermore, ACIP's guidance is foundational to public health functions at the state level, where numerous state laws directly reference and incorporate its recommendations across at least four distinct categories:

a. State School Entry Immunization Requirements: States universally set vaccine requirements for attendance at daycare, primary, secondary, and higher education institutions, and these legal requirements are frequently tied directly to ACIP recommendations.<sup>48</sup>

b. Provider Legal Scope of Practice: States determine the legal authority for various health professionals, including pharmacists, to administer vaccines, often defining that authority by reference to the ACIP recommendations.<sup>49</sup>

c. Health Care Worker & Patient Requirements: Many states require that workers in health care facilities be vaccinated according to ACIP recommendations as a condition of employment, and similar requirements can apply to patients in certain residential care settings to prevent outbreaks.<sup>50</sup>

d. Insurance Coverage Requirements: Beyond federal mandates, state laws may impose separate requirements on state-regulated private insurers or Medicaid managed care organizations to cover ACIP-recommended vaccines.

44. Federal and state governments, health care providers, public health officials, pharmacists—nearly everyone who plays a part in the vaccine infrastructure in this country—have

<sup>48</sup> See Association of State and Territorial Health Officials, *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, (June 23, 2025) <https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/>; Anna Larson, et al., *School-Entry Vaccine Policies: States' Responses To Federal Recommendations Varied From Swift To Substantially Delayed*, 43 HEALTH AFFAIRS 11, 1561 (Nov. 2024).

<sup>49</sup> See, e.g., Spreeha Choudhury, *Implications for Pharmacies: Navigating Shared Clinical Decision-Making in Vaccination*, PHARMACY TIMES, (June 13, 2024) <https://www.pharmacytimes.com/view/implications-for-pharmacies-navigating-shared-clinical-decision-making-in-vaccination>.

<sup>50</sup> See *State Vaccination Requirements*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/vaccines/php/requirements-laws/state-vaccination-requirements.html> (last visited July 5, 2025).

built strong reliance interests on ACIP recommendations and the process that underlies those recommendations.

45. The statutory scheme that regulates the vaccine infrastructure in this country demonstrates Congress' repeated policy decision to require that ACIP recommendations, made by a fairly balanced ACIP membership,<sup>51</sup> be the basis for what is put on or taken off of the CDC immunization schedules—not the unilateral decision of a single individual. Congress has repeatedly shielded the CDC's immunization schedules from the meddling of politicians and political appointees.

#### **D. The Secretary's Actions To Undermine Trust In Vaccines**

46. Since his confirmation on February 13, 2025, the Secretary has demonstrated a clear pattern of hostility toward established scientific processes, a disregard for expert guidance, an affinity for placing persons who align with his anti-vaccination views in positions of authority at HHS, and a reliance on bias and pretext to further his apparent agenda: to undermine trust in vaccines and reduce the rate of vaccinations in this country.

47. Within a week of his confirmation, on February 19, 2025, the Secretary canceled the CDC's "Wild to Mild" influenza vaccination awareness campaign. This campaign was "aimed to inform the public that while getting immunized against the flu doesn't guarantee you won't catch an influenza virus, it can protect you from severe illness, hospitalization, and death."<sup>52</sup> The Secretary's killing of the Wild to Mild campaign came amidst "the worst flu season the nation has seen in nearly 30 years."<sup>53</sup>

48. The next day, February 20, 2025, the Secretary postponed without explanation a meeting of the ACIP that had long been previously scheduled for February 26–28, 2025. The APHA, AAP, and IDSA signed the "Sign-on Letter to Preserve ACIP Meeting" published by the Partnership

<sup>51</sup> See 5 U.S.C. § 1004(b)(2) (requiring that federal advisory committees be "fairly balanced").

<sup>52</sup> Lindsey Leake, *Amid worst U.S. flu season in decades, RFK Jr.-led CDC pulls vaccine campaign*, FORTUNE (Feb. 20, 2025) <https://fortune.com/well/article/rfk-jr-cdc-cancels-flu-vaccine-campaign-amid-surge/>.

<sup>53</sup> *Id.*

to Fight Infectious Disease that stated, *inter alia*: “Each ACIP meeting holds tremendous weight and relevance. Infectious diseases are constantly evolving opponents; vaccines are among the best tools for constantly adapting and responding to the latest public health threats. ACIP meetings, which review the latest vaccination data, vote on recommendations, and produce public transparency via a live video stream, three times a year, are the exact activities in which a thoughtful, transparent and well-organized scientific community engages.”<sup>54</sup> The ACP issued the following statement regarding the ACIP meeting postponement: “The American College of Physicians is concerned that the postponement of the Centers for Disease Control and Prevention’s (CDC) Advisory Committee on Immunization Practices (ACIP) meeting that had been scheduled to take place next week puts our nation’s public health at risk. Our country is currently facing the worst epidemic of influenza in several decades, a measles outbreak in Texas, and an ongoing national outbreak of pertussis. The work that the ACIP does in developing evidence-based recommendations about the use of vaccines is critical to helping prevent the spread of these and other vaccine preventable illnesses.”<sup>55</sup>

49. On February 26, 2025, the Secretary canceled a meeting of the Vaccines and Related Biological Products Advisory Committee (“VRBPAC”) scheduled for March 13, during which the committee was scheduled to make recommendations for the flu strains to be included in the 2025-26 flu shot or nasal spray for the Northern Hemisphere. The VRBPAC typically meets in March to make recommendations based on the flu strains expected to be circulating in the fall and winter. The FDA uses those recommendations to direct vaccine manufacturers on the composition of the shots, which take approximately six months to produce. The IDSA issued the following statement in response to the VRBPAC meeting cancellation:

Ensuring that all people are protected from the flu must remain a top priority of our nation’s health leaders. Cancelling a critically important

<sup>54</sup> Partnership to Fight Infectious Disease, *Sign-on Letter to Robert F. Kennedy Jr., Secretary, U.S. Department of Health and Human Services to Preserve ACIP Meeting* (Feb. 20, 2025) <https://www.fightinfectiousdisease.org/post/sign-on-letter-to-preserve-acip-meeting>.

<sup>55</sup> Isaac O. Opole, *Internal Medicine Physicians Call for Prompt Rescheduling of Vaccine Advisory Meeting*, AMERICAN COLLEGE OF PHYSICIANS (Feb. 21, 2025) <https://www.acponline.org/acp-newsroom/internal-medicine-physicians-call-for-prompt-rescheduling-of-vaccine-advisory-meeting>.



Food and Drug Administration meeting that is vital to the development of effective flu vaccines for next flu season is irresponsible, ignores science and shows a lack of concern for the protection of the public from this potentially severe disease. This decision — and other federal efforts to undermine well-established science about vaccine safety — puts everyone at risk, especially when we are currently experiencing the worst U.S. flu season in more than a decade.

Cancelling this meeting means vaccine makers may not have the vital information and time they need to produce and distribute targeted vaccines before the next flu season. If the FDA meeting is not immediately rescheduled, many lives that could be saved by vaccination will be lost.<sup>56</sup>

50. A measles outbreak that began in a largely unvaccinated community in West Texas earlier this year spread to 38 states as of July 2, 2025.<sup>57</sup> In response to this outbreak, the Secretary has made, at best, disingenuous statements about the measles vaccine. For example, he stated in a written commentary on March 2, 2025 about the Texas measles outbreak that “he has a shared responsibility [with other public health officials] to protect public health ... ensuring that accurate information about vaccine safety and efficacy is disseminated ... make vaccines readily accessible for all those who want them ... [and] [t]he decision to vaccinate is a personal one.”<sup>58</sup> In the very next paragraph of his commentary, the Secretary implied that vitamins could prevent measles: “Good nutrition remains a best defense against most chronic and infectious illnesses. Vitamins A, C, and D, and foods rich in vitamins B12, C, and E should be part of a balanced diet.” There is no evidence that Vitamins, A, C, D, B12, C, and E are defenses against measles. In fact, the Secretary’s endorsement of Vitamin A as a preventative against measles has resulted in children being hospitalized for Vitamin A toxicity that caused abnormal liver function.<sup>59</sup>

<sup>56</sup> Tina Tan, *Statement on Cancellation of FDA Vaccine Advisory Committee Meeting*, INFECTIOUS DISEASES SOCIETY OF AMERICA <https://www.idsociety.org/news--publications-new/articles/2025/statement-on-cancellation-of-fda-vaccine-advisory-committee-meeting/> (last visited July 5, 2025).

<sup>57</sup> *Measles Cases and Outbreaks*, CENTERS FOR DISEASE CONTROL & PREVENTION (July 2, 2025) <https://www.cdc.gov/measles/data-research/index.html>.

<sup>58</sup> Robert F. Kennedy Jr., *Measles outbreak is call to action for all of us*, FOX NEWS (Mar. 2, 2025) <https://www.foxnews.com/opinion/robert-f-kennedy-jr-measles-outbreak-call-action-all-us>.

<sup>59</sup> David Martin Davies, *West Texas children treated for vitamin A toxicity as medical disinformation spreads alongside measles outbreak*, TEXAS PUBLIC RADIO (Mar. 27, 2025) <https://www.tpr.org/public-health/2025-03-27/west-texas-children-treated-for-vitamin-a-toxicity-as-medical-disinformation-spreads-alongside-measles-outbreak>; Shauna Devitt, *Poison Centers Observe Increased Vitamin A Exposures in Children During Measles Outbreak*, AMERICA’S POISON CENTERS (Apr. 7, 2025) <https://poisoncenters.org/news-alerts/13484508>.



51. The Secretary's misleading statements about the measles outbreak stand in sharp contrast to what his own agency's website states definitively, *i.e.*, that "[t]he best way to protect against the measles is to get the measles, mumps, and rubella (MMR) vaccine."<sup>60</sup> The CDC further notes that one dose of the MMR vaccine is 93% effective against measles, and two doses are 97% effective against measles.<sup>61</sup> The CDC's website additionally states that "[M]ost people who are vaccinated with MMR & MMRV will be protected for life."<sup>62</sup> The Secretary, however, in a CBS news interview, asserted that "we're always going to have the measles, no matter what happens, as the vaccine wanes very quickly."<sup>63</sup>

52. In late March, senior leaders at the CDC ordered staff not to release their experts' assessment that found the risk of catching measles is increased in areas near outbreaks where vaccination rates are lagging. The report would have emphasized the importance of vaccinating people against the measles that, by that time, had spread to 19 states. A CDC spokesperson said in a written statement that the agency decided against releasing the assessment "because it does not say anything that the public does not already know."<sup>64</sup>

53. On March 25, 2025, the Secretary announced the immediate rescission of approximately \$11 billion in public health funds that states and localities were relying on to support core immunization infrastructure.<sup>65</sup> As one state's department of health noted: "'sudden loss of federal funding threatens Colorado's ability to track Covid trends and other emerging diseases,

<sup>60</sup> *Measles Vaccination*, CENTERS FOR DISEASE CONTROL AND PREVENTION, (Jan. 17, 2025) <https://www.cdc.gov/measles/vaccines/index.html>.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.*

<sup>63</sup> CBS News, *Watch: RFK Jr.'s first network TV interview as HHS secretary*, (YouTube Apr. 9, 2025) <https://www.youtube.com/watch?v=o2U0csKvqMY>; Steven Ross Johnson and Cecelia Smith-Schoenwalder, *Calling the Shots: Tracking RFK Jr. on Vaccines*, U.S. NEWS & WORLD REPORT (June 12, 2025) <https://www.usnews.com/news/health-news/articles/calling-the-shots-tracking-robert-f-kennedy-jr-s-moves-on-vaccines#recommendation>.

<sup>64</sup> Patricia Callahan, *The CDC Buried a Measles Forecast That Stressed the Need for Vaccinations*, PROPUBLICA (March 28, 2025, 4:35 PM), <https://www.propublica.org/article/measles-vaccine-rfk-cdc-report>.

<sup>65</sup> Brandy Zadrozny, *CDC Is Pulling Back \$11B in COVID Funding Sent to Health Departments Across the U.S.*, NBC NEWS (March 25, 2025, 12:18 PM), <https://www.nbcnews.com/health/health-news/cdc-pulling-back-11b-covid-funding-sent-health-departments-us-rcna198006>.

modernize disease data systems, respond to outbreaks, and provide critical immunization access, outreach, and education—leaving communities more vulnerable to future public health crises.”<sup>66</sup>

54. The Secretary also directed the CDC in March to conduct a study of links between vaccines and autism despite multiple studies negating any link between vaccines and autism. The Secretary hired a vaccine skeptic to assist with the study who long promoted false claims about the connections between immunization and autism and who was disciplined by Maryland regulators for practicing medicine without a license. More than two dozen studies have been performed since the 2000s on whether there is a link between vaccines and autism, and none have found a link.<sup>67</sup>

55. The Secretary has also placed into positions of authority throughout HHS individuals who are unlikely to challenge his views on vaccines or stand in the way of his agenda. FDA Commissioner Makary was confirmed on March 25, 2025. He previously made headlines for his comments during the pandemic, including advocating for looking at natural immunity, questioning the requirement for booster shots in younger people, and opposing vaccine mandates.<sup>68</sup>

56. NIH Director Bhattacharya, who also was confirmed on March 25, 2025, was an author in 2020 of the “Great Barrington Declaration” that advocated for “herd immunity” through natural infection—*i.e.*, allow the disease to spread through the “healthy” population while somehow isolating the elderly and other vulnerable populations.<sup>69</sup> There is no precedent in history for advocating for the uncontrolled spread of an infectious disease to control an epidemic.<sup>70</sup>

<sup>66</sup> *Id.*

<sup>67</sup> Lena H. Sun, Fenit Nirappil, *Vaccine skeptic hired to head federal study of immunizations and autism*, The WASHINGTON POST (Mar. 25, 2025), <https://www.msn.com/en-us/health/other/vaccine-skeptic-hired-to-head-federal-study-of-immunizations-and-autism/ar-AA1BEvp0>.

<sup>68</sup> Jordan King, *Everything Marty Makary Has Said About Vaccines*, NEWSWEEK (Mar. 26, 2025), <https://www.newsweek.com/dr-marty-makary-fda-vaccines-health-2050757>.

<sup>69</sup> Bruce Werness, *Debunking Heard Immunity: A Review of We Want Them Infected*, GLOBAL AUTOIMMUNE INST. (Dec. 16, 2024), <https://www.autoimmuneinstitute.org/articles/debunking-herd-immunity-a-review-of-we-want-them-infected/>.

<sup>70</sup> Bruce Werness, *Debunking Heard Immunity: A Review of We Want Them Infected*, GLOBAL AUTOIMMUNE INST. (Dec. 16, 2024), <https://www.autoimmuneinstitute.org/articles/debunking-herd-immunity-a-review-of-we-want-them-infected/>.

57. On or about March 28, 2025, the Secretary forced out Peter Marks, MD, PhD, as Director, Center for Biologics Evaluation and Research (“CBER”).<sup>71</sup> CBER is situated within the FDA and is responsible for reviewing applications for new biological products, like vaccines, “by evaluating scientific and clinical data submitted by manufacturers to determine whether the product meets CBER's standards for approval.”<sup>72</sup> In his resignation letter, Marks wrote: “Undermining confidence in well-established vaccines that have met the high standards for quality, safety, and effectiveness that have been in place for decades at FDA is irresponsible, detrimental to public health, and a clear danger to our nation’s health, safety, and security.”<sup>73</sup> He further wrote that: “I was willing to work to address the Secretary’s concerns regarding vaccine safety and transparency by hearing from the public and implementing a variety of different public meetings and engagements with the National Academy of Sciences, Engineering, and Medicine. However, *it has become clear that truth and transparency are not desired by the Secretary, but rather he wishes subservient confirmation of his misinformation and lies.*”<sup>74</sup>

58. Marks was replaced by Dr. Vinay Prasad, a critic of vaccine mandates, mask mandates, and booster shots,<sup>75</sup> who was named the head of CBER on May 7, 2025. On May 16, 2025, Prasad issued “A Center Director Decisional Memo” that overruled the recommendation from FDA’s vaccine staff members to approve for licensure a new protein-based Covid vaccine for all individuals 12 and older.<sup>76</sup> On May 30, 2025, Prasad issued a “Center Director Override Memo”

<sup>71</sup> Berkeley Lovelace, Jr., *FDA's Top Vaccine Scientist is Out, Citing Kennedy's 'Minsinformation and Lies,'* NBC NEWS (Mar. 28, 2025), <https://www.nbcnews.com/health/health-news/fdas-top-vaccine-scientist-dr-peter-marks-rcna198682>.

<sup>72</sup> *About CBER*, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/about-cber> (last visited July 5, 2025).

<sup>73</sup> *Letter from Peter Marks, Dir., Ctr. for Biologics Evaluation and Rsch., U.S. Food and Drug Admin., to Sara Brenner, Acting Comm'r of Food and Drugs*, U.S. FOOD AND DRUG ADMIN. (Mar. 28, 2025), <https://s3.documentcloud.org/documents/25873243/peter-marks-resignation-letter.pdf> (informing of his resignation).

<sup>74</sup> *Id.* (emphasis added).

<sup>75</sup> *Dr. Vinay Prasad to Head FDA, Biologics Division*, VACCINE ADVISOR (May 20, 2025), <https://www.vaccineadvisor.com/news/dr-vinay-prasad-to-head-fda-vaccine-biologics-division/>.

<sup>76</sup> Vinayak Prasad, Director, Ctr. for Biologics Evaluation and Research, *Center Director Decisional Memo* (May 16, 2025), <https://static01.nyt.com/newsgraphics/documenttools/24b944c1a77fbcd7/209038df-full.pdf> (regarding CBER's decision on the submission of Nuvaxovid (COVID-19 Vaccine, Adjuvanted)).

that overrode FDA vaccine staff members' recommendation to license the next generation of mRNA vaccines.<sup>77</sup>

59. Also hired by the Secretary to work at the FDA was Dr. Tracy Beth Høeg ("Høeg"). Høeg was hired as a "special assistant" at the FDA on or about April 2, 2025. Shortly thereafter, Høeg was involved in delaying approval of the protein-based vaccine that was the subject of Prasad's Center Director Decisional Memo of May 16.<sup>78</sup> Høeg is a former sports medicine doctor whose Board certification is in Physical Medicine and Rehabilitation who also has promoted incorrect information and misinterpreted data about vaccines.<sup>79</sup>

#### **E. The Secretary's Stacking Of The ACIP**

60. In addition to hiring individuals opposed to settled science, the Secretary's complete overhaul of the ACIP also evidences his agenda.

61. On June 9, 2025, at exactly 4 p.m. Eastern Time, an Opinion Commentary written by the Secretary appeared in the online version of the *Wall Street Journal*. In the column, the Secretary announced he was "totally reconstituting the Advisory Committee for Immunization Practices (ACIP)" and "retiring the 17 current members of the committee."<sup>80</sup>

62. The 17 members of the ACIP first learned of their terminations from a *Wall Street Journal* column. A few hours after the column appeared online, each of the 17 members received an email that stated:

Per the June 9, 2025 directive from the Secretary of the U.S. Department of Health and Human Services, this email serves as formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP).

We appreciate your prior service and commitment.

<sup>77</sup> Christina Jewett, *Top F.D.A. Official Overrode Scientists on Covid Shots*, NEW YORK TIMES (July 2, 2025), <https://www.nytimes.com/2025/07/02/health/fda-covid-vaccines.html>.

<sup>78</sup> Sarah Karlin-Smith, *'Highly Problematic': Acting FDA Commissioner Paused Planned OK Of Novavax Shot*, CITELINE (Apr. 4, 2025), <https://insights.citeline.com/pink-sheet/agency-leadership/us-fda/highly-problematic-acting-fda-commissioner-paused-planned-ok-of-novavax-shot-GUT6LR4X6ZALRMMZAEXYZHY36Y/>.

<sup>79</sup> *Id.*

<sup>80</sup> Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, WALL STREET JOURNAL (June 9, 2025, 4:00 PM), <https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112>.

63. The Secretary fired the ACIP members, although he promised Senator Bill Cassidy, whose vote was critical to his confirmation, that he would “maintain the Centers for Disease Control and Preventions Advisory Committee on Immunization Practices without changes.”<sup>81</sup>

64. The Secretary’s June 9, 2025 column made a host of false accusations against the 17 ACIP members, including that they had “been plagued with persistent conflicts of interest,” had “become little more than a rubber stamp for any vaccine,” and, by innuendo and implication, accused them of being “corrupt” and “directly work[ing] for the vaccine industry.” None of these accusations are remotely true. He also justified the terminations by referencing reports from 1997, 2000, and 2009 on the ACIP, years in which none of the 17 members were on the ACIP.

65. The AAP, the ACP, the APHA, the IDSA, and many other public health stakeholders condemned the terminations.

66. The AAP stated:

The American Academy of Pediatrics is deeply troubled and alarmed by Secretary Kennedy’s mass firing of all 17 experts on the Advisory Committee on Immunization Practices. This unprecedented action, against the backdrop of contradictory announcements from the Administration in recent days about vaccines, will cause even more confusion and uncertainty for families.

We are witnessing an escalating effort by the Administration to silence independent medical expertise and stoke distrust in lifesaving vaccines. Creating confusion around proven vaccines endangers families' health and contributes to the spread of preventable diseases. This move undermines the trust pediatricians have built over decades with our patients and leaves us without critical scientific expertise we rely on.<sup>82</sup>

67. The ACP stated:

The American College of Physicians (ACP) is highly concerned and outraged about today’s announcement from the Department of Health and Human Services (HHS) dismissing all 17 members of the Advisory Committee on Immunization Practices (ACIP). This announcement,

<sup>81</sup> KFF Health News, *Sen. Cassidy Says RFK Jr. Promised Key Vaccine Safety Commitments*, at 2:02 (YouTube Feb. 4, 2025), <https://www.youtube.com/watch?v=QrJcBtkfwvo>.

<sup>82</sup> Susan Kressly, MD, FAAP, *AAP Statement on Changes to Advisory Committee on Immunization Practices*, AMERICAN ACADEMY OF PEDIATRICS (June 9, 2025), <https://www.aap.org/en/news-room/news-releases/aap/2025/aap-statement-on-changes-to-advisory-committee-on-immunization-practices/>.

coupled with the recent, preemptive actions HHS took on the COVID-19 vaccines that circumvented the standard, transparent vaccine review process, interferes with the practice of evidence-based medicine and destabilizes a trusted source and its evidence-based process for helping guide decision-making for vaccines to protect the public health in our country. Today's announcement will seriously erode public confidence in our government's ability to ensure the health of the American public and it will endanger the safety, welfare and lives of our patients. We call on the administration to immediately reverse course.<sup>83</sup>

68. The APHA stated:

The Trump administration's action to 'retire' all members of ACIP and install a new slate, instead of allowing people to finish their term, is a coup. Today's ACIP members are some of the most qualified individuals to evaluate vaccines. They possess deep understanding of science and were vetted for conflicts of interest prior to appointment. Removing all ACIP members at once is not how democracies work and it's not good for the health of the nation. RFK says he wants to restore trust and transparency. This action immediately raises concern over the ability of any slate of committee members appointed by the Trump administration to be viewed as impartial to RFK's views on any decision, and therefore *their actions will be suspect and likely mistrusted*.<sup>84</sup>

69. The IDSA stated:

Secretary Kennedy's allegations about the integrity of CDC's Advisory Committee on Immunization Practices are completely unfounded and will have a significant negative impact on Americans of all ages.

Scientific recommendations about infectious diseases and vaccines that the public can trust require established experts to make them.

ACIP is a highly qualified group of experts that has always operated with transparency and a commitment to protecting the public's health.

Unilaterally removing an entire panel of experts is reckless, shortsighted and severely harmful.<sup>85</sup>

<sup>83</sup> Jason M. Goldman, MD, MACP, *American College of Physicians Highly Concerned About Dismissal of Vaccine Experts from ACIP*, AMERICAN COLLEGE OF PHYSICIANS (June 9, 2025), <https://www.acponline.org/acp-newsroom/american-college-of-physicians-highly-concerned-about-dismissal-of-vaccine-experts-from-acip>.

<sup>84</sup> Georges C. Benjamin, MD, *Trump administration attempts coup of the Advisory Committees on Immunization Practices*, AMERICAN PUBLIC HEALTH ASSOCIATION (June 9, 2025), <https://www.apha.org/news-and-media/news-releases/apha-news-releases/trump-coup-of-acip>. (Emphasis added).

<sup>85</sup> Tina Tan, MD, FIDSA, PFIDS, FAAP, *Statement on the Advisory Committee on Immunization Practices*, INFECTIOUS DISEASES SOCIETY OF AMERICA (June 9, 2025), <https://www.idsociety.org/news--publications-new/articles/2025/statement-on-the-advisory-committee-on-immunization-practices/>.

70. Two days after the terminations, on June 11, 2025, the Secretary announced the appointment of eight new members to the ACIP. Only one of the eight met the qualifications for ACIP membership articulated in the ACIP Charter.<sup>86</sup>

71. The other seven do not possess the required scientific and medical expertise to serve on ACIP:

a. a psychiatrist and neuroscientist whose career has focused on nutrition and mental health, particularly the role of dietary fats in mood, behavior, and neurodevelopment, who has published extensively on omega-3s and psychiatric outcomes, but has no background in vaccines, infectious disease, or immunology;

b. a professor of obstetrics and gynecology with no discernible expertise in vaccines, infectious disease or immunology;

c. an emergency medicine specialist with no discernible expertise in vaccines, infectious disease, or immunology;

d. a coauthor of the Great Barrington Declaration that promoted “natural immunity” over public health measures; who opposed vaccination in children against Covid, as well as masking, lockdowns and vaccine mandates; and who lost positions at Brigham and Women’s Hospital and Harvard after refusing to get vaccinated;

e. a professor of operations management with no discernable expertise in vaccines, infectious disease, or immunology, who tweeted on May 25, 2025: “That these vaccines [are] still recommended in pregnancy is incomprehensible!”; who wrote of the “need to evaluate vaccines using clinical endpoints that extend beyond their targeted diseases;” who retweeted a post that said “It has become painfully obvious that as a result of Big Pharma-driven vaccine ideology, these products do not receive the safety scrutiny they should”; and who has called for the “pulling out” of vaccine programs;

<sup>86</sup> *ACIP Charter*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/acip/about/acip-charter.html> (last visited July 5, 2025).



f. a current staff member at the National Vaccine Information Center, whose mission “is dedicated to preventing vaccine injuries and deaths” through public education and advocating for informed consent and vaccine exemptions and who attributes her son’s autism to vaccines;

g. a medical doctor who has spoken at anti-vaccine and anti-vaccine-mandate rallies, who claims to be the inventor of the mRNA technology used in the FDA-approved and ACIP-recommended Covid vaccines.

72. Thus, two weeks before the next scheduled the ACIP meeting on June 25, 2025, the Secretary stacked the ACIP with unqualified members with histories of taking anti-vaccine positions.

73. None of the new ACIP members were required to follow the rigorous application process to become an ACIP member.<sup>87</sup> Historically, the application process to become a voting ACIP member has taken up to two years. The Secretary filled ACIP with new members in two days.

74. To qualify for membership on the new ACIP, upon information and belief, a candidate had to be a registered Republican or Independent and could not have previously made public criticisms of the President or the Secretary.

75. Concerned with the credentials of the newly-appointed ACIP members, on the eve of the June 25, 2025 meeting, Senator Bill Cassidy, M.D., posted on X the following call for postponement of the June 25 meeting:

Although the appointees to ACIP have scientific credentials, many do not have significant experience studying microbiology, epidemiology or immunology. In particular, some lack experience studying new technologies such as mRNA vaccines, and may even have a preconceived bias against them. Robust and transparent scientific discussion is important, so long as it is rooted in evidence and understanding. Wednesday's meeting should not proceed with a relatively small panel, and no CDC Director in place to approve the panel's recommendations.<sup>88</sup> The meeting should be

<sup>87</sup> *Id.*; *Apply for ACIP Membership*, CENTERS FOR DISEASE CONTROL AND PREVENTION <https://www.cdc.gov/acip/apply-for-membership/> (last visited July 4, 2025); Edwin J. Asturias, MD, Noel T. Brewer, PhD, Oliver Brooks, MD, *Advisory Committee on Immunization Practices at a Crossroads*, JAMA NETWORK (June 16, 2025), <https://jamanetwork.com/journals/jama/article-abstract/2835626>.

<sup>88</sup> With no CDC Director in place as of the June 25–26 meeting, the decision whether to approve ACIP recommendations falls to—guess who—the Secretary. See 42 C.F.R. § 147.130(a)(1)(ii).



delayed until the panel is fully staffed with more robust and balanced representation—as required by law—including those with more direct relevant expertise. Otherwise, ACIP’s recommendations could be viewed with skepticism, which will work against the success of this Administration’s efforts.<sup>89</sup>

76. The Secretary did not delay the ACIP meeting as Senator Cassidy suggested and the newly restacked ACIP met on June 25–26, 2025 in Atlanta.

77. The final agenda for the June 25-26 ACIP meeting was posted on the CDC’s website the night before.<sup>90</sup> Based on discussions at the April ACIP meeting, expectations were that a vote on updated Covid vaccines would be scheduled for the June meeting. No such vote was on the June 25–26 final agenda.

78. A notable item new on the agenda was thimerosal. A presentation and a vote on thimerosal in flu vaccines were scheduled for June 26, 2025, with the presentation to be delivered by Lyn Redwood, a former long-time President of Children’s Health Defense,<sup>91</sup> the anti-vaccine organization founded by the Secretary.<sup>92</sup> The Children’s Health Defense website credits Redwood as the co-author of “a landmark paper” published in 2000 that linked autism to exposure to mercury.<sup>93</sup> The Secretary appointed Redwood to lead the CDC’s Immunization Safety Office on June 25, 2025.<sup>94</sup> Redwood, like the Secretary, has argued for decades that mercury causes autism.<sup>95</sup> However, the CDC website states in big, bold print that: **Vaccines do not cause autism.**<sup>96</sup>

<sup>89</sup> United States Senator Bill Cassidy, MD, (@SenBillCassidy), X (Jun. 23, 2025, 3:54 PM), <https://x.com/SenBillCassidy/status/1937283186758680766>.

<sup>90</sup> *Final Agenda: Meeting of the Advisory Committee on Immunization Practices*, CENTERS FOR DISEASE CONTROL AND PREVENTION (June 24, 2025), <https://www.cdc.gov/acip/downloads/agendas/Final-posted-2025-06-24-508.pdf>.

<sup>91</sup> *Directors & Advisors Emeriti*, CHILD.’S HEALTH DEF., <https://childrenshealthdefense.org/about-us/director-emeritus/> (last visited July 5, 2025).

<sup>92</sup> *Id.*; Will McDuffie, Jade Cobern, MD, *RFK Jr. appoints longtime anti-vaccine ally Lyn Redwood to HHS position*, ABC NEWS (June 25, 2025, 4:49 PM), <https://abcnews.go.com/US/rfk-jr-appoints-longtime-anti-vaccine-ally-lyn/story?id=123213887>.

<sup>93</sup> *Directors & Advisors Emeriti*, CHILD.’S HEALTH DEF., <https://childrenshealthdefense.org/about-us/director-emeritus/> (last visited July 5, 2025).

<sup>94</sup> Alexander Tin, *CDC to hire former head of anti-vaccine group founded by RFK Jr.*, CBS NEWS (June 25, 2025, 8:49 PM), <https://www.cbsnews.com/news/cdc-vaccine-safety-office-hire-former-head-anti-vaccine-group-founded-rfk-jr/>.

<sup>95</sup> Robert F. Kennedy, Jr., *Attack on Mothers*, HUFFINGTON POST (June 19, 2007), [https://web.archive.org/web/20070622053901/http://www.huffingtonpost.com/robert-f-kennedy-jr/attack-on-mothers\\_b\\_52894.html](https://web.archive.org/web/20070622053901/http://www.huffingtonpost.com/robert-f-kennedy-jr/attack-on-mothers_b_52894.html)

<sup>96</sup> *Autism and Vaccines*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Dec. 30, 2024) <https://www.cdc.gov/vaccine-safety/about/autism.html> [https://perma.cc/T6VN-L8WL].

79. The ACIP voted on June 26, 2025 that children, pregnant women, and adults all should “receive seasonal influenza vaccines only in single-dose formulations that are free of thimerosal as a preservative.”<sup>97</sup> The Secretary has yet to adopt the new ACIP’s votes on thimerosal. It should be noted that the Secretary advocated for the removal of thimerosal from vaccines for decades.

80. After the June 25–26 meeting, the IDSA released the following statement:

This week’s meeting of the Advisory Committee on Immunization Practices, or ACIP, was politicized, chaotic and not transparent. That kind of process is harmful to the American people.

Agenda items were added last minute, limiting the ability of members to review data. Disclosures about potential conflicts of interest of the newly appointed ACIP members have not been made public.

Re-examining the childhood vaccine schedule and the use of thimerosal are both politically motivated actions that are not based on science. Raising questions without adequate data casts doubt on vaccination, which can further drive down confidence in vaccines. More than any other medications, vaccines are extensively and constantly reviewed and evaluated. Vaccination saves lives.

The American people deserve an objective and transparent review process based on scientific evidence, not political agendas with no basis in facts.<sup>98</sup>

**F. The Secretary’s Arbitrary and Capricious Directive**

81. The foregoing provides the backdrop and context for the Directive. Curiously, in the video announcement posted on X on May 27, 2025, Defendant Makary (FDA Commissioner) flanks him on his right and Defendant Bhattacharya (NIH Director) on his left:

<sup>97</sup> CDC’s *Advisory Committee on Immunization Concludes Meeting with Joint Statement*, CENTERS FOR DISEASE CONTROL AND PREVENTION (June 26, 2025), <https://www.cdc.gov/media/releases/2025/2025-cdcs-advisory-committee-on-immunization-concludes-meeting-with-joint-statement.html>.

<sup>98</sup> Tina Tan, *Statement on the June meeting of the Advisory Committee on Immunization Practices*, IDSA (June 26, 2025) <https://www.idsociety.org/news--publications-new/articles/2025/statement-on-the-june-meeting-of-the-advisory-committee-on-immunization-practices/>.



82. No representative of the CDC or ACIP appears in the video, even though CDC and ACIP, not the FDA or NIH, have responsibility for making recommendations as to which vaccines are added to or removed from the CDC’s immunization schedules.

83. This announcement came as a surprise to officials at the CDC, who five hours after the video was posted on X, received the Directive.<sup>99</sup> CDC staff were confused that the Directive was dated May 19, eight days prior.<sup>100</sup>

84. Just a week before this video appeared on X, and a day after the Directive is dated, FDA Commissioner Makary published an article that he co-authored with Prasad dated May 20, 2025 in *The New England Journal of Medicine* stating that “pregnancy and recent pregnancy” are factors which “increase a person’s risk of severe COVID-19.” Thus, the Directive, announced one week later, shows that “‘they literally contradicted themselves over the course of a couple of days.’ ... ‘It appears RFK Jr. reversed his own FDA’s decision.’”<sup>101</sup>

85. The CDC’s immunization schedules were changed after the May 27 announcement, indisputably making the Directive a final agency action.

86. The Secretary did not consult with the ACIP before he signed the Directive.

<sup>99</sup> *CDC blindsided as RFK Jr. changes covid-19 vaccine recommendations*, THE WASHINGTON POST (May 28, 2025) <https://www.washingtonpost.com/health/2025/05/28/vaccines-cdc-rfk-jr-covid/>.

<sup>100</sup> *Id.*

<sup>101</sup> Louis Jacobson, Amy Sherman, *RFK Jr. Ended COVID Vaccine Recommendation for Kids, Pregnant Women. What do Facts Show About Risk?* POLITIFACT (May 29, 2025), <https://www.politifact.com/article/2025/may/29/COVID-19-vaccine-RFK-children-pregnant/>.

87. The Secretary did not consult with any ACIP Work Group before he signed the Directive.

88. Secretary did not consult with the CDC about the Directive.<sup>102</sup>

89. The Secretary cited no emergency, let alone change in circumstances, to justify the Directive.

90. The Secretary signed the Directive only five days after he testified before Congress that: “what I would say is my opinions about vaccines are irrelevant,” and “I don’t think people should be taking medical advice from me.”<sup>103</sup>

91. The Directive is contrary to the wealth of data and peer-reviewed studies that demonstrate the safety and efficacy of Covid vaccines for children and pregnant women.

92. Two CDC employees gave presentations at the June 25 ACIP meeting that contradicted the Directive.<sup>104</sup>

93. The Directive does not follow the science.

94. The Secretary did not follow the longstanding process for making changes to the CDC immunization schedules upon which vaccination stakeholders have relied for decades.

95. The Directive is in direct contradiction of multiple federal and state laws that require reliance on ACIP recommendations for the CDC immunization schedules, not the decisions of a single individual like the Secretary.

#### **G. Injury To The Plaintiffs**

96. The Directive has adversely affected the physician-patient relationship because, *inter alia*, it has injected mistrust, misinformation, uncertainty, and confusion into that relationship,

<sup>102</sup> Lena H. Sun, *CDC blindsided as RFK Jr. changes covid-19 vaccine recommendations*, WASHINGTON POST (May 28, 2025), <https://www.washingtonpost.com/health/2025/05/28/vaccines-cdc-rfk-jr-covid/>.

<sup>103</sup> Cecelia Smith-Schoenwalder, *RFK Jr. Gets Grilled on Capitol Hill: 4 Takeaways*, U.S. NEWS (May 14, 2025), <https://www.usnews.com/news/health-news/articles/2025-05-14/rfk-jr-defends-trumps-budget-plan-addresses-vaccines-on-capitol-hill>.

<sup>104</sup> Adam MacNeil, *Current Epidemiology of COVID-19*, CDC ACIP Meeting, at 22 (June 25, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/02-MacNeil-COVID-508.pdf> (presented by Dr. Adam MacNeil); Sarah Meyer, *Update on CDC’s COVID-19 Vaccine Safety Monitoring*, CDC ACIP Meeting, 24 (June 25, 2025), <https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf>.

putting physicians in the conflict position of either advising patients on what they believe is the proper standard of care or adhering to conflicting federal guidance. The Directive will also result in decreased rates of vaccination, increased rates of transmission, long-lasting illness, and ultimately deaths among pregnant women, unborn children, and all children – deaths that could have been prevented.

97. Dr. Susan J. Kressly is the current President of the AAP. She has learned from AAP members that, because of the May 19 Directive, AAP members are experiencing great frustration and new barriers in effectively counseling patients and their families regarding the Covid vaccine. AAP members believe that they are compromising the standard of care that they should be providing to their patients due to the confusion and distrust created by the May 19 Directive. That Directive has caused physician members to spend more time counseling patients regarding the effectiveness of the Covid vaccines, which adds up to time and resources diverted from other patients. Due to the confusion and lack of evidence-based data supporting the Secretary's Directive modifying the recommendation for Covid vaccinations for children ages six months to 17 years old, the AAP ceased its endorsement of the CDC's current Child and Adolescent Schedule, and instead published and endorsed the CDC Child and Adolescent Immunization Schedule in effect prior to the issuance of the Directive. The Directive has put all AAP members (and, indeed, all other physicians in this country) in the untenable position of telling their patients that the country's top-ranking government health official's advice and recommendations are wrong and that we are right. This erodes trust, which is the foundation of a healthy physician-patient relationship and vital to the success of AAP members' medical practices.

98. AAP member Dr. Mary Doherty-O'Shea Galluci is a pediatrician and owns two practices in Michigan. She is experiencing an uptick in vaccine hesitancy after the Directive was issued. Parents are now questioning Dr. Galluci whether they should vaccinate their children against Covid, or worse, whether they can. Parents are now distressed and unsure about Covid vaccines where they were not before. Dr. Galluci is especially concerned about pregnant patients and infants

under 12 months old whom she sees at her clinics. During pregnancy, the immune system is suppressed to protect the developing fetus. This puts pregnant women at high risk for severe Covid complications, and the only way to protect their newborns is through maternal vaccination and early-life immunization. Covid infection in infants can be severe or fatal. Denying or delaying access to the Covid vaccine in this population is medically dangerous and ethically indefensible. The May 19 Directive is immediately and irreparably endangering the lives of patients she is seeing right now at her clinics. The CDC's current emphasis on "shared decision-making" for the Covid vaccine for children has put a chilling effect on her practice. Shared decision-making implies that the Covid vaccine is optional or suspect, making it harder to hold Covid vaccine clinics, limiting her practice's ability to order vaccines in bulk, and creating reimbursement challenges. Her billing team is spending excessive time navigating unclear insurance coverage rules. Parents also fear receiving unexpected co-pays for the Covid vaccine due to the conflicting directives and recommendations from HHS, which further discourages vaccination. Access to Covid vaccines is reduced as a result of the May 19 Directive. In short, the May 19 Directive is interfering with her ability to provide the standard of care recommended by the AAP and interfering with her ability to comply with the oath she took as a doctor to do no harm.

99. Shannon E. Scott-Vernaglia, M.D. is a board-certified pediatrician practicing in Boston, Massachusetts. She is a member of the American Academy of Pediatrics. She treats patients in a pediatric clinic that distributes vaccines, including the Covid-19 vaccine through the Vaccines for Children Program. The Secretary's Directive has limited her clinic's ability to consistently stock Covid-19 vaccinations for healthy children. She attests that there is clear scientific evidence that missed opportunities for vaccination during regular office visits leads to a greater risk of future immunization status for children and having irregular or uncertain vaccine availability due to the Secretary's Directive puts her patients at risk of remaining unvaccinated in the future. The Secretary's Directive has caused confusion about appropriate medical recommendations, erodes the

relationship between the pediatric physician and patient family, and further exacerbates the difference in the demand and availability of medical resources for children, such as her patients.

100. Dr. Jason Goldman is the current President of the ACP and owns his own internal medicine practice in Florida. Since Covid vaccines were first approved for pregnant patients, physician members of ACP have been recommending and administering the Covid vaccine to pregnant patients. This routine administration of the vaccine to pregnant women has become the standard of care for physician members of the ACP. ACP physician members have informed Dr. Goldman that the Directive has placed them in a conflict situation with their patients. When a pregnant patient has requested a Covid vaccine, some ACP member physicians have turned patients away because administering the Covid vaccine is contrary to both the Directive and the CDC's Adult Immunization Schedule, which could lead to licensure problems for the physician. ACP physicians who now administer the Covid vaccine face financial harm because some insurers do not cover vaccines that are not on the CDC immunization schedules. ACP members are placed in the untenable position of either complying with a directive from the government's top health official or not providing their patients with the standard of care that they believe they should be providing to their patients.

101. Dr. Robert H. Hopkins, Jr., is an Internal Medicine and Pediatrics physician in Arkansas. He is an active ACP member and current chair of the ACP Immunization Committee. He has served on several ACIP vaccine Work Groups. Because of the May 19 Directive, Dr. Hopkins has been required to spend more time counseling patients regarding the safety of the Covid vaccine for pregnant persons and parents of children. He estimates that he has had discussions with at least 20–25 patients in the last six weeks regarding the effectiveness of the Covid vaccines and recommending a booster shot. Approximately half of the patients he sees in a given day require counseling on Covid vaccines. In those discussions, Dr. Hopkins has counseled patients that, based on the evidence, the Covid vaccine is safe and beneficial for children and pregnant women. However, after these discussions, several patients, such as parents of young children, have decided



to trust the Secretary's advice and refused to get the Covid vaccine for their child. His relationship with these patients has deteriorated as a result of the Secretary's May 19, 2025 Directive. Dr. Hopkins has also provided vaccines for children through the Vaccines For Children ("VFC") program. As of July 2, 2025, he has been unable to order the Covid vaccine for children eligible through the VFC program.

102. Dr. Georges C. Benjamin is the current Executive Director of the APHA. He attests that APHA members across the country are faced with an untenable conflict between counseling patients and their communities on what the CDC recommends, and the optimal standard of care that members have been following since the Covid vaccines were approved. Members are either forced to provide inferior care to pregnant women and children that increases the risk of preventable illness, hospitalization and death, or risk losing their medical license or professional certifications. For public health administrators, this creates a professional conflict with the standard of public health practice required to control a disease outbreak in their community and the non-evidence-based May 19 Directive. Moreover, the clinician and other public health members' ability to consult with individuals and their families or advise those communities regarding the effectiveness of the Covid vaccine at preventing serious illness and death has been frustrated by the May 19 Directive. It is already compromising the standard of care by encouraging delays or refusals of vaccination. Because of vaccine hesitancy and loss of trust caused by the May 19 Directive, APHA members are required to spend more time correcting misinformation with individuals and families regarding the effectiveness of the Covid vaccines, which diverts time and resources away from other important health care or public health duties.

103. J. Edward Johnson is the Assistant Health Commission for External Affairs at the Columbus Department of Public Health ("Columbus Public Health"). He attests that Columbus Public Health is a member of APHA. Columbus Public Health's mission is to "Build public health capacity and promote effective policy and practice." In particular, Columbus Public Health endeavors to curb transmission of an infection by vaccine-preventable illnesses by operating an

immunization clinic which offers several immunizations including immunizations against Covid-19 through its Columbus Public Health Vaccine Preventable Diseases Clinic and Program (the “CPH Clinic”). The purpose and mission of Columbus Public Health and its Secretary’s Directive’s Clinic is frustrated by the Secretary’s Decision because the CPH Clinic staff can no longer advise pregnant women to receive a Covid-19 immunization, which is completely at odds with the mission, vision, and values of Columbus Public Health and the standards it holds itself to. Because of the Secretary’s Directive, the CPH Clinic staff are unable to provide adequate counseling about the safety and efficacy of Covid-19 immunizations to patients. Furthermore, CPH Clinic purchases the immunizations it stocks at a “super low price” which is available only for immunizations that have been approved by the FDA and recommended by the CDC. The Secretary’s Directive prevents the CPH Clinic from purchasing Covid-19 vaccines at the “super low price.” Despite having offered the Covid-19 immunization for several years, decision that have increased the cost and/or removed eligible groups from the recommendation to be immunized have resulted in CPH Clinic to cease stocking all Covid-19 immunizations and impact Columbus Public Health’s ability to serve all residents. The Secretary’s Directive is an existential threat to Columbus Public Health.

104. Dr. Andrew Pavia is an infectious disease doctor in Utah, has served as a Board member for IDSA, and is an active member of IDSA as Chair of the Avian Influenza Task Force and co-Chair of the IDSA Influenza Treatment Guidelines Committee. Consistent with ACIP recommendations before the Secretary took office this year, IDSA adopted ACIP’s recommendations on the Covid vaccine, which has become the standard of care for IDSA physician members and which IDSA has adopted into its guidelines. The Directive, however, places IDSA members into a conflict situation between following a federal recommendation for Covid vaccination that is no longer evidence-based versus following the optimal standard of care that IDSA physician members have been following since the vaccines were approved. Because of the Directive, IDSA members are now encountering with parents who are expressing increasing concern and confusion about whether their infants and children should get the Covid vaccine even

though IDSA members continue to recommend the vaccine for children and pregnant women in the face of the Directive. This conflict is destroying the trust that is the cornerstone of the physician-patient relationship.

105. Dr. Ravi Jhaveri is an infectious disease expert, board certified in Pediatrics and Infectious diseases, and practices in Illinois. He is a member of both the Pediatric Infectious Disease Society (“PIDS”) and the IDSA. It is his clinical judgment that the standard of care in his practice is to recommend the Covid vaccine for pediatric patients ages six months to 17 years, as he has seen that the vaccine protects children from getting the disease and/or from suffering the effects of long Covid. The Directive has placed him in an impossible position because it contradicts the standard of care for pediatricians. His patients have already suffered harm from confusion about the vaccine, canceled vaccine appointments, and an erosion of trust between him and his patients’ families, which is damaging to his practice. He feels that his ability to protect his youngest, most vulnerable patients, is under direct assault.

106. Regina LaRocque, MD, MPH, FIDSA, is a physician board certified in infectious diseases. She is a member of IDSA and attests that, she presently treats patients, including pediatric patients and pregnant individuals, in a traveler’s advice and immunization clinic. The Secretary’s Directive disincentivizes physicians from recommending Covid-19 vaccines for pregnant individuals and children ages 6 months through 17 years and creates uncertainty about eligibility for this vaccination as well as patient access to those vaccines. She has advised patients of child-bearing age and one patient who was planning a pregnancy to receive the vaccine. Dr. LaRocque attests that the Secretary’s Directive will create cost and logistical barriers for children and pregnant women to receive the vaccination. Her recommendation for healthy children and pregnant women to receive the vaccination is based on her professional assessment of the standard of care, but it may require some patients to choose between paying for daily necessities and paying for the vaccine, which creates an ethical challenge for her clinical practice. Based on her more than 20 years in the field of infectious disease, she asserts confidently and without qualification, that based on her

professional experience, more patients of all ages will contract Covid-19 and experience severe symptoms, including death, if there are barriers to vaccinating pregnant individuals and children between the ages of six months and 17 years, such as the Secretary's Directive.

107. Carlene Pavlos is the Executive Director of the Massachusetts Public Health Alliance ("MPHA"), a nonprofit organization that advocates for health equality and strong public systems across the Commonwealth of Massachusetts. She attests that the Secretary's May 19 Directive is a life-threatening recommendation that irreparably harms MPHA members by frustrating the work they do to support maternal and child health, vaccine delivery, and pandemic response in Massachusetts. The Secretary's Directive harms MPHA members across the Commonwealth by forcing them into an ethical dilemma: choosing between providing evidence-based, medically sound recommendations for pregnant patients that advances good public health and conforming with what HHS now sets as the standard of care for Covid-19 vaccines, undermining its members' independent medical judgment, and critically weakens the medical infrastructure its members rely on to perform their jobs.

108. Dr. Sindhu K. Srinivas is a physician and board certified in Obstetrics and Gynecology. She is the President of the Society of Maternal Fetal Medicine ("SMFM"). She attests that the Secretary's May 19 Directive has harmed SMFM's 7,000 physician-members who provide direct patient care to high-risk pregnant patients in hospital and outpatient settings nationwide. The Secretary's Directive has completely frustrated SMFM's members' ability to effectively counsel patients regarding the effectiveness of the Covid-19 vaccine at preventing serious illness, and the Secretary's Directive is compromising the standard of care by inciting patient delays or refusals to receive the Covid-19 vaccination. She attests that, since the Secretary's Directive, SMFM members have reported that their pregnant patients are being denied access to Covid-19 vaccines by pharmacies, some patients being denied at multiple pharmacies who denied them a vaccine citing perceived legal risks or confusion created by the Secretary's Directive. SMFM members also report that the Secretary's Directive harms their practices by undermining and eroding the physician-

patient relationship and requires SMFM members to divert resources to addressing confusion about the Covid-19 vaccine that the Secretary's Directive created.

109. SMFM member Dr. Caroline Rouse is a board-certified maternal-fetal specialist in Indiana who treats high-risk pregnant patients. The Secretary's May 19 Directive has had harmful effects on her practice because it has disrupted vaccination schedules for her patients and caused dangerous confusion for her clinical practice. She has been placed in the conflict situation of either following the Directive or following the established standard of care to recommend and provide the Covid vaccine to pregnant patients. Her clinical judgment is now in direct conflict with federal guidance. Many of her current patients are immunocompromised by virtue of being pregnant, and they are now presenting at her practice as afraid, misinformed and at increased risk of preventable illness and death as a result of the Directive. In short, the Directive is endangering the health and lives of her patients and their unborn children as well as undermining the trust and confidence upon which the physician-patient relationship is built.

110. Plaintiff Jane Doe 1 is a doctor who works in a hospital where she is exposed to infectious diseases every day. She is currently pregnant and was shocked to learn of the Directive. The Directive has and will make it more difficult for her to get a Covid vaccine while she is pregnant, which in turn will endanger her unborn child.

## **CAUSES OF ACTION**

### **COUNT I**

#### **Violation of the Administrative Procedure Act – Arbitrary & Capricious**

111. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

112. The Directive constitutes a final agency action subject to the Administrative Procedure Act ("APA").

113. The APA authorizes courts to “hold unlawful and set aside agency action, findings, and conclusions found to be” “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]” 5 U.S.C. § 706(2)(A).

114. 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. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

115. The Directive is an arbitrary and capricious final agency action. The evidence of its arbitrariness and capriciousness is vast and irrefutable, including, but not limited to, the following:

a. five days before issuing the Directive, the Secretary testified under oath before Congress that “my opinions about vaccines are irrelevant” and that “I don’t think people should be taking medical advice from me,” thus admitting that he is unqualified to issue the Directive;

b. the Directive contradicts the article published seven days before that states “the policy position of the Food and Drug Administration”<sup>105</sup> that “[p]regnancy and recent pregnancy were underlying medical conditions that increased a person’s risk of severe COVID-19.” The Secretary has provided no explanation for why he overruled his FDA Commissioner;

c. the Secretary failed to explain what prompted him to issue the Directive when he did. The Directive states in the first paragraph that HHS “continually considers and evaluates available science and evidence related to ... approved or authorized vaccines,” but he failed to identify the available science or evidence that prompted him to issue the Directive when he did;

<sup>105</sup> Vinay Prasad and Martin A. Makary, *An Evidence-Based Approach to Covid-19 Vaccination*, 392 NEW ENGLAND J. MED. 2484–86 (2025).

d. the Directive states that the Secretary based his decision with regard to children ages six months to 17 years “on review of the recommendation of the FDA and National Institutes of Health,” but he did not identify the recommendation or recommendations to which he was referring that prompted him to issue the Directive when he did;

e. the Directive states that the Secretary’s decision with regard to pregnant women was based “on a review of the recommendation of the FDA,” but he does not explain what recommendation of the FDA he based the Directive on; nor does he explain how or why “the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy” came to his attention to prompt him to issue the Directive when he did;

f. the Secretary failed to explain why he ignored and bypassed without explanation the longstanding, well-accepted, science- and evidence-based ACIP process for developing recommendations for the CDC immunization schedules that stakeholders across the country have relied upon for years;

g. the Secretary failed to explain why he consulted with the FDA Commissioner and the NIH Director and had them by his side when he made his May 27 announcement on X, where neither of them have responsibility for making recommendations for the CDC immunization schedules;

h. the Secretary failed to explain why he did not consult with any voting member of the ACIP or anyone on any ACIP Working Group;

i. the Secretary failed to explain why he rejected the data, reports, and peer-reviewed studies that underlay the ACIP and ACIP Work Group recommendations that the Directive rescinded;

j. the Secretary failed to explain why he issued the Directive after irrefutable evidence was presented at the April 2025 ACIP meeting that pregnant women and healthy children continue to face grave risk from Covid;



k. the Secretary has failed to explain why he issued the Directive in contravention of the numerous federal and state laws that require reliance on ACIP recommendations – not the unilateral decisions of political appointees – as to which vaccines are to be covered by insurance or entitlement programs, which vaccines are required of aliens for entry into the country, or what vaccines are required for school entry.

l. the Secretary failed to explain whether he considered the impact that his sudden, unilateral Directive would have on the standard of care that applies to physicians who are members of the AAP, the ACP, the APHA, the IDSA, the SMFM, and many other physician organizations and associations around the country;

116. The Secretary issued the Directive in contravention of science and clinical expertise.

117. The Directive was issued without the reasoned or rational explanation that is required by the APA.

118. The reasons stated in the Directive are contrived and pretextual.

119. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaration that the Directive violates the APA because it is arbitrary and capricious.

120. The Directive has injured all of the Plaintiffs in this action.

121. Plaintiffs are also entitled to vacatur of the Directive and a preliminary and permanent injunction ordering the Secretary to reinstate to the CDC immunization schedules the routine recommendations that pregnant women and children ages six months to 17 years be vaccinated against Covid.

## **COUNT II**

### **Violation of the Administrative Procedure Act – Not In Accordance With Law**

122. Plaintiffs incorporate by reference the foregoing paragraphs of this Complaint as if set forth herein.

123. Under the APA, a court must “hold unlawful and set aside agency action, findings, and conclusions found to be ... not in accordance with law; ... [or] without observance of procedure required by law; ...” 5 U.S.C. § 706(2)(A), (D).

124. The Directive constitutes a final agency action subject to the APA.

125. Over the decades, Congress has developed a statutory scheme governing vaccines that has repeatedly placed responsibility and authority in the ACIP to make recommendations as to which vaccines are on the CDC’s immunization schedules and upon which stakeholders can rely. In requiring reliance on the recommendations of the ACIP, which by law is required to be fairly balanced, Congress has demonstrated repeatedly its intent that political appointees like the Secretary not meddle in deciding what vaccines are on the CDC’s immunization schedules. The Directive contravenes this statutory scheme and is not in accordance with law.

126. The Directive has injured all the Plaintiffs in this action.

127. Pursuant to 5 U.S.C. § 706 and 28 U.S.C. § 2201, Plaintiffs are entitled to a declaration that the Directive is contrary to law and in violation of the APA.

128. Plaintiffs are also entitled to vacatur of the Directive and a preliminary and permanent injunction ordering the Secretary to reinstate the Covid vaccine recommendations for pregnant women and children ages six months to 17 years to the CDC immunization schedules.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs pray for judgment against Defendants for each of the causes of action raised herein. Plaintiffs respectfully request that this Court enter judgment in their favor and that the Court:

1. Should declare unlawful and set aside the Directive as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under the APA; order the restoration of the Covid vaccine recommendations for pregnant women and healthy children ages six months to 17 years to the CDC immunization schedules posted on its website; and order the Secretary to announce on X that those immunizations are now reinstated to the CDC immunization schedules.

2. Preliminary and permanent injunctive relief barring Defendants from enforcing, publicizing, or otherwise encouraging any person or court to follow or to defer to the challenged Directive dated May 19, 2025 on Pediatric Covid Vaccines for Children Less Than 18 Years of Age and Pregnant Women.

3. Award to Plaintiffs reasonable attorney's fees and costs incurred in pursuing this action, and pre-judgment and post-judgment interest at the highest lawful rates; and

4. Grant all such other and further relief as this Court deems just and appropriate.

[Signatures on following pages]

Dated: July 7, 2025

Respectfully submitted,

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