

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF
PEDIATRICS, *et al.*,

Plaintiffs,

- v. -

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of the Department of
Health and Human Services, *et al.*,

Defendants.

Case No. 1:25-cv-11916

Leave to file granted on
February 5, 2026

**BRIEF OF AMICI CURIAE AMERICAN ASSOCIATION OF
IMMUNOLOGISTS AND AMERICA'S PHYSICIAN GROUPS IN SUPPORT OF
PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION**

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CORPORATE DISCLOSURE STATEMENT

None of the amici curiae has any parent corporation or any publicly held corporation that owns 10% or more of its stock.

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INTERESTS OF AMICI CURIAE¹

The American Association of Immunologists (AAI) is the nation's largest organization of immunologists and scientists in related disciplines. Its mission is to improve global health and well-being by advancing immunology and elevating public understanding about the immune system. AAI members have made many of the most significant biomedical discoveries of the past century, advancing our understanding of the immune system and developing life-saving immunotherapies and vaccines. Over the last five years, discoveries by immunologists have been central to the global response to COVID-19, including rapid development of effective vaccines and ongoing research into the long-term effects of SARS-CoV-2 infection. AAI is committed to ensuring continued support for the life-saving immunology research that makes vaccine development possible. AAI educates the public through its programs, disseminates scientific findings through its meetings and leading professional journals, and engages in public advocacy on issues involving science and health.

America's Physician Groups (APG) is a national association representing approximately 340 physician groups. Its members collectively work with about 260,000 physicians and multiple other clinicians to provide care for about 90 million patients nationwide. APG and its members are committed to clinically integrated, coordinated, value-based health care. APG members provide evidence-based preventative care and services that are proven to reduce illness, hospitalization, and death, and that preclude the costs associated with treating avoidable conditions. Vaccines, whether for infants, children, or adults—including those for COVID-19 and other respiratory illnesses—are a central pillar of value-based care. They prevent serious illness, reduce

¹ Neither a party nor counsel to this lawsuit authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than the amici curiae or their counsel made a monetary contribution to this brief's preparation or submission.

hospitalizations, reduce the burden of disease, and save avoidable healthcare costs. APG's members rely on the expert recommendations of the Advisory Committee on Immunization Practices (ACIP) and its unbiased review of data relating to vaccines in providing value-based care. That guidance has enabled APG's members to provide and pay for vitally important preventative interventions in a credible, science-based manner.

Amici submit this brief to provide their perspectives on the importance of vaccines and to highlight the consequences of the U.S. Department of Health and Human Services' (HHS) assault on a scientific field that is vitally important to public health. Vaccines have saved millions of lives—and will save millions more if the actions undertaken by the Department are reversed. Amici urge this Court to grant Plaintiffs' motion for a preliminary injunction.

PRELIMINARY STATEMENT

Vaccines are one of the most significant public health advancements of the last century. They save lives and reduce the burden of diseases that were leading causes of childhood morbidity and mortality. They have contributed substantially to a thirty-year increase in average American lifespan over the last century.² They save patients, practitioners, and insurers hundreds of billions of dollars by avoiding costly medical care. And they are extensively tested and monitored to ensure that they remain safe and effective. Demand for vaccines drives groundbreaking innovation, which yields vast public health improvements. During the COVID-19 pandemic, emerging technologies fueled by decades of fundamental research enabled the development of safe and effective vaccines with astonishing speed and precision, enabling faster containment of COVID-19 and improving the public health system's capacity to respond to future disease outbreaks. Messenger RNA

² Corey J. Hebert et al., *Lessons Learned and Applied: What the 20th Century Vaccine Experience Can Teach Us About Vaccines in the 21st Century*, 8 Hum. Vaccines & Immunotherapeutics 560, 560 (2012), <https://tinyurl.com/4vmn8wp2>.

(mRNA) technology in particular has empowered a promising new era of vaccines for other serious conditions, including cancer.

Bypassing all standard vetting procedures, Secretary Kennedy has reconstituted ACIP with members inexperienced in vaccine science, immunology, and epidemiology, as well as noted vaccine skeptics. That new ACIP quickly departed from its longstanding evidence-based approach to vaccine policy. Over several chaotic meetings, ACIP unraveled prior recommendations that were reached through evidence-based review and expert consultation. Senator Bill Cassidy (R-LA), chair of the Senate Health, Education, Labor and Pensions Committee, who cast a pivotal vote to confirm Secretary Kennedy, has declared that ACIP is “totally discredited.”³ Yet in January 2026, HHS removed several vaccines from the childhood vaccine schedule—defying its statutory mandate⁴ to encourage vaccination and denying decades of robust science.

These actions will have far-reaching consequences for health, healthcare, and human lives. ACIP’s messaging shapes the public’s understanding of vaccine science and influences individual health decisions across the country. Physicians reference CDC guidance to counsel patients and make clinical recommendations. Entities across the healthcare industry rely on that guidance to determine insurance coverage and make long-term business commitments to vaccine production. With vaccine hesitancy an increasing threat to public health—as evidenced by the highest number of U.S. measles cases in over three decades—HHS’s actions will destabilize the healthcare sector, expose millions of people to preventable diseases, and cost precious lives. HHS should reaffirm its commitment to vaccination and return to the transparent, science-based processes that have guided American healthcare for the past sixty years.

³ Bill Cassidy (@SenBillCassidy), X (Dec. 4, 2025, 7:55 AM), <https://tinyurl.com/5n7u7j6z>.

⁴ See 42 U.S.C. § 245(a) (directing HHS to “increase awareness and knowledge of the safety and effectiveness of vaccines” and “combat misinformation,” with the goal of “increasing rates of vaccination”).

ARGUMENT

Under Secretary Kennedy, HHS has taken multiple actions that undermine vaccination. Beginning in June 2025, the Secretary reconstituted ACIP with numerous vaccine skeptics. Fourth Am. Compl. (Compl.) ¶¶ 3, 76-78. In the ensuing months, ACIP voted to remove the recommendation for COVID-19 vaccination for pregnant women and healthy children; to remove recommendations for routine infant hepatitis B vaccinations; and to reclassify the COVID-19 vaccine as “shared clinical decision-making for adults” —a designation that requires case-by-case immunization decisions. *Id.* ¶¶ 4–5. Then, in January 2026, HHS overhauled the childhood vaccine schedule by changing longstanding recommendations for multiple childhood vaccines from “routine” to “shared clinical decision-making,” or “for certain high risk groups only.” *Id.* ¶¶ 2, 53-57. Those actions ignore the broad scientific consensus supporting vaccination to protect public health, and have precipitated a cascade of negative consequences for patients, providers, and the public. Those consequences will only worsen if this Court does not issue a preliminary injunction.

I. Vaccines are a cornerstone of preventative care and the most powerful tool to combat infectious disease.

Secretary Kennedy and his chosen ACIP members have cast aspersions on the safety and effectiveness of vaccines and made statements that contradict the scientific consensus. *See, e.g., id.* ¶¶ 77(a)-(n) (collecting remarks by ACIP members and highlighting credential deficiencies). Their statements are false. Vaccines in current clinical use, for the vast majority of people, are safe, effective, and backed by centuries of settled science. They have prevented or lessened the severity of disease and saved more than 150 million lives.⁵ They are also remarkably cost-

⁵ World Health Org. Media Team, *Global Immunization Efforts Have Saved at Least 154 Million Lives Over the Past 50 Years*, World Health Org. (Apr. 24, 2024), <https://tinyurl.com/3t4nh4my>.

effective, collectively saving hundreds of billions of dollars in treatment costs.⁶ The recent changes to the CDC immunization schedule without sound scientific justification are unlawful and will have tragic consequences if not reversed.

A. Vaccines are the product of centuries of robust science and bold innovation.

Vaccines strengthen the body’s natural immunity by training the immune system to fight specific diseases.⁷ The immune system targets disease-causing pathogens by generating antibodies, specific molecules that are induced by parts of pathogens called antigens and that target bacteria or other pathogens living outside of cells for elimination.⁸ They also support cell-mediated immunity by activating T-cells, important white blood cells that eliminate pathogen-infected cells.⁹ Vaccines induce these responses through a controlled exposure to pathogen-derived antigens, leveraging the body’s natural mechanisms to build a “memory” of that encounter that fosters immunity.¹⁰ Most modern vaccines contain dead pathogens or antigens that can train the immune system with no risk of infection.¹¹ Some, known as “live-attenuated vaccines,” contain minuscule amounts of a weakened pathogen that the immune system can respond to robustly and eliminate with ease.¹²

⁶ Fangjun Zhou et al., *Health and Economic Benefits of Routine Childhood Immunizations in the Era of the Vaccines for Children Program — United States, 1994–2023*, 73 *Morbidity and Mortality Wkly. Rep.* 682, 683 (2024), <https://tinyurl.com/5d97m2xa>.

⁷ *Vaccines: The Myths and the Facts*, *Am. Acad. of Allergy, Asthma & Immunology* (Jan. 6, 2026), <https://tinyurl.com/5cnh8wdc>.

⁸ Inst. for Quality and Efficiency in Health Care, *In Brief: The Innate and Adaptive Immune Systems*, *Nat’l Ctr. for Biotech. Info.* (Aug. 14, 2023), <https://tinyurl.com/3cf9c6j7>.

⁹ Morgan Coulson, *Vaccines 101: The Basics of Vaccines and Vaccination*, *Johns Hopkins Bloomberg Sch. of Pub. Health* (Feb. 19, 2025), <https://tinyurl.com/mtebcuxt>; *T Cells*, *Cleveland Clinic* (Jan. 17, 2023), <https://tinyurl.com/3cn6b8ey>.

¹⁰ *How Do Vaccines Work?*, *World Health Org.* (Feb. 25, 2025), <https://tinyurl.com/57mjt2sr>.

¹¹ Coulson, *supra* note 9; see also *Immunize.Org, Vaccinations Are Safe: Explaining Why*, <https://tinyurl.com/yrfaz96k> (last visited Feb. 3, 2026).

¹² See *Off. of Infectious Disease and HIV/Aids Policy, Vaccine Types*, *Dep’t of Health & Hum. Servs.* (Dec. 22, 2022), <https://tinyurl.com/tccrwxsk>.

Today’s vaccines build on immunization techniques that have been practiced and honed since antiquity.¹³ For centuries, various societies engaged in “variolation,” a practice that involved the controlled exposure of healthy individuals to the smallpox virus.¹⁴ That method carried health risks, and as science evolved, researchers developed safer and more effective forms of controlled exposure.¹⁵ In 1796, British scientist Edward Jenner developed the first form of “vaccination,” intentionally transmitting the relatively-benign cowpox virus to inoculate patients against the smallpox virus.¹⁶ In the 1870s, French scientist Louis Pasteur developed the first laboratory-produced vaccine to target fowl cholera.¹⁷ In the 1940s, American virologists invented the first influenza vaccine.¹⁸ In the 1950s, Dr. Jonas Salk developed the vaccine against polio.¹⁹ A global vaccination effort by the World Health Organization led to the eradication of smallpox in 1980—bringing vaccination full circle by ending the disease that spurred its invention.²⁰

The nation, and indeed the world, is on the precipice of another public health revolution with groundbreaking vaccine technology.²¹ Newly developed mRNA vaccines use synthetic RNA molecules to generate proteins from specific pathogens that are then targeted by the immune system to generate protective antibodies and T-cell responses.²² This technology is low-cost and

¹³ *A Brief History of Vaccination*, World Health Org., <https://tinyurl.com/3aekrhvm> (last visited Feb. 3, 2026).

¹⁴ *Id.*

¹⁵ *See id.*

¹⁶ *Id.*

¹⁷ *Id.*; *The Final Years 1877-1887*, Institut Pasteur, <https://tinyurl.com/49yf79uw> (last visited Feb. 3, 2026).

¹⁸ *See* World Health Org., *supra* note 13.

¹⁹ *Id.*

²⁰ *Id.*; *see also* Nat’l Found. for Infectious Diseases, *The Triumph of Science: The Incredible Story of Smallpox Eradication* (May 8, 2023), <https://tinyurl.com/wjwwt4tn>.

²¹ *See generally* Annette Prieto et al., *A Brief Overview of Emerging Vaccine Technologies for Pandemic Preparedness*, PubMed Cent. (Dec. 20, 2023), <https://tinyurl.com/jfuy4npr> (discussing the application of modern vaccine technologies for pandemic preparedness).

²² Kai Yuan Leong et al., *Revolutionizing Immunization: A Comprehensive Review of mRNA Vaccine Technology and Applications*, *Virology J.* 2, 9 (Mar. 12, 2025), <https://tinyurl.com/mty9xfcj>.

rapidly deployable, and it enabled the development of some of the vaccines that curbed the COVID-19 pandemic.²³ “Already, mRNA vaccines are being tested for other infectious agents, such as Ebola, Zika virus, and influenza.”²⁴ And because vaccines based on mRNA can be “tailored to target a cancer patient’s unique tumor mutations,” mRNA vaccines are poised to “revolutionize cancer treatment.”²⁵ In a recent study, patients with certain forms of lung cancer or melanoma who received a COVID-19 mRNA vaccine within 100 days of starting immune checkpoint inhibitor cancer treatment had significantly improved survival, suggesting a potential effect of mRNA vaccines in sensitizing tumors to immune-modulated treatments.²⁶

B. Vaccines have saved millions of lives and hundreds of billions of dollars in avoided treatment costs.

These centuries of innovation have yielded extraordinary benefits to health and human life. Vaccination sharply improves “the overall health of our population by reducing the transmission of disease, permanent and temporary disability, and infant mortality.”²⁷ Vaccines against just 14 pervasive diseases have saved an estimated 154 million lives, contributing to a 30-year increase in American lifespan between 1900 and 2000.²⁸ They have halted the spread of diseases that were once leading causes of death and disability—such as smallpox, polio, diphtheria, measles, mumps,

²³ *Id.*; Anthony L. Komaroff, *Why are mRNA Vaccines So Exciting?*, Harv. Health Publ. (Nov. 1, 2021), <https://tinyurl.com/yduc7zw6>.

²⁴ Komaroff, *supra* note 23.

²⁵ Rowan M. Gerety, *Personalized mRNA Vaccines Will Revolutionize Cancer Treatment – If Funding Cuts Don’t Doom Them*, Sci. Am. (Nov. 18, 2025), <https://tinyurl.com/328nf4rk>; Jim Stallard, *In Early-Phase Pancreatic Cancer Clinical Trial, Investigational mRNA Vaccine Induces Sustained Immune Activity in Small Patient Group*, Mem’l Sloan Kettering Cancer Ctr. (Feb. 19, 2025), <https://tinyurl.com/4872ryyt>.

²⁶ Adam J. Grippin et al., *SARS-CoV-2 mRNA Vaccines Sensitize Tumours to Immune Checkpoint Blockade*, 647 Nature 488, 488 (2025), <https://tinyurl.com/bwwv4dr>.

²⁷ See Am. Acad. of Allergy, Asthma & Immunology, *supra* note 7.

²⁸ *Vaccines and Immunization: Vaccine Safety*, World Health Org. (Sep. 23, 2025), <https://tinyurl.com/4syhtxmj>; Hebert et al., *supra* note 2.

and rubella.²⁹ They also contribute to improved secondary health outcomes. Studies have shown that the flu, RSV, and pneumococcal vaccines help reduce the risk of cardiac events in older adults,³⁰ and that the shingles vaccine significantly lowers the risk of dementia.³¹ Vaccines also support childhood developmental health by improving immune memory.³² “The measles vaccine is especially important in this context” because an infection can “damage protective immune memory” for two or three years, increasing susceptibility to a variety of dangerous infections against which the individual previously had immune memory.³³

Vaccines contribute to “herd immunity,” a population’s collective resistance to a disease.³⁴ Achieving herd immunity is critical to protect individuals who cannot receive certain vaccines, such as severely immunocompromised individuals who cannot receive live attenuated vaccines, or those who do not generate sufficiently protective immune responses such as infants or the elderly.³⁵ Moreover, herd immunity is an important step toward eradicating any disease,³⁶ and is difficult or impossible to achieve without widespread vaccination, particularly for diseases with a high rate of infection. For example, 93–95% of the population must be immune to measles to

²⁹ See Callum Brodie, *Vaccines Have Killed Off These Deadly Diseases*, World Econ. F. (Sep. 11, 2017), <https://tinyurl.com/53v6vmd3>.

³⁰ Aliza Rosen, *Vaccines Do More Than Prevent Disease*, Johns Hopkins Bloomberg Sch. of Pub. Health (Nov. 4, 2025), <https://tinyurl.com/mr3sfhfw>.

³¹ Markus Eytting et al., *A Natural Experiment on the Effect of Herpes Zoster Vaccination on Dementia*, 641 *Nature* 438, 440 (2025), <https://tinyurl.com/yc223urx>.

³² Arindam Nandi & Anita Shet, *Why Vaccines Matter: Understanding the Broader Health, Economic, and Child Development Benefits of Routine Vaccination*, Human Vaccines & Immunotherapeutics (Nov. 8, 2019), <https://tinyurl.com/mchesjkz>.

³³ *Id.*

³⁴ *Herd Immunity*, Cleveland Clinic (Oct. 20, 2025), <https://tinyurl.com/yc2pznt8>.

³⁵ *How Herd Immunity Works*, Coll. of Physicians of Phila. (Feb. 23, 2025), <https://tinyurl.com/2rxw9eut>.

³⁶ See Angel Corona, *Disease Eradication: What Does it Take to Wipe Out a Disease*, Am. Soc’y for Microbiology (Mar. 6, 2020), <https://tinyurl.com/y9thmzc7>.

prevent measles outbreaks.³⁷ Reaching and maintaining herd immunity thus “requires trust in science, access to vaccines, and global cooperation.”³⁸

Vaccines are also critically important for reducing healthcare costs.³⁹ Studies examining outbreaks of preventable illnesses have found that the costs of treatment far eclipse the costs of vaccination.⁴⁰ For example, studies conducted in 2022 found that the COVID-19 vaccines saved between \$900 billion and \$1.15 trillion.⁴¹ According to an analysis by the Johns Hopkins Bloomberg School of Public Health, an outbreak of five measles cases could be expected to cost \$325,466.05, while an outbreak of 50 measles cases is estimated to cost \$1,054,336.90⁴²—outlays that can be avoided through the cost-effective provision of vaccines, which are far less expensive than treatment.⁴³ In other words, vaccines are not just a lifesaving innovation but a cost-effective investment in public health.

While countermeasures such as antiviral medications can help individuals fight disease, vaccines are the best tool available to prevent and contain outbreaks. The COVID-19 vaccines applied cutting-edge technology to beat back the most significant pandemic of the last century. Not long after the pandemic tightened its grip, the first Trump Administration announced Operation Warp Speed, a “bold and groundbreaking effort” that facilitated the rapid, multi-disciplinary, multi-sector development of COVID-19 vaccines.⁴⁴ That surge in federal funding supercharged the first mass-produced mRNA vaccines developed to fight COVID-19, which

³⁷ Coll. of Physicians of Phila., *supra* note 35.

³⁸ *Id.*

³⁹ See Zhou et al., *supra* note 6, at 684.

⁴⁰ See Rosen, *supra* note 30.

⁴¹ Stephanie Soucheray, *Report: COVID-19 Vaccines Saved US \$1.15 Trillion, 3 Million Lives*, Ctr. for Infectious Disease Rsch. & Pol’y (Dec. 13, 2022), <https://tinyurl.com/2a85rxa6>; Pratha Sah et al., *Estimating the Impact of Vaccination on Reducing COVID-19 Burden in the United States: December 2020 to March 2022*, 12 J. of Glob. Health 1, 3 (2022), <https://tinyurl.com/57ysz74y>.

⁴² Victoria Willens, *Estimating the Financial Costs of Measles Outbreaks*, Johns Hopkins Bloomberg Sch. of Pub. Health: Int’l Vaccine Access Ctr. (Oct. 28, 2025), <https://tinyurl.com/mwj3pept>.

⁴³ Rosen, *supra* note 30.

⁴⁴ Victor J. Dzau, *Effectiveness of COVID-19 Vaccines Under Operation Warp Speed*, Nat’l Acad. of Med. (Sep. 5, 2025), <https://tinyurl.com/3wekby2d>.

received FDA approval in a year, and were rapidly adapted by vaccine manufacturers to suppress new variants.⁴⁵ Experts estimate that the COVID-19 vaccines prevented 3 million deaths and 18 million hospitalizations in the U.S. between 2020 and 2022.⁴⁶ Similar technology and innovations will be critical to enable society to rapidly respond to a future pandemic. Though estimates vary, some experts place the odds of another deadly pandemic by 2033 at about 30%.⁴⁷

C. Vaccines are safe, effective, and subject to rigorous oversight.

The Secretary and many newly appointed ACIP members have stated that vaccines cause multiple harms, especially to infants and young children, without sound scientific data to justify their claims. They have repeated unfounded claims that vaccines cause autism, and that the small amounts of vaccine ingredients such as aluminum have harmful effects.⁴⁸ They have also insisted that longstanding vaccines are not adequately tested or monitored.⁴⁹ These claims have been soundly rejected by scientific studies.⁵⁰ The side effects of most vaccines are generally “very minor and of short duration,”⁵¹ such as fevers, soreness, and other acute symptoms. In general, more “severe side effects, such as an allergic reaction or a seizure,” only “[r]arely” occur.⁵² And the

⁴⁵ See *Here’s What We Know: The Impact of mRNA Vaccines*, Weill Cornell Med. (Sep. 25, 2025), <https://tinyurl.com/wffkbfu>; Simi V. Siddalingaiah, *Operation Warp Speed Contracts for COVID-19 Vaccines and Ancillary Vaccination Materials*, Cong’l Rsch. Serv. (Mar. 1, 2021), <https://tinyurl.com/4skryzbu>.

⁴⁶ Meagan C. Fitzpatrick et al., *Two Years of U.S. COVID-19 Vaccines Have Prevented Millions of Hospitalizations and Deaths*, Commonwealth Fund (Dec. 13, 2022), <https://tinyurl.com/3397rbbn>.

⁴⁷ See Nita K. Madhav, et al., *Estimated Future Mortality from Pathogens and Pandemic Potential*, Center for Global Development 29 (2023), <https://tinyurl.com/stbkwku5>.

⁴⁸ See, e.g., Rob Stein & Pien Huang, *The CDC Revives Debunked ‘Link’ Between Childhood Vaccines and Autism*, NPR (Nov. 20, 2025), <https://tinyurl.com/27h2v2ky>.

⁴⁹ See, e.g., Lauren Weber & Caitlin Gilbert, *RFK Jr. Says Vaccines Aren’t Tested Enough. Experts Say That’s Baseless*, Wash. Post (Feb. 11, 2025), <https://tinyurl.com/5n6nsmmc>.

⁵⁰ See, e.g., *Fact Checked: There is No Link Between Vaccines and Sudden Infant Death Syndrome*, Am. Acad. of Pediatrics, <https://tinyurl.com/3vaut7yn> (last visited Feb. 3, 2026); *Fact Checked: Vaccines: Safe and Effective, No Link to Autism*, Am. Acad. of Pediatrics, <https://tinyurl.com/3sm2yhpu> (last visited Feb. 3, 2026).

⁵¹ World Health Org., *supra* note 28.

⁵² Mayo Clinic Staff, *Childhood Vaccines: Tough Questions, Straight Answers*, Mayo Clinic (May 28, 2023), <https://tinyurl.com/4xdu5kj8>.

Centers for Disease Control and Prevention (CDC) provides advice on vaccines to avoid for at-risk patients—such as those who are severely immunocompromised or allergic to vaccine components.⁵³

Meanwhile, the benefits of vaccines can “last a lifetime.”⁵⁴ Routine childhood vaccinations “protect children and teens from serious diseases” that could prove debilitating or fatal.⁵⁵ And even when vaccines fail to prevent infections, they give the immune system a head start—ensuring that vaccinated individuals are far less likely to develop severe symptoms, require hospitalization, and die.⁵⁶ The COVID-19 vaccines followed this pattern. Data from September 2023 to January 2024 demonstrate that patients with COVID-19 who have been vaccinated are 50% less likely to face critical illness and 30% less likely to require hospitalization in the first ten months after vaccination.⁵⁷ Additionally, newborns are 54% less likely to be hospitalized if their mothers were vaccinated during pregnancy.⁵⁸

Contrary to the Secretary’s assertions, vaccines are thoroughly tested and validated for safety and efficacy. “The United States has one of the most advanced systems in the world for tracking vaccine safety.”⁵⁹ To receive FDA approval, vaccines must undergo multiple rounds of preclinical safety testing and rigorous clinical trials.⁶⁰ Once a vaccine is approved, its side effects

⁵³ Amy Boulanger, *Vaccines: Who Should Avoid Them and Why*, Healthline (June 21, 2018), <https://tinyurl.com/3xw2jxfz>.

⁵⁴ *Explaining How Vaccines Work*, CDC (Aug. 10, 2024), <https://tinyurl.com/yckdedx5>.

⁵⁵ *Fact Checked: Immunizations Are Essential for Public Health and Child Safety*, Am. Acad. of Pediatrics (Mar. 20, 2025), <https://tinyurl.com/5ec6pz6y>.

⁵⁶ See, e.g., Sara Bergs, *What Doctors Wish Patients Knew About Breakthrough COVID Infections*, AMA (Jan. 20, 2022), <https://tinyurl.com/ad36nffh>; Allison Bartlett, *No, Really, Get a Flu Shot: Frequently Asked Questions About the Flu Vaccine*, UChicagoMedicine (Oct. 2, 2024), <https://tinyurl.com/4kkunh7w>.

⁵⁷ *Benefits of Getting Vaccinated*, CDC (June 11, 2025), <https://tinyurl.com/v8bdvb8v>.

⁵⁸ *Id.*

⁵⁹ Off. of Infectious Disease Prevention and HIV/AIDS Policy, *Vaccine Safety*, U.S. Dep’t of Health & Hum. Servs. (Apr. 29, 2021), <https://tinyurl.com/mr4y2f74>.

⁶⁰ *How Vaccines are Developed and Approved for Use*, CDC (Aug. 10, 2024), <https://tinyurl.com/mpeat9v9>.

are monitored through programs such as the Vaccine Safety Datalink, which cross-references medical data to track adverse events,⁶¹ and the Vaccine Adverse Events Reporting System, which allows doctors and their patients to report potential side effects and adverse events for investigation.⁶² The COVID-19 vaccines are no different. Advances in technology and researchers' experience with other coronaviruses enabled the relatively rapid development of safe, effective vaccines by applying a platform vaccine technology tailored to the SARS-CoV-2 virus that causes COVID-19.⁶³ But while those vaccines used emerging technology, their development was made possible by “three decades of research and large-scale clinical trials” and the preceding centuries of knowledge about disease and vaccination.⁶⁴ These vaccines were “thoroughly tested for safety” and validated through rigorous FDA oversight before they entered mass production.⁶⁵

D. Government support for vaccines is critical to controlling the spread of infectious disease.

The federal government has long supported vaccines. In 1964, the Surgeon General established ACIP under the Public Health Service Act to ensure uniform federal vaccine policies.⁶⁶ ACIP is a federal advisory committee subject to the Federal Advisory Committee Act. 5 U.S.C. § 1001 *et seq.* That act requires committees like ACIP to offer advice that is fairly balanced and not inappropriately influenced by special interests. 5 U.S.C. § 1004(b)(2)–(3). Before a newly

⁶¹ *About the Vaccine Safety Datalink (VSD)*, CDC (Sep. 12, 2025), <https://tinyurl.com/5b7sdx6c>; see also Kristina Fiore, ‘There’s No Conspiracy’: An Inside Look at CDC’s Key Vaccine Safety Database, *MedpageToday* (May 22, 2025), <https://tinyurl.com/nbtmeyrn> (“[T]he VSD has been one of the most valuable tools for detecting true vaccine-related adverse events in the U.S.”).

⁶² See HHS et al., *Vaccine Adverse Event Reporting System (VAERS)*, CDC Wonder (Jan 27, 2026), <https://tinyurl.com/2pmvbudh>.

⁶³ Weill Cornell Med, *supra* note 45.

⁶⁴ *Id.*; see *supra* Section I.A.

⁶⁵ Am. Acad. of Allergy, Asthma & Immunology, *supra* note 7; Joshua M. Sharfstein et al., *The US Regulatory System and COVID-19 Vaccines: The Importance of a Strong and Capable FDA*, *JAMA* (Feb. 15, 2021), <https://tinyurl.com/3uaat93m>.

⁶⁶ 42 U.S.C. § 217a; Cong’l Rsch. Servs., *The Advisory Committee on Immunization Practices (ACIP)*, Congress.gov (Sept. 15, 2025), <https://tinyurl.com/y5h38zua>.

FDA-licensed vaccine reaches the market, the vaccine must undergo ACIP review.⁶⁷ ACIP grounds its decisions in scientific consensus and is required to hold meetings that are open to the public.⁶⁸ Its voting members are “scientific experts *independent* from the federal government and from industry”⁶⁹ who are selected for their clinical, scientific, and public health expertise.⁷⁰ They must “observe the highest standards of impartiality, integrity and objectivity in their deliberations” and make recommendations “driven by available scientific evidence.”⁷¹ Additionally, ACIP formulates its guidance through “work groups” that are designed to include outside, independent leaders in the medical profession.⁷² Leading medical organizations, such as the American Academy of Pediatrics and the Infectious Diseases Society of America, have participated as expert work-group liaison members.⁷³

This deliberative process has made ACIP the foremost authority on vaccine policy, and its recommendations “form the foundation” for American health care and public health policy.⁷⁴ ACIP recommendations become official CDC policy once they are adopted by the CDC director. The vaccine schedule shapes decisions across the healthcare industry, with ripple effects on state public health law and insurance coverage. 42 U.S.C. § 300gg-13(a)(2).⁷⁵ It has a pivotal impact on “the availability and accessibility of vaccines across private and public markets,” shaping how

⁶⁷ CDC, *supra* note 60.

⁶⁸ CDC, Advisory Committee on Immunization Practices Policies and Procedures 7, 14 (June 2022), <https://tinyurl.com/4s5vu57w> [hereinafter ACIP Policy Manual].

⁶⁹ Grace Lee et al., *Former Chairs of the Advisory Committee on Immunization Practices on the Panel’s Role*, Stat10 (Mar. 5, 2025), <https://tinyurl.com/rch2p9h5>.

⁷⁰ *ACIP Charter*, CDC (Dec. 3, 2025), <https://tinyurl.com/3ap36pmu>.

⁷¹ ACIP Policy Manual, *supra* note 68, at 14.

⁷² Ram Koppaka, *When ACIP Abandons Clarity, Public Health Suffers*, HealthAffairs (Nov. 17, 2025), <https://tinyurl.com/2s76py9m> (“Work groups have long been the engines of the ACIP’s rigor.”).

⁷³ ACIP Policy Manual, *supra* note 68, at 18.

⁷⁴ Sarah Moselle & Elif Alyanak, *A Turning Point for US Vaccine Policy? Signals from the June ACIP Meeting*, Avalere Health (June 30, 2025), <https://tinyurl.com/3zrp6tez>.

⁷⁵ *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, Ass’n of State & Territorial Health Off. (June 23, 2025), <https://tinyurl.com/mvutve5z>.

doctors counsel their patients, informing coverage requirements and vaccine quality measures used by payors, and affecting the eligibility of immunizations under the National Vaccine Injury Compensation Program (VCIP).⁷⁶ Broadly, ACIP’s messaging has been instrumental in increasing vaccine uptake, helping Americans achieve the widespread levels necessary for herd immunity and to curb the spread of disease.⁷⁷

II. ACIP’s abrupt reversals of longstanding vaccine recommendations will irreparably harm public health, undermine physicians’ efforts to protect patients, and increase avoidable healthcare costs.

For more than sixty years, ACIP has served as the foremost authority on vaccine policy, making recommendations based on evidence and expert deliberation.⁷⁸ But over the past year, HHS has rapidly reconstituted ACIP with members who lack relevant expertise and have spread misinformation about vaccines. This “abrupt and total dismissal of all ACIP members undermines the integrity and continuity of evidence-based policymaking.”⁷⁹ The newly constituted ACIP has raced to undo science-backed vaccine recommendations without regard for the scientific evidence or reliance interests in existing policy. *See FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) (holding that an agency must “provide a more detailed justification” where “its new policy rests upon factual findings that contradict those which underlay its prior policy[,] or when its prior policy has engendered serious reliance interests”). These actions have disrupted downstream

⁷⁶ Avalere Health, *The Advisory Committee on Immunization Practices: How Evolving Policies and Processes Shape the US Immunization Landscape* 8-10 (2025), <https://tinyurl.com/3zfuzj7s>.

⁷⁷ See Noel T. Brewer et al., *Increasing Vaccination: Putting Psychological Science Into Action*, 18 Psych. Sci. in the Pub. Interest 3 (Apr. 3, 2018), <https://tinyurl.com/286ka9yj>.

⁷⁸ See generally L. Reed Walton, *The History of the United States Advisory Committee on Immunization Practices (ACIP)*, 33 Vaccine 405 (2015), <https://tinyurl.com/yt5s62t5> (providing an overview of ACIP’s history since its inception).

⁷⁹ AAI, *AAI Urges RFK Jr. to Ensure New ACIP Appointments are Grounded in Scientific Expertise and Public Health Experience*, News & Views (June 10, 2025), <https://tinyurl.com/3cxe85km>.

clinical and operational policies, have the potential to undercut insurance coverage, and have already threatened public health.

A. The Secretary has undercut ACIP’s evidence-based process, derailing science-driven vaccine policy and sowing confusion.

The Secretary has undermined ACIP’s credibility as a stable, expert advisory committee by overhauling its membership and reversing longstanding vaccine recommendations. On June 9, 2025, he abruptly announced in a Wall Street Journal opinion piece that he had removed all sitting ACIP members.⁸⁰ In their stead, he repopulated ACIP with known vaccine skeptics, many of whom lacked relevant immunology experience. Compl. ¶ 54. Former CDC Director Susan Monarez testified before Congress that the Secretary “directed [her] to commit in advance to approving every ACIP recommendation regardless of the scientific evidence.”⁸¹ And former CDC Chief Medical Officer Debra Houry testified that important vaccine policy changes were made with no advance notice to ACIP, its advisors, or CDC personnel.⁸²

The newly constituted ACIP has rapidly adopted positions adverse to consensus vaccine science and catalyzed the spread of vaccine misinformation. Shortly after the Secretary’s overhaul, respected advisors were removed without explanation;⁸³ work groups were stranded without agendas or instructions; and liaisons that had participated for years were excluded.⁸⁴ With ACIP comprising individuals who have a history of expressing vaccine skepticism and falsehoods about

⁸⁰ Robert F. Kennedy Jr., *RFK Jr.: HHS Moves to Restore Public Trust in Vaccines*, Wall Street J. (June 9, 2025), <https://tinyurl.com/5b4admrc>.

⁸¹ Kerry Cullinan, *Kennedy Wanted CDC to ‘Rubber Stamp’ His Decisions, Former Officials Tell Senate*, Health Pol’y Watch (Sep. 18, 2025), <https://tinyurl.com/ba6je8e3>.

⁸² Debra Houry, *Restoring Trust Through Radical Transparency: Reviewing Recent Events at the Centers for Disease Control and Prevention and Implications for Children’s Health*, at 5 (Sept. 17, 2025), <https://tinyurl.com/4un5y5d4> (stating that “all of CDC” learned about important vaccine policy changes “from an X social media post”).

⁸³ Associated Press, *CDC Director is Out After Less Than a Month; Other Agency Leaders Resign*, NPR (Aug. 27, 2025), <https://tinyurl.com/msftf2hz>.

⁸⁴ Melody Schreiber, *Threat to US Vaccines as CDC Staff Supporting Key Advisory Panel Laid off*, Guardian (Oct. 27, 2025), <https://tinyurl.com/597as2nv>.

vaccines, misinformation and confusion have disrupted its credible, transparent process. The December 2025 ACIP meeting is a stark example. Before the meeting, there was uncertainty about the committee’s agenda.⁸⁵ During the first day, members noted that language proposed for votes had changed several times—and expressed confusion about the proposed recommendations before ultimately agreeing to a one-day delay in the vote.⁸⁶ During the second day, ACIP approved dramatic changes to the longstanding hepatitis B vaccine recommendation after hearing several presentations that were dominated by misinformation and/or cherry-picked data.⁸⁷ And the leading guest speaker was not a medical expert at all, but a lawyer who has built a career participating in anti-vaccine litigation.⁸⁸

HHS and ACIP have also spread misinformation as part of a broader effort to cast doubt on the safety of vaccines. Among other examples, HHS produced a “Frequently Asked Questions” document that cited two scientific articles for the alleged notion that “studies in pregnant women showed higher rates of fetal loss if vaccination was received before 20 weeks of pregnancy.”⁸⁹ But the cited studies concluded precisely the opposite.⁹⁰ Similarly, the CDC and ACIP suggested that “shared clinical decision-making,” meaning case-by-case individual vaccination decisions with a

⁸⁵ Demetre Daskalakis et al., *CDC’s Vaccine Advisory Panel Faces a Crisis of Its Own Making*, STAT (Dec. 3, 2025), <https://tinyurl.com/2usspjnz>.

⁸⁶ Pien Huang, *CDC Advisers Delay Planned Vote on Hepatitis B Vaccine for Infants*, NPR (Dec. 4, 2025), <https://tinyurl.com/2s4f6ct7>.

⁸⁷ See Laine Bergeson et al., *Relatively Calm Afternoon ACIP Session Still Cauldron of ‘Misinformation, Disinformation, and Information Taken Out of Context’*, Univ. of Minn. Ctr. for Infectious Disease Rsch. & Pol’y (Dec. 5, 2025), <https://tinyurl.com/4496cvbh>.

⁸⁸ Aria Bendix, *Lawyer With Ties to Kennedy Sparks Outcry Over Vaccine Misinformation at CDC Advisory Meeting*, NBC News (Dec. 5, 2025), <https://tinyurl.com/mterfe9k>.

⁸⁹ HHS, *COVID Recommendation FAQ*, Ctr. for Infectious Disease Rsch. & Pol’y 2, <https://tinyurl.com/4r2734y2> (last visited Feb. 3, 2026).

⁹⁰ Sophia Gardner & Lauren Gardner, *HHS Justifies Decision to Stop Recommending Covid Shots During Pregnancy with Studies Supporting the Shot’s Safety*, Politico (June 10, 2025), <https://tinyurl.com/mrcs4fa2>; Kate Yandell, *HHS ‘FAQ’ Distorts Data on COVID-19 Vaccination During Childhood and Pregnancy*, FactCheck.org (Aug. 25, 2025), <https://tinyurl.com/3f2emrtc> (“A closer look at the citations shows that the authors of the document misrepresented the studies’ findings and cited research that itself misused data.”).

health-care provider,⁹¹ is necessary to achieve informed consent.⁹² But as experts have observed, “[d]octors have always been required to obtain informed consent” from patients receiving vaccines.⁹³ This move away from universal vaccine recommendations risks a reduction in vaccine adoption and access.⁹⁴

Leading groups have cautioned that CDC’s actions will “undermine protections against a half-dozen diseases,”⁹⁵ and urged the agency “to recommit to a transparent, evidence-based process that puts children’s health and safety first.”⁹⁶ As Susan Dentzer, President and CEO of amicus APG, emphasized: “It will now be up to the nation as a whole to determine whether we can reassemble a credible federal structure to support public health, or devolve into a competing set of realities and pseudo-realities based on geography and ideology.”⁹⁷ Many health care organizations and the majority of states are now disregarding ACIP’s new vaccine recommendations in favor of those set forth by respected medical societies such as the American

⁹¹ HHS Press Office, *ACIP Recommends COVID-19 Immunization Based on Individual Decision-Making*, HHS (Sep. 19, 2025), <https://tinyurl.com/yc2cbez5>.

⁹² See, e.g., CDC Media Relations, *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus*, CDC (Dec. 16, 2025), <https://tinyurl.com/bde9b2e7>.

⁹³ Rob Stein & Pien Huang, *The CDC Says People Must Consult a Health Professional Before COVID Shot*, NPR (Oct. 6, 2025), <https://tinyurl.com/mss5y7j8> (source brackets omitted).

⁹⁴ See Jess Steier et al., *Informed Consent is Alive and Well—Despite What You’ve Been Told*, UnbiasedScience (Nov. 24, 2025), <https://tinyurl.com/ydu6dj5x> (explaining the steps taken by physicians to achieve informed consent in conversations with patients about vaccines).

⁹⁵ Ali Swenson & Luran Neergaard, *Physicians Slam Move by U.S. to Cut the Number of Vaccines Recommended for Every Child*, Birmingham Times (Jan. 6, 2026), <https://tinyurl.com/wsvysyrj>.

⁹⁶ Sandra A. Fryhofer, *AMA Statement on Changes to Childhood Vaccine Schedule*, AMA (Jan. 5, 2026), <https://tinyurl.com/bnzc22hk>.

⁹⁷ Erin Hemlin, *Launch of West Coast Health Alliance Coalition A Key Step Forward in Science-Driven Public Health, Says America’s Physician Groups*, APG (Sep. 4, 2025), <https://tinyurl.com/bdh9y95u>.

Academy of Pediatrics⁹⁸ or entities like the Vaccine Integrity Project.⁹⁹ States and cities have been forced to form partnerships to evaluate vaccine science and make recommendations.¹⁰⁰ And concerns about the credibility of the government’s vaccine-related news have led private journals to create science-based, trustworthy alternatives.¹⁰¹ These fragmented efforts to educate the public are no substitute for ACIP’s uniform messaging regarding vaccines and their safety.

B. The CDC’s changes to the vaccine schedule could have disastrous effects on public health and serious economic ramifications.

The CDC has made significant changes to the childhood vaccination schedule, reducing the recommended number of vaccines for all children from 18 to 11, while reclassifying other immunizations (based on risk) to “shared-clinical decision making” or “recommended for high-risk groups only.”¹⁰² These include vaccines against rotavirus, hepatitis A, meningococcal disease, influenza, COVID-19, and hepatitis B.¹⁰³ This seismic shift in the vaccine schedule runs counter to the best scientific evidence, has been denounced by experts in the scientific and medical fields, and will imperil the most vulnerable among us.

⁹⁸ See, e.g., Jennifer Kates & Clea Bell, *State Recommendations for Routine Childhood Vaccines: Increasing Departure from Federal Guidelines*, KFF (Jan. 22, 2026), <https://tinyurl.com/2t8dzyt8>; Julia S. Sammons et al., *CHOP’s Response to Recommended Changes to the Childhood Vaccine Schedule*, Children’s Hosp. of Phila. (Jan. 6, 2026), <https://tinyurl.com/4s5ahv7s>.

⁹⁹ See generally Vaccine Integrity Project, *Our History*, Univ. of Minn. (last visited Feb. 3, 2026), <https://tinyurl.com/33ms2ach>.

¹⁰⁰ *Id.*; N.Y.C. Health Dep’t, *Several Northeastern States and America’s Largest City Announce the Northeastern Public Health Collaborative*, NYCHHealth (Sep. 18, 2025), <https://tinyurl.com/msfph4dp>; *Working Together for Public Health*, Governors Pub. Health All. (last visited Feb. 3, 2026), <https://tinyurl.com/54u9wpsr>.

¹⁰¹ Chana A. Sacks et al., *Public Health Alerts – A New Section in NEJIM Evidence, in Partnership with CIDRAP*, New England J. Med.: NEJM Evidence (Dec. 17, 2025), <https://tinyurl.com/7jhzvcbx>.

¹⁰² See Jay Battacharya et al., *Decision Memo: Adopting Revised Childhood and Adolescent Immunization Schedule*, HHS (Jan. 5, 2026), <https://tinyurl.com/yc3z4wa6> (signed Jan. 5, 2026, by Jim O’Neill, Acting Director of the CDC); *CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule*, HHS (Jan. 5, 2026), <https://tinyurl.com/j5j8ztew>.

¹⁰³ See Battacharya et al., *supra* note 102.

The overhaul of the U.S. childhood vaccine schedule is modeled on vaccine practices in Denmark, and makes the U.S. an outlier among peer nations.¹⁰⁴ As one expert has noted, where America’s vaccine schedule is a “jet engine,” Denmark’s is a “toy plane.”¹⁰⁵ Denmark and America have vast differences in population size, disease profile, and healthcare access.¹⁰⁶ Simply put, “Denmark’s schedule is calibrated to Danish realities. Adopting it here would leave American children unprotected against diseases we have spent decades bringing under control.”¹⁰⁷

Indeed, this new vaccination schedule will reinforce a growing trend of patients refusing vaccines and rejecting science.¹⁰⁸ Even before the recent changes, vaccinations have declined at troubling rates,¹⁰⁹ with childhood vaccination rates among the lowest in ten years.¹¹⁰ More families are currently refusing vaccines for preventable diseases, such as measles, mumps, and pertussis.¹¹¹ As HHS endorses misinformation and abandons support for many vaccines, vaccine hesitancy will increasingly “threaten[] our ability to effectively protect communities from vaccine-preventable diseases.”¹¹² That is particularly so for families facing resource barriers—who are already more likely to miss routine immunization and less likely to catch up in a timely manner.¹¹³ Lower

¹⁰⁴ Helen Branswell, *When it Comes to Vaccine Schedules, the U.S. is Now the Outlier*, Stat (Jan. 9, 2026), <https://tinyurl.com/2fyxyr56>.

¹⁰⁵ Demetre C. Daskalakis, *The U.S. Vaccine Schedule is a Jet Engine. Denmark’s is a Toy Plane*, Wash. Post (Dec. 29, 2025), <https://tinyurl.com/3epjkj2d>.

¹⁰⁶ Maria Godoy, *Should the U.S. Model Its Vaccine Policy on Denmark’s? Experts Say We’re Nothing Alike*, NPR (Dec. 26, 2025), <https://tinyurl.com/29w5kash>.

¹⁰⁷ Jake Scott, *Why Denmark’s Vaccine Schedule Works for Denmark – but not for the United States*, Stat (Dec. 19, 2025), <https://tinyurl.com/szfnvt9>.

¹⁰⁸ Amy Maxmen, *How Fringe Anti-Science Views Infiltrated Mainstream Politics — and What It Means in 2024*, KFF Health News (Jan. 29, 2024), <https://tinyurl.com/yvnt8f6e>.

¹⁰⁹ Ron Southwick, *Vaccine Hesitancy: Doctors and Health Systems Face More Skepticism, and They Need New Strategies*, Chief Healthcare Exec. (Aug. 25, 2025), <https://tinyurl.com/3b4727kw>.

¹¹⁰ Maxmen, *supra* note 108.

¹¹¹ *Id.*; *The Dangers of Immunization Refusal*, Regis College (Dec. 5, 2024), <https://tinyurl.com/mstfcpuv> (discussing commonly refused childhood vaccines).

¹¹² Allison Fisher, et al., *Addressing Vaccine Hesitancy in the Age of COVID-19*, 21 Acad. Pediatrics S3, S3 (2021), <https://tinyurl.com/yjh5n9ab>.

¹¹³ See *Ensuring Vaccine Access for All People*, CDC (Oct. 11, 2024), <https://tinyurl.com/y4a5n66v>.

vaccination coverage and weakened community protection increase the risk of outbreaks and preventable illness, which in turn elevates school absenteeism and leads to poor outcomes in academic achievement and educational readiness.¹¹⁴

The effects of declining vaccination are quickly becoming apparent. Experts have warned that “measles, whooping cough and worse [diseases] could roar back,”¹¹⁵ and throughout 2025, long-suppressed, preventable diseases spiked in communities across America. Although the United States had eliminated measles in 2000,¹¹⁶ our nation saw 2,255 confirmed cases of measles and at least 3 related deaths in 2025, two of which were unvaccinated children.¹¹⁷ There is an ongoing measles outbreak in South Carolina, where the state’s department of public health reports that as of early February, 800 of 876 documented measles cases (just over 91%) have been among unvaccinated individuals, with the vaccination status of an additional 38 cases unknown.¹¹⁸ Cases of pertussis—or whooping cough—are trending higher than they have in many years.¹¹⁹ And experts now predict that CDC’s decision related to hepatitis B vaccination may return our nation to pre-1990s infection levels.¹²⁰ The erosion of herd immunity will endanger those who cannot be

¹¹⁴ See, e.g., James C. King Jr. et al., *Direct and Indirect Impact of Influenza Vaccination of Young Children on School Absenteeism*, *Vaccine* (Jan. 5, 2012), <https://tinyurl.com/55u8xssn>; Rachel E. Gicquelais et al., *Association of School-Based Influenza Vaccination Clinics and School Absenteeism—Arkansas, 2012-2013*, *J. Sch. Health* (Apr. 2016), <https://tinyurl.com/236suxhd>.

¹¹⁵ Arthur Allen, *How Measles, Whooping Cough and Worse Could Roar Back on RFK Jr.’s Watch*, NPR (Dec. 6, 2024), <https://tinyurl.com/6s9uhdjw>.

¹¹⁶ Adekunle F. Adeoye et al., *The 2025 United States Measles Crisis: When Vaccine Hesitancy Meets Reality*, 17(7) *Cureus* 1,1 (2025).

¹¹⁷ See, e.g., *Measles (Rubeola): Measles Cases and Outbreaks*, CDC (Dec. 23, 2025), <https://tinyurl.com/bxwnt9t9>; Rene F. Najera, *The Return of Measles: A Global Health Crisis Unfolding in 2025*, *History of Vaccines* (Sep. 30, 2025), <https://tinyurl.com/2nxwz5>.

¹¹⁸ *Measles Dashboard*, S.C. Dep’t of Pub. Health, <https://tinyurl.com/mu6eds6s> (last visited Feb. 3, 2026).

¹¹⁹ *Pertussis Cases by Year (1922-2023)*, CDC (Dec. 2, 2025), <https://tinyurl.com/29d2un7f>; *Pertussis: (Week 53) Weekly Cases* of Notifiable Diseases, United States, U.S. Territories, and Non-U.S. Residents Week Ending January 03, 2026*, CDC (Jan. 3, 2026), <https://tinyurl.com/3y9c6nhz>.

¹²⁰ Chad Terhune, et al., *Kennedy Vaccine Advisers ‘Turned Back the Clock,’ Experts Say*, Reuters (Dec. 7, 2025), <https://tinyurl.com/ytasx54y>.

vaccinated—including infants and the immunocompromised. Infants are particularly vulnerable, as over 90% of infants infected with hepatitis B will develop chronic infection, which can cause lifelong complications, including cirrhosis and hepatocellular carcinoma, as well as death.¹²¹

These changes also have serious economic ramifications. As patients decline vaccines, they may be exposed to disease and treatment costs.¹²² Lower demand may reduce manufacturers' ability to maintain vaccine stock and drive companies from the market.¹²³ Misinformation may also contribute to consumer exploitation and waste. During the COVID-19 pandemic, vaccine hesitancy likely contributed to demand for unproven treatments, driving an estimated \$272 million in wasteful consumer spending between January 2020 and June 2023.¹²⁴

Crucially, misleading federal guidance also frustrates physicians' ability to treat patients, with downstream health effects on families and children. When patients are confused about public health messaging, they turn to their doctors for information and advice.¹²⁵ As a result, doctors must spend more time on counseling and educating patients rather than treatment, limiting the number of patients they are able to treat daily.¹²⁶ Physicians have reported that they are having more, and longer, conversations about vaccinations with patients who have been influenced by prevalent misinformation.¹²⁷ Declining trust in conventional preventative care may also reduce attendance

¹²¹ *Why We Give Hepatitis B Vaccines to Infants*, Nat'l Found. for Infectious Diseases (Oct. 20, 2025), <https://tinyurl.com/3wyyah4j>.

¹²² *See supra* Section I.B (comparing costs of prevention and costs of treatment).

¹²³ Hajra Faha, *Vaccines and Fluctuating Market Conditions*, Vaccine All. (Sept. 16, 2025), <https://tinyurl.com/mvcamve6>.

¹²⁴ Enrique Rivero, *Ivermectin, Hydroxychloroquine Prescriptions During the COVID-19 Pandemic Soared Far Above Pre-Pandemic Levels*, UCLA Health (Feb. 20, 2025), <https://tinyurl.com/572cyt2s>.

¹²⁵ Fisher, *supra* note 112 at S3.

¹²⁶ *See* Southwick, *supra* note 109.

¹²⁷ *Id.*

at pediatric care visits—limiting physicians’ opportunities to prevent, identify, and manage other childhood developmental issues and health conditions.¹²⁸

C. The Secretary’s challenged actions are part of a broader assault on vaccine science that will precipitate a cascade of negative consequences.

The actions challenged here are not isolated: they are part of a broader effort to discredit vaccine science. In November 2025, the CDC edited its webpage entitled “Autism and Vaccines” to add an asterisk and disclaimer: “[V]accines do not cause autism’ is not an evidence-based claim because studies have not ruled out the possibility that infant vaccines cause autism.”¹²⁹ But overwhelming scientific evidence confirms that vaccines do not cause autism.¹³⁰ In December 2025, ACIP recommended ending universal hepatitis B vaccines for infants, even though that vaccine is credited with dramatically reducing perinatal transmission, and overwhelming evidence demonstrates its safety and effectiveness.¹³¹ That same month, the FDA announced new vaccine-testing requirements that experts warn are “impossible” to satisfy, risking dramatic downturns in vaccine availability.¹³² These examples illustrate a broad effort to undercut vaccine science. They will destabilize the evidence-based framework that has supported individual and herd immunity, suppressed preventable diseases, saved lives, and protected the health of millions.

More deleterious changes appear to be on the way. The FDA has indicated that it may revise the annual flu vaccine framework and apply additional warnings to the COVID-19

¹²⁸ See Tina L. Cheng & James M. Perrin, *Launching Lifelong Health by Improving Care for Children, Youth, and Families*, Nat’l Acads. of Sci., Eng’g, and Med. (2024), <https://tinyurl.com/4wfy7syx>.

¹²⁹ Robert Tait, *CDC Website Altered to Reflect RFK Jr’s Belief in Link Between Vaccines and Autism* (Nov. 20, 2025), <https://tinyurl.com/yvw5sr6z>; *Autism and Vaccines*, CDC (Nov. 19, 2025), <https://tinyurl.com/4h86ep8p>

¹³⁰ Am. Acad. of Pediatrics *supra* note 50.

¹³¹ See *supra* Section II.A; Aliza Rosen, *Hepatitis B Vaccination is an Essential Safety Net for Newborns*, Johns Hopkins Bloomberg Sch. of Pub. Health (Sept. 24, 2025), <https://tinyurl.com/5n8htmv6>.

¹³² Liz Szabo, *FDA Official Proposes ‘Impossible’ Standards for Vaccine Testing that Could Curtail Access to Immunizations*, Ctr. for Infectious Disease Rsch. & Pol’y (Dec. 1, 2025), <https://tinyurl.com/zdarb4bx>.

vaccine.¹³³ An internal FDA memo leaked in in late 2025 included plans to tighten immunization standards,¹³⁴ and reports have noted that the FDA might adopt unrealistic approval thresholds and timelines to block new vaccines.¹³⁵ The Centers for Medicare and Medicaid Services has announced that it will no longer require states to report on childhood, adolescent, and prenatal immunization,¹³⁶ a move that could sharply reduce the childhood immunization data necessary to understand trends and problems in vaccine access.¹³⁷ Most significantly, despite the settled science that vaccines do not cause autism, reports indicate that HHS may attempt to allow parents of children with autism to apply for compensation from the Vaccine Injury Compensation Program (VICP).¹³⁸ This would overwhelm VICP and deplete its funds, as about 48,000 children would immediately be eligible to seek compensation¹³⁹ under a program that has processed only about 28,000 claims since its inception in 1988.¹⁴⁰

CONCLUSION

This Court should grant Plaintiffs' motion for a preliminary injunction.

¹³³ Nyah Phengsitthy, *RFK Jr.'s FDA Adds to Agenda Putting Pressure on Vaccine Access*, Bloomberg L. (Jan. 2, 2026), <https://tinyurl.com/4mvw3jww>

¹³⁴ *Id.*

¹³⁵ Lisa Jarves, *The US' Year of Health-Care Chaos Has Consequences: Lisa Jarvis*, Bloomberg L. (Dec. 30, 2025), <https://tinyurl.com/45928nn6>.

¹³⁶ Dan Brillman, *Letter to State Health Officials re: 2027 Updates to the Child and Adult Core Health Care Quality Measurement Sets and Mandatory Reporting Guidance*, Ctr. for Medicare & Medicaid Services 4 (Dec. 30, 2025), <https://tinyurl.com/464drjvb>.

¹³⁷ Liz Szabo, *CMS to Stop Requiring States to Report Childhood Vaccination Levels*, Ctr. for Infectious Disease Rsch. & Pol'y (Jan. 2, 2026), <https://tinyurl.com/47mawcsz>.

¹³⁸ Céline Gounder, *Inside the High-Stakes Battle Over Vaccine Injury Compensation, Autism, and Public Trust*, KFF Health News, (Oct. 6, 2025), <https://tinyurl.com/2ebswf7c>.

¹³⁹ *Id.*; Peter Grossi, *An Outline on How Adding Autism to the National Vaccine Injury Compensation Program Would Likely Destroy It*, 32 Va. J. of Soc. Pol'y & the L. 1, 16 (2025), <https://tinyurl.com/2uzes328>.

¹⁴⁰ Grossi, *supra* note 139, at 16.

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CERTIFICATE OF SERVICE

I certify that the foregoing brief was served on all counsel of record through the court's CM/ECF system.

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