IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*., *Plaintiffs,* vs. 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 District Judge: Hon. William G. Young Magistrate Judge: M. Page Kelley **REQUEST FOR ORAL ARGUMENT**

PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND DECLARATORY RELIEF AND REQUEST FOR EXPEDITED CONSIDERATION

Pursuant to Federal Rule of Civil Procedure 65 and Local Rule 7.1, Plaintiffs 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 (collectively, "Plaintiffs"), by and through their counsel, move this Court for a preliminary injunction and declaratory relief (the "Motion").

Department of Health and Human Services' Secretary, Robert F. Kennedy, Jr. (the "Secretary") issued a directive dated May 19, 2025 (the "Secretarial Directive") rescinding prior evidence-based recommendations that healthy children ages six months to 17 years old be routinely immunized against Covid and directing the CDC to remove Covid vaccines from the recommended Child and Adolescent Immunization Schedule by Age.

Unless the Secretary's baseless and uninformed policy decision is vacated, pregnant women and children remain at grave and immediate risk of contracting serious illness. The Secretary's Directive immediately exposes these vulnerable populations to a serious illness with potentially irreversible long-term effects and, in some cases, death. This is a pressing public health emergency that demands immediate legal action and correction, making Plaintiffs entitled to a preliminary injunction and declaratory relief.

Plaintiffs are likely to succeed on the merits of their claims set forth in the Complaint under 5 U.S.C. § 706(2)(A), (D). Indeed, the Secretarial Directive is arbitrary and capricious under the Administrative Procedure Act (the "APA") because the Secretary abandoned his duty to keep Americans safe and healthy by unilaterally issuing a directive rescinding years' worth of carefully considered, evidenced-based recommendations regarding the safety and effectiveness of the administration of the Covid vaccine to pregnant women and healthy children. The Secretary provided no reasoned explanation for the decision, and it is wholly unsupported by the evidence. In addition, the Secretary contravened his mandate under 42 U.S.C. § 245(a) to carry out a national evidence-based campaign to increase knowledge of and fight misinformation about vaccines and disseminate scientific and evidenced-based vaccine related information when he issued his Secretarial Directive. Therefore, the Directive is also not in accordance with law and must be declared unlawful and set aside under the APA.

In addition, Plaintiffs are facing and will continue to face irreparable harm absent injunctive and declaratory relief. Plaintiffs are individuals and physician and public health associations who live and practice across the United States. Plaintiffs have been irreparably harmed by the Secretary's arbitrary, capricious, and unlawful Secretarial Directive, and without injunctive and declaratory relief, pregnant women and children remain at grave and immediate risk

of series illness or death. Moreover, the Secretarial Directive is forcing physicians to choose between following HHS's recommendations or exposing themselves to professional liability by following the optimal standard of care to protect their patients.

Last, the balance of harms and the public interest greatly weigh in favor of the Plaintiffs. The interest in public safety and protecting our nation's most vulnerable populations—pregnant women and children—greatly outweigh any government interest. In fact, the Secretary's responsibility is to enhance the health and well-being of all Americans, not cause them direct, irreparable harm.

For the reasons set forth in more detail in Plaintiffs' Memorandum of Law in Support of their Motion, declarations, and exhibits, which are incorporated herein by reference, Plaintiffs respectfully request that the Court grant the Plaintiffs injunctive and declaratory relief, vacate the Directive nationwide, and issue an order consistent with the proposed order attached to Plaintiffs' Motion as Exhibit A.

Dated: July 7, 2025

Respectfully submitted,

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LOCAL RULE 7.1 CERTIFICATE REGARDING PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND DECLARATORY RELIEF AND FOR EXPEDITED CONSIDERATION

I, Elizabeth J. McEvoy, certify that on July 7, 2025, I provided a copy of the foregoing to the following individuals to provide notice contemporaneous with filing this motion:

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Prior to filing the motion, I emailed the above-named individuals on behalf of the Defendants to meet and confer on this motion. As of the time of filing, Defendants have not responded. Plaintiffs are proceeding with this filing given the need for prompt relief, as set forth in Plaintiffs' Motion for Preliminary Injunctive and Declaratory Relief and for Expedited Consideration.

CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the ECF system and served upon the following parties by Process Server on this 7th day of July 2025:

Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services

Marty Makary, in his official capacity as Commissioner of the Food and Drug Administration

Jay Bhattacharya, in his official capacity as Director of the National Institutes of Health

Matthew Buzzelli, in his official capacity as Acting Director Centers for Disease Control and Prevention

c/o Leah Belaire Foley, US Attorney
Office of the US Attorney for the District of Massachusetts
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/s/ Elizabeth J. McEvoy (BBO No. 683191)
Elizabeth J. McEvoy (BBO No. 683191)

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al*.,

Plaintiffs,

vs.

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

District Judge: Hon. William G. Young
Magistrate Judge: Hon. M. Page Kelley

REQUEST FOR ORAL ARGUMENT

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND DECLARATORY RELIEF AND REQUEST FOR EXPEDITED CONSIDERATION

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

I. INTRODUCTION

In the short time he has been in office, United States Health and Human Services Secretary Robert F. Kennedy, Jr. (the "Secretary") has recklessly disregarded the statutory and regulatory framework that governs the process for deciding which vaccines are listed on federal immunization schedules upon which the nation's entire healthcare system lies. The Secretary's "Secretarial Directive" dated May 19, 2025 (the "Directive") rescinds and removes Covid-19 (hereinafter, "Covid") vaccine recommendations for pregnant individuals and children from federal immunization schedules. The Secretary provided no evidentiary support for the Directive, and it was issued outside the well-established, required processes for developing and implementing the nation's vaccine recommendations. The Directive is a quintessential arbitrary and capricious agency action, is not in accordance with law, and violates the Administrative Procedure Act. Secretary Kennedy cannot be permitted to override sound public health policy, jeopardize public trust, and place millions of lives at immediate and irreparable risk of severe illness or death.

Through the decades, the executive and congressional branches have worked together to establish a complex statutory and regulatory framework to ensure that vaccine recommendations are developed and modified through careful, transparent, and expert-driven processes—not through unilateral fiat or ideology. The Directive represents a dangerous departure from those critical protections and undermines the very infrastructure designed to prevent the spread of infectious diseases and protect the lives of Americans. Accordingly, this Court should declare the Directive unlawful, vacate it in its entirety, and require the CDC to restore to its immunization schedules the vaccines which the Directive ordered removed.

Plaintiffs American Academy of Pediatrics, American College of Physicians, American Public Health Association, Infectious Disease Society of America, Massachusetts Public Health

Alliance, Society for Maternal-Fetal Medicine (collectively, the "Association Plaintiffs" or individually referred to as an "Association Plaintiff"), and Jane Doe (together with Association Plaintiffs, "Plaintiffs") are an individual and physician and public health associations who have been irreparably harmed by the Secretary's arbitrary, capricious, and unlawful Directive. Without injunctive relief vacating the Secretary's action, pregnant individuals and children face preventable illness and death. For the reasons set forth below, Plaintiffs' motion for preliminary injunction and declaratory relief should be granted.

II. BACKGROUND

A. Processes And Procedures For Developing Vaccination Recommendations

The Department of Health and Human Services ("HHS") oversees the process by which vaccines are approved and recommended. To harmonize this process, it has entrusted the Food and Drug Administration ("FDA") and the Centers for Disease Control and Prevention (the "CDC") to support aspects of vaccine review and recommendation relevant to their respective areas of expertise. Since their inception, vaccines have undergone a rigorous and continued safety and efficacy review in the United States. Initially, the FDA reviews applications to market new vaccines and decides whether to license vaccines for use. 42 U.S.C. § 262(2). Following FDA approval, the Advisory Committee on Immunization Practices (the "ACIP"), an advisory committee subject to the Federal Advisory Committee Act, 5. U.S.C. §§ 1001, *et seq.*, is charged with developing recommendations for whether and how vaccines are listed on the CDC's immunization schedules (the "Schedules").[1] The CDC Director has the authority to adopt ACIP recommendations, and, once approved, the CDC publishes all ACIP recommendations on its

[1] Ex. 1, *The Advisory Committee on Immunization Practices Policies and Procedures*, CDC at 1 (June 2022).

website and in the Morbidity and Mortality Weekly Report ("MMWR").[2] 45 C.F.R. § 147.130(a)(1)(ii). Meanwhile, the FDA, the ACIP, and the CDC continue to monitor and review the vaccines on the immunization schedule to ensure they remain up-to-date and comport with emerging peer-reviewed, evidence-based data and studies.

The centrality of the CDC's immunization schedules 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, which deliberately and repeatedly tie essential public health programs and insurance coverage mandates directly to the CDC's immunization schedules. For example, after voting to recommend the inclusion of a vaccine on the Child and Adolescent Immunization Schedule by Age, the ACIP held a special vote to also include that vaccine in the Vaccines for Children Program ("VFC"), a program which is statutorily mandated to provide all ACIP-recommended vaccines to millions of eligible children, free of cost. 42 U.S.C. § 1396s(e) (specifying that the list of approved vaccines is "the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the" CDC)). Similarly, the Affordable Care Act ("ACA") explicitly prohibits all commercial health insurance plans and Medicaid expansion programs from imposing any cost-sharing requirements for "immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices." 42 U.S.C. § 300gg-13 (a)(2).

Even during the height of the Covid pandemic, the FDA, the ACIP, and the CDC consistently adhered to this established vaccine approval-and-recommendation process.[3] The Directive, however, upends this carefully balanced, evidence-based process.

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[2] *Id.* at 9.

[3] Ex. 2, Summary of Covid Vaccine Approval and Recommendations.

B. Secretary Kennedy's Announcement Of The Rescission Of The Covid Recommendations For Healthy Children And Pregnant Women

The Secretary posted a video on his X social media account on May 27, 2025, directing the removal of the Covid vaccine from the Schedules for "healthy children" and "healthy pregnant women."[4] This came as a shock to the Plaintiffs.[5] The fifty-eight second video features the Secretary, FDA Commissioner Marty Makary, and National Institute of Health ("NIH") Director Jay Bhattacharya. In the video, the Secretary claims that there is a "lack of any clinical data to support the repeat booster strategy in children."[6] He then looked to Commissioner Makary, who stated "there's no evidence healthy kids need it today, and most countries have stopped recommending it for children."[7] None of these leaders, however, directed viewers to *any* evidence supporting these statements.[8]

That same day, Secretary Kennedy issued the Directive, even though it is dated May 19, 2025.[9] The Directive "CDC recommendations" for the use of the Covid vaccine "for children ages six months to 17 years" and for "pregnant women" and directs the CDC to remove these vaccines from the Schedules.[10] Like his X post, the Directive is devoid of any evidence supporting changes to the Schedules. Instead, the Directive states that the Secretary based his decision to rescind these recommendations on review of only unidentified FDA and NIH recommendations that led him to "determine[] that the knowns risks … do not outweigh the benefits of the vaccine."[11] The Directive

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[4] *See* @SecKennedy, X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138.

[5] Ex. 3, Declaration of Jamie Loehr, MD, FAAFP, dated July 6, 2025 ("Dr. Loehr Decl.") at ¶ 10; Ex. 4, Declaration of Jane Doe, MD, dated July 5, 2025 ("Jane Doe Decl.") at ¶ 5.

[6] *See* @SecKennedy, X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138.

[7] *Id.*

[8] *Id.*

[9] Ex. 5, Secretary Kennedy, *Secretarial Directive on the Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women* (May 19, 2025).

[10] *Id.*

[11] *Id.*

does not identify anything else upon which the Secretary based his decision, evidencing that the Secretary did not review or consider the multiple published recommendations from the ACIP that detail their careful and deep analysis of the data regarding the safety and effectiveness of Covid vaccines for these population groups.[12]

On May 29, 2025, the CDC complied with the Directive and removed the Covid vaccine from the CDC's Adult Immunization Schedule.[13] The CDC did not, however, remove its recommendations in the "Vaccine Recommendations Before, During, and After Pregnancy" fact sheet, which—as of the date of this filing—warns that "Covid-19 vaccine recommendations have recently been updated for some populations" but still advises that "[p]regnant women are more likely to get severely ill with COVID-19 compared to women who are not pregnant. If you are pregnant, you should stay up to date on your COVID-19 vaccine."[14]

Further, although the Directive ordered the CDC "to remove Covid-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age," the CDC did not do so. Instead, on May 29, 2025, the CDC updated the Child and Adolescent Immunization Schedule to reflect a "shared clinical decision-making" recommendation for the Covid vaccination, which the CDC had previously classified as a routine vaccination for children.[15] Shared clinical decision-making recommendations ("SCDM") are intended to apply to situations where a broad deployment of a vaccination to an entire population would be inappropriate, but certain individuals, based upon their individual characteristics and preferences, may benefit from the vaccination.[16] Patients are

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[12] *See* Ex. 2, Summary of Covid-19 Vaccine Approval and Recommendations.

[13] Ex. 6, CDC, *Adult Immunization Schedule by Medical Condition and Other Indication* (May 29, 2025).

[14] Ex 7, CDC, *Vaccine Recommendations Before, During, and After Pregnancy* (June 24, 2024).

[15] Ex. 8, CDC, *Child and Adolescent Immunization Schedule by Age* (May 29, 2025).

[16] CDC, *ACIP Shared Clinical Decision-Making Recommendations*, CDC: Advisory Committee on Immunization Practices (ACIP) (Jan. 7, 2025), https://www.cdc.gov/acip/vaccine-recommendations/shared-clinical-decision-making.html.

thus encouraged to discuss vaccines designated with SCDM with their providers. Unlike a "routine" recommendation, which is essentially an unqualified recommendation, a vaccine categorized as SCDM can cause difficulty in obtaining insurance coverage of the vaccination.[17] But, despite the Directive to remove this vaccine entirely from the Schedules, it has not been removed.

During the June 25, 2025, ACIP meeting, the CDC provided a detailed presentation to new members of the ACIP reiterating the importance and effectiveness of administering routine Covid vaccines to children and pregnant women. The presentation contained a wealth of undisputed data that demonstrated the safety of the Covid vaccine for children and pregnant women.[18] Nevertheless, on July 2, 2025, the CDC began wiping its website clean of fact sheets stating that the Covid vaccine is safe during pregnancy. For example, until July 2, 2025, the CDC maintained fact sheets on its website stating: "It is safe to receive an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech), before and during pregnancy."[19] This webpage now directs to a broken weblink.

C. The Devastating Effects Of The Rescission And Removal Of The CDC's Vaccine Recommendations

The Secretary's unilateral changes to the Schedules and chaotic, inconsistent implementation of the Directive on the CDC's website, resulting in an aftermath of mixed

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[17] Some commercial health insurance plans interpret routine and shared clinical decision-making vaccine recommendations on the Schedules as triggering coverage, while other commercial health insurance companies only provide coverage for "required" (*i.e.*, routine) vaccine recommendations. *See, e.g.*, UnitedHealthCare, *UnitedHealthCare Commercial Medical Benefit Drug Policy* at 1 (Dec. 1, 2024) (only providing coverage for immunizations "subject to explicit the ACIP recommendations (e.g., 'should', 'shall', 'is'), and not permissive ('may') recommendations, for routine use"), https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/vaccines.pdf,.

[18] *See generally* Adam MacNeil, *Advisory Committee on Immunization Practices COVID-19 Session*, CDC ACIP Meeting (June 25, 2025), https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/01-MacNeil-COVID-508.pdf.

[19] Ex. 9, CDC, *COVID-19 Vaccination for Women Who Are Pregnant or Breastfeeding* (Sept. 10, 2024).

messages regarding the CDC's vaccine recommendations, have upended the established, evidence-based processes and practices that govern vaccine recommendations that protect human life and public health. For decades, the Schedules have served as a trusted guidepost for healthcare providers and the public, offering vaccine recommendations grounded in rigorous scientific review and providing essential clarity in moments of uncertainty. The Secretary's unilateral directive to alter the Schedules for these vulnerable populations arbitrarily departs from long-standing practices rooted in reliance on data from peer-reviewed, evidence-based, scientific studies, and creates a conflict with the standards of care physicians must follow. As the CDC's presentations and statements from leading federal public health officials confirm,[20] the Directive was issued without reliance on any scientific evidence and without reasonable, rational explanation for this dramatic reversal.

The Declarations attached to this motion from doctors across the country and the individual Plaintiff show the harm that the Directive has caused. The Directive, in combination with the Secretary's other anti-vaccine actions and statements, has damaged the physician-patient relationship. Doctors who do not trust the Directive are faced with the conflict of either meeting their duty of care and recommending the vaccine to pregnant women or healthy children, or complying with a federal Directive that is not based on science and comes from an individual who said under oath that no one should trust his medical advice.[21] This sudden and unsupported action irreparably discredits years of carefully built scientific consensus and recommendations, sows

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[20] *See* Ex. 10, Declaration of Susan J. Kressly, MD, FAAP, dated July 3, 2025 ("Dr. Kressly Decl.") at ¶¶ 11, 20–23; Ex. 11, Declaration of Charlotte Moser, MS (dated July 6, 2025) at ¶ 10; Ex. 3, Dr. Loehr Decl. ¶ 10.

[21] Ex. 10, Dr. Kressly Decl. ¶ 17; Ex. 12, Declaration of Ravi Jhaveri, MD, dated July 5, 2025 ("Dr. Jhaveri Decl.") at ¶ 10; Ex. 13, Declaration of Mary Doherty-O'Shea Gallucci, MD, dated July 3, 2025 ("Dr. O'Shea Decl.") at ¶¶ 9, 17; Ex. 14, Declaration of Shannon Scott-Vernaglia, MD (dated July 7, 2025), at ¶¶ 19.

confusion among providers and patients nationwide, and directly endangers the health of countless pregnant and pediatric patients who depend on timely access to this life-saving vaccine.[22]

D. The Plaintiffs

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 currently provide direct care to infants, children, adolescents, and young adults, in both hospital and outpatient settings.[23]

The American College of Physicians ("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.[24]

The American Public Health Association ("APHA") has promoted public 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.[25]

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[22] *See, e.g.*, Ex. 12, Dr. Jhaveri Decl. ¶ 11; Ex. 13, Dr. O'Shea Decl. ¶¶ 5, 9; Ex. 10, Dr. Kressly Decl. ¶¶ 15, 23; Ex. 15, Declaration of Caroline E. Rouse, MD, dated July 4, 2025 ("Dr. Rouse Decl.") at ¶¶ 2, 8; Ex. 16, Declaration of Robert H. Hopkins, Jr., MD, MACP, dated July 3, 2025 ("Dr. Hopkins Decl.") at ¶¶ 32, 37; Ex. 4, Jane Doe Decl. ¶¶ 9–11.

[23] Ex. 10, Dr. Kressly Decl. ¶¶ 6, 7.

[24] Ex. 17, Declaration of Jason M. Goldman, MD, MACP, dated July 3, 2025 ("Dr. Goldman Decl.") at ¶¶ 7, 8.

[25] Ex. 18, Declaration of Georges C. Benjamin, MD, dated July 3, 2025 ("Dr. Benjamin Decl.") at ¶¶ 8–9.

The Infectious Diseases Society of America ("IDSA") is a professional organizational 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 currently provide direct care to pregnant women, newborns, and children in both hospital and outpatient settings. The 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.[26]

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 field of high-risk pregnancy care through evidence-based practices to optimize maternal and fetal outcomes and assure medically appropriate treatment options are available to all patients.[27]

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.[28]

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[26] Ex. 19, Declaration of Andrew T. Pavia, MD, FAAP, FACP, FIDSA, dated July 4, 2025 ("Dr. Pavia Decl.") at ¶¶ 10, 11, 13.

[27] Ex. 20, Declaration of Sindhu K. Srinivas, MD, MSCE, dated July 7, 2025 ("Dr. Srinivas Decl.") at ¶¶ 3–5.

[28] Ex. 21, Declaration of Carlene Pavlos, dated July 6, 2025 ("Pavlos Decl.") at ¶¶ 3–5.

All Association Plaintiffs have suffered and will continue to suffer greatly because of the Directive. Indeed, the Directive is already undermining physician-patient trust, disrupting essential immunization schedules for patients, creating dangerous confusion in the clinical setting, and forcing physician members to choose between following HHS's recommendations or expose themselves to professional liability by following the standard of care that requires administering previously recommended vaccines for pregnant women, which has been supported by scientific studies for years.[29]

Finally, 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, including patients with Covid or those asymptomatically spreading the virus. Jane Doe is more than 20 weeks pregnant. Although she was vaccinated for Covid before becoming pregnant, her doctors have advised her to get another dose of the vaccine later in her pregnancy to better protect herself and her baby from contracting this deadly disease. Pregnancy increases the risk of severe illness and complications from Covid, including preterm birth and stillbirth. However, with the Secretary's removal of the Covid recommendation for pregnant women, the barriers to access the vaccine have 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.[30]

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[29] Ex. 10, Dr. Kressly Decl. ¶¶ 11, 17; Ex. 17, Dr. Goldman Decl. ¶¶ 28–29; Ex. 18, Dr. Benjamin Decl. ¶ 21; Ex. 19, Dr. Pavia Decl. ¶ 20–21, 25; Ex. 20, Dr. Srinivas Decl. ¶¶ 6–8; Ex. 21, Pavlos Decl. ¶¶ 7–8.

[30] Ex. 4, Jane Doe Decl. ¶¶ 4, 6, 7, 9–10.

E. Harmful Repercussions Of The Secretary's Baseless Directive To Change the CDC Vaccination Recommendations

1. Pregnancy

The FDA, the ACIP, and the CDC have researched and analyzed the safety and effectiveness of Covid vaccination during pregnancy for years, including analysis and consideration of peer-reviewed studies *specifically* investigating the safety and effectiveness of administering Covid vaccinations during pregnancy.[31]

In the MMWR published on December 18, 2020,[32] the CDC referred providers consulting with pregnant patients regarding the Covid vaccination to materials stating, "[i]f pregnant people are part of a group that is recommended to receive a COVID-19 vaccine (e.g., healthcare personnel), they may choose to be vaccinated."[33] Since then, pregnant individuals have consistently been included in broader Covid vaccine recommendations. For example, presentations delivered during the February 2021 meeting of the Advisory Committee on Immunization Practices (ACIP) included information from evidence-based, peer-reviewed studies showing that (1) "pregnant people with COVID-19 have an increased risk of severe illness" and (2) the FDA-approved Covid vaccines were "unlikely to pose a risk to the pregnant person or fetus" because they are inactivated vaccines.[34]

Similar evidence-based, peer-reviewed, scientific research has consistently shown that the Covid vaccine is a safe and effective way to prevent pregnant individuals, who have a higher risk

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[31] Ex. 20, Dr. Srinivas Decl. ¶ 8.

[32] Sara E. Oliver et al., *The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine—United States*, 69 *Morbidity & Mortality Weekly Rep.* 1922, 1923 (Dec. 18, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6950e2.htm.

[33] Ex. 22, CDC, *Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States* (December 30, 2020).

[34] CDC, *Advisory Committee on Immunization Practices Summary Report*, at 67 (February 28–March 1, 2021), https://stacks.cdc.gov/view/cdc/113294.

of severe illness from Covid, from contracting the disease.[35] In fact, at the June 25, 2025, ACIP meeting, CDC staff closely monitoring studies regarding potential adverse effects of administering the Covid vaccine during pregnancy reported that "[a]cross CDC studies, evidence shows NO increased risk of" serious adverse maternal, pregnancy, or infant outcomes resulting from the administration of the Covid vaccine during pregnancy.[36]

By contrast, to date, no data has been presented suggesting that pregnant individuals should not receive Covid vaccines.[37]

2. Children

Since the inception of the Covid vaccine, HHS regulatory agencies, advisory committees, and divisions have engaged in rigorous analyses and conducted extensive reviews of safety and efficacy data for specific age groups to determine whether to recommend administration of the vaccine to children. On June 18, 2022, after years of carefully analyzing the safety and effectiveness data and evaluating the balance of the risks compared to the severity of the disease across all age brackets, the FDA, the ACIP, and the CDC unwaveringly recommended that the Covid vaccine be administered to children ages six months to 17 years old.[38]

The decision to rescind the Covid recommendation for children, issued via the Directive, is in direct opposition with the data the CDC has relied on since its approval of the first Covid vaccination in December 2020. In his Directive, the Secretary stated, "Based on a review of the

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[35] *See* Ex. 11, Moser Decl. ¶ 11; Lakshmi Panagiotakopoulos, *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, CDC ACIP Meeting, at pp. 11, 53 (April 15, 2025) (hereinafter "April 2025 ACIP Covid-19 Presentation"), https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf.

[36] Sarah Meyer, *Update on CDC's COVID-19 Vaccine Safety Monitoring*, CDC ACIP Meeting, at p. 29 (June 25, 2025) (emphasis in original), https://www.cdc.gov/acip/downloads/slides-2025-06-25-26/04-Meyer-COVID-508.pdf.

[37] *Id.*

[38] Ex. 10, Dr. Kressly Decl. ¶ 21.

recommendation of the FDA and National Institutes of Health (NIH), I have determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine. Accordingly, the HHS Secretarial Directives ratifying the CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years and [*sic*] are rescinded" and "the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age…."[39]

Inexplicably, instead of following the Secretary's Directive, the CDC has downgraded the Covid recommendation for all children to SCDM.[40] Notably, no evidence-to-recommendation framework was created, evaluated, or presented to the ACIP for consideration before this change was made.[41]

III. ARGUMENT

A. Preliminary Injunction Standard

To issue a preliminary injunction, the district court considers: "(i) the movant's likelihood of success on the merits of its claims; (ii) whether and to what extent the movant will suffer irreparable harm if the injunction is withheld; (iii) the balance of hardships as between the parties; and (iv) the effect, if any, that an injunction (or the withholding of one) may have on the public interest." *Corp. Techs., Inc. v. Harnett*, 731 F.3d 6, 9 (1st Cir. 2013) (citing *Ross–Simons of Warwick, Inc. v. Baccarat, Inc*., 102 F.3d 12, 15 (1st Cir. 1996)). When the government is a defendant in the suit, the final two factors merge. *Nken v. Holder,* 556 U.S. 418, 435–36 (2009).

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[39] Ex. 5, Secretarial Directive.

[40] Ex. 17, Dr. Goldman Decl., Ex. B at p. 68; Ex. 23, CDC, *Child and Adolescent Immunization Schedule by Age* (July 2, 2025).

[41] *See* Ex. 17, Dr. Goldman Decl. ¶¶ 21–24.

B. The Court Has Jurisdiction over the Legal Claims

1. Article III Standing

"For a legal dispute to qualify as a genuine case or controversy, at least one plaintiff must have standing to sue." *Dept. of Commerce v. New York*, 139 S. Ct. 2551 (2019). Standing requires three elements: (1) an injury in fact that is actual or imminent, not conjectural or hypothetical; (2) caused by a party before the court; and (3) the injury is likely to be redressed by a favorable decision. *Id*. (citing *Davis v. Fed. Elec. Comm'n*, 554 U.S. 724, 733 (2008)); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992).

"[A]n association has standing to bring suit on behalf of its members when: (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977); *see also In re Fin. Oversight & Mgmt. Bd. for Puerto Rico*, 110 F.4th 295, 308 (1st Cir. 2024). Only one member of an organization need have individual standing in order for that organization to satisfy the first *Hunt* factor. *Ass'n of Am. Univs. v. Dep't of Energy*, 2025 WL 1414135, at *8 (D. Mass. May 15, 2025) (citing *Playboy Enters., Inc. v. Pub. Serv. Comm'n of P.R.*, 906 F.2d 25, 34 (1st Cir. 1990)). "Whether an association has standing to sue on behalf of its members 'depends in substantial measure on the nature of the relief sought.' " *Ass'n of Am. Univs. v. Nat'l Sci. Found*., 2025 WL 1725857, at *7 (D. Mass. June 20, 2025) (quoting *Int'l Union, United Auto., Aerospace & Agr. Implement Workers of Am. v. Brock*, 477 U.S. 274, 287 (1986)). Actions seeking declaratory, injunctive, and other forms of prospective relief "have generally been held particularly suited to group representation." *Id*. (quoting *Camel Hair & Cashmere Inst. of Am., Inc. v. Associated Dry Goods Corp*., 799 F.2d 6, 12 (1st Cir. 1986)).

Jane Doe has demonstrated that the Directive has caused her an actual, concrete injury. Jane Doe faces an impossible decision: try to get the Covid vaccine now, if even possible, which will be less beneficial for her unborn baby during the upcoming viral respiratory season, or wait until later in her pregnancy in the hopes that she can access a Covid vaccine to give her baby stronger immunity through viral respiratory season.[42] The Directive states that she should not have access the vaccine at all. Indeed, Jane Doe now faces a dangerous gamble with her and her baby's health because of the Directive.[43] A decision vacating the Directive will redress the life-threatening harm Jane Doe and her unborn child currently face.

The Association Plaintiffs also have standing because each Association Plaintiff's members are suffering irreparable harm absent a decision vacating the Directive. Indeed, each Association Plaintiff attests that its physician and public health members are currently facing an untenable conflict between: (i) following the Secretary's non-evidence-based decision by refusing to provide Covid vaccines for pregnant individuals and children, thereby delivering an inferior standard of care that increases the risk of preventable illness, hospitalization and death, or (ii) recommending and administering the Covid vaccine in violation of the Directive, if they can even obtain for these populations,[44] and risk professional repercussions.[45] Further, all Association Plaintiffs report that their physician members' pregnant and pediatric patients face widespread

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[42] Ex. 4, Jane Doe Decl. ¶ 10.

[43] *Id.* ¶ 11.

[44] *See* Ex. 10, Dr. Kressly Decl. ¶ 17; Ex. 17, Dr. Goldman Decl. ¶ 28; Ex. 18, Dr. Benjamin Decl. ¶ 21; Ex. 19, Dr. Pavia Decl. ¶ 24; *see also* Ex. 16, Dr. Hopkins Decl. ¶ 32 (stating that, as of the date of his declaration, Dr. Hopkins is unable to order the Covid vaccine for children eligible for the VFC program); Dr. Scott-Vernaglia Decl. ¶¶ 13–19 (stating that, the pediatric clinic she works in has run out of Covid vaccines to give to distribute to pediatric patients; including one patient who could not receive a Covid vaccine at the patient's wellness appointment in June 2025 and had to return with his family on another day when the clinic was able to obtain more doses, causing harm and disruption to his family); Ex. 24, Declaration of Regina LaRocque dated July 5, 2025 ("Dr. LaRocque Decl.") at ¶¶10, 13; Ex. 25, Declaration of J. Edward Johnson dated July 7, 2025 ("Johnson Decl.") at ¶¶ 26, 32.

[45] Ex. 10, Dr. Kressly Decl. ¶¶ 17; Ex. 13, Dr. O'Shea Decl. ¶¶ 9–10; Ex. 17, Dr. Goldman Decl. ¶ 28.; Ex. 18, Dr. Benjamin Decl. ¶ 21; Ex. 19, Dr. Pavia Decl. ¶ 24, 25; Dr. Scott-Vernaglia Decl. ¶¶ 20–22; Ex. 24, Dr. LaRocque Decl. at ¶¶11-13; Ex. 25, Johnson Decl. at ¶¶26, 32.

confusion regarding whether they can receive the Covid vaccine, frustrating members' ability to consult with their patients and eroding patients' trust in vaccine recommendations across the board, not just the Covid vaccine.[46] As the Association Plaintiffs' members practice nationwide, group representation is thus suitable for this case.[47] Therefore, absent an order vacating the Directive, Plaintiffs Associations and the patients that their members are responsible for protecting will continue to experience preventable illness, hospitalizations, and death. Consequently, Plaintiffs have standing to sue.

2. APA Standing and Jurisdiction

This Court has jurisdiction to hear this case under the Administrative Procedure Act ("APA"), which provides that any "person suffering legal wrong because of agency action . . . is entitled to judicial review thereof" where they are "seeking relief other than money damages." 5 U.S.C. § 702. Because Plaintiffs seek equitable relief enjoining final agency action, the APA provides for judicial review in district court. *See generally* 5 U.S.C. § 704; *Bowen v. Massachusetts*, 487 U.S. 879 (1988).

"Before proceeding to judicial review, the court must ensure the agency action is considered 'final' and thus ripe for review." *Massachusetts v. Nat'l Inst. of Health*, 770 F. Supp. 3d 277, 303 (D. Mass. 2025) (citing 5 U.S.C. § 704). An agency action is final if it (1) marks the consummation of the government's decision-making process and is not "merely tentative or

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[46] *See* Ex. 10, Dr. Kressly Decl. ¶¶ 13, 15; Ex. 13, Dr. O'Shea Decl. ¶ 6; Ex. 19, Dr. Pavia Decl. ¶¶ 2,8; Ex. 12, Dr. Jhaveri Decl. ¶ 11; Ex. 15, Dr. Rouse Decl. at ¶¶ 2,8; Ex. 17, Dr. Goldman Decl. ¶¶ 28, 30; Ex. 18, Dr. Benjamin Decl. ¶¶ 21–23; Ex. 10, Dr. Kressly Decl. ¶ 23–24; Dr. Scott-Vernaglia Decl. ¶ 20; Ex. 24, Dr. LaRocque Decl. at ¶10.

[47] *See* Ex. 10, Dr. Kressly Decl. ¶ 7; Ex. 18, Dr. Benjamin Decl. ¶ 9; Ex. 17, Dr. Goldman Decl. ¶ 7; Ex. 19, Dr. Pavia Decl. ¶ 13. Moreover, should Defendants argue, or the Court have any doubt, the Supreme Court's recent decision in *Trump v. CASA, Inc.*, does not apply to the relief the Plaintiffs seek in this case under 5 U.S.C. § 706(2) to vacate the May 19 Secretarial Directive. *Trump v. CASA, Inc.*, 2025 WL 1773631, at *8 n.10 (U.S. 2025) ("Nothing we say today resolves the distinct question whether the Administrative Procedure Act authorizes federal courts to vacate federal agency action." (citing 5 U.S.C. § 706(2) (authorizing courts to "hold unlawful and set aside agency action")).

interlocutory" and (2) is an action "from which rights and obligations have been determined, or from which legal consequences will flow." *Id.* (quoting *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997)).

The Directive is the authoritative pronouncement of HHS's recommendations pertaining to the administration of the Covid vaccination to (1) children between the ages of six months and 17 years old and (2) pregnant people. Nothing in the Directive indicates that it is tentative or subject to further review, nor is it an abstract policy statement. Indeed, on May 29, 2025, the CDC changed the Child and Adolescent Immunization Schedule by Age and the Adult Immunization Schedule by Age in response to the Directive.[48] This directly informs ACA coverage requirements and dictates the standard of care the CDC promotes and recommends to providers administering vaccinations.

C. Plaintiffs Have Established A Substantial Likelihood Of Success On The Merits

1. The Secretary's Action Is Arbitrary And Capricious.

Under the APA, agency action must be set aside where it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The Directive falls well within this standard.

An agency's action is arbitrary and capricious if it "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. Assn. of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983).

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[48] *See* Ex.8, CDC, *Child and Adolescent Immunization Schedule by Age* (May 29, 2025); Ex. 6, CDC, *Adult Immunization Schedule by Age* (May 29, 2025).

Courts must ensure that an agency's decisions "are founded on a reasoned evaluation of the relevant factors" by "carefully reviewing the record and satisfying itself that the agency has made a reasoned decision." *Id.* (quoting *Massachusetts v. Nat'l Inst. of Health*, 2025 WL 702163 at *16 (D. Mass. Mar. 5, 2025)).

The APA serves as a check against executive authority and the unelected administrators "whose zeal might otherwise have carried them to excesses not contemplated." *Loper Bright Enters. v. Raimondo*, 603 U.S. 369, 391 (2024) (quoting *United States v. Morton Salt Co.*, 338 U.S. 632, 644 (1950)). Ultimately, the APA cabins federal agencies within the confines of accountability to the public and the courts. *See Am. Pub. Health Ass'n v. Nat'l Inst. of Health*, Case No. 1:25-cv-10814-WGY, ECF No. 163 at *78 (D. Mass. July 2, 2025).

The following factors illustrate the serious flaws in the Directive, rendering it arbitrary and capricious and inconsistent with the law.

a. The Secretary's Directive Lacks Reasoned Decision-Making Or An Explanation For The Change In Position.

Agency action must be reasonable and reasonably explained to withstand scrutiny under the arbitrary and capricious standard. *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). While arbitrary and capricious review is narrow, it does demand that an agency *engage* in some reasoned decision-making. *Am. Pub. Health Ass'n*, Case No. 1:25-cv-10814-WGY, ECF No. 163 at *83. At bottom, arbitrary and capricious review is a search for some satisfactory explanation for the agency's action. *Id.* (quoting *Ohio v. E.P.A.*, 603 U.S. 279, 292 (2024)).

The Directive fails to meet this low bar and lacks any "genuine justification" or reason that the courts and the public can scrutinize. *Dep't. of Comm.*, 588 U.S. at 785 (2019). Indeed, data the CDC presented to the ACIP on June 25, 2025, directly contradicts the Secretary's assertions in his

May 27, 2025, announcement.[49] Moreover, the Directive is devoid of any citations to a single peer-reviewed study or any research, data, or findings to support or substantiate the Secretary's determination that the Covid vaccine is not necessary for children or pregnant women. This failure is egregious, not only in light of the scourge of deaths Covid has caused since 2020, but also because it is directly at odds with years' worth of carefully considered, evidenced-based ACIP recommendations regarding the safety and effectiveness of the administration of the Covid vaccine for pregnant women and healthy children and because it overtly contradicts the standard of care that physician members have followed since the CDC's approval of the Covid vaccination.[50]

This stark contrast highlights the Secretary's failure to "examine the relevant data and articulate a satisfactory explanation" for his action, "including a rational connection between the facts found and choices made." *State Farm*, 463 U.S. at 43 (cleaned up); *see also Am. Ass'n. of Colls. For Teacher Educ.*, 2025 WL 833917, at *21 (use of boilerplate corroborates that agency failed to "consider individual, or any, data or information," in violation of the APA). The Secretary makes no effort to grapple with or address these inconsistencies and realities, and he offers no reasons for his action. *Fox v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). Instead, the Directive operates as though the evidence to the contrary does not exist. There is no satisfactory explanation for this action or rational connection between the objective facts and the Directive's rescission and removal of Covid vaccine recommendations, as required to survive arbitrary and capricious scrutiny. *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 591 U.S. 657, 682–83 (2020); *see also Penobscot Air Servs., Ltd. v. FAA*, 164 F.3d 713, 719 (1st Cir. 1999).

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[49] *See* April 2025 ACIP Covid-19 Presentation, *supra* note 35, at pp. 11, 53.

[50] Ex. 18, Dr. Benjamin Decl. ¶¶ 17, 18, 21; Ex. 12, Dr. Jhaveri Decl. ¶¶ 7, 10; Ex. 15, Dr. Rouse Decl. ¶ 8; Ex. 13, Dr. O'Shea Decl. ¶¶ 1, 4, 9.

The Directive offers nothing for this Court or the public to credibly weigh to determine the sufficiency of the reasoning or underpinnings of the Secretary's decision. This leaves no basis to ensure that the Secretary acted within a "zone of reasonableness" and compels the conclusion that the Secretary did not "reasonably consider[] the relevant issues and reasonably explain[] the decision," strongly signaling that the Secretary's actions are arbitrary and capricious. *Federal Commc'ns Comm'n. v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

For these same reasons, the Directive also fails arbitrary and capricious review because it did not articulate or explain the drastic change in agency position or policy. While an agency may modify its policies, the APA "ordinarily demand[s] that [the agency] display awareness that it *is* changing position" and "show that there are good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). While the Secretary may have acknowledged the former, he has not addressed the latter.

For years, the federal government has included the Covid vaccine on the Schedules for children and pregnant women.[51] The Association Plaintiffs have relied on and grown to trust the scientific, evidence-based process and procedure which the ACIP, historically comprised of genuine subject-matter experts, has followed for years in order to make recommendations for the Schedules. In one fell swoop, the Directive has destroyed the trust that the Association Plaintiffs have had in the ACIP recommendation process and the resulting CDC Schedules.[52]

The Directive upends this longstanding practice without any "reasoned analysis for the change." *See State Farm*, 463 U.S. at 42. Moreover, the Directive rests on assertions that contradict prior HHS policy, evincing a lack of decision-making premised on the application of agency

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[51] *See* Ex. 2, Summary of COVID-19 Vaccine Approval and Recommendations.
[52] Ex. 10, Dr. Kressly Decl. ¶¶ 19–20; Dr. Pavia Decl. ¶¶ 14–16; Dr. Goldman Decl. ¶¶ 9–12.

expertise. *A.M. L. Int'l., Inc. v. Daley*, 107 F.Supp.2d 90, 97 (D. Mass. Jul. 28, 2000). Neither the Directive nor the Secretary's announcement on X describe *why* this change in agency policy is occurring; rather, this change rests entirely on unsupported, conclusory assertions that "healthy kids" and "healthy pregnant women" don't need the Covid vaccine.[53] This departure from years of public health policy without any supporting evidence is precisely the type of "inscrutable reasoning" that is "facially irrational," *Marasca & Nesselbush, LLP v. Collins*, 6 F. 4th 150, 173 (1st Cir. 2021), or "devoid of data or any independent explanation," *Rhode Island v. Trump*, 2025 WL 1303868, at *11 (D. Mass. May 6, 2025).

Finally, the Directive is arbitrary and capricious for lack of reasoned decision-making because it is an impermissible pretext for nothing more than naked partisan politics. *Dep't of Comm. v. New York*, 588 U.S. 752, 785 (2019). The Secretary closed his remarks on X by tying his directive back to the "Make America Healthy Again" ("MAHA") initiative, a political movement that intentionally echoes and parallels the political slogan, "Make America Great Again" ("MAGA").[54] As part of this MAHA initiative, the Secretary has repeatedly promoted his personal anti-vaccination viewpoints, stacked the ACIP and HHS leadership with persons who agree with his view on vaccines, and now, with the Directive, changed the CDC Schedules with no reasoned explanation or support.

Although political considerations may influence agency actions, this cannot substitute or displace the requirement for reasoned decision-making. *See Dep't of Homeland Sec'y v. Regents of the Univ. of Cal.*, 591 U.S. 1, 16 (2020) (observing that engaging in reasoned decision-making is a necessary component to agency action). Formulating agency action based on political

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[53] *See* @SecKennedy, X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138.

[54] *Id.*

motivations alone is no different from taking agency action for pretextual reasons, as prior administrations have attempted. *See Dep't of Comm.*, 588 U.S. at 782–85. Even a political body such as Congress could not have intended for something as critical as national public health policy to be based on reasonless pretext. *State Farm,* 463 U.S. at 43. In this instance, the Directive fails because the unsupported and unfounded statements he offers to justify his action are nothing more than a pretext to fulfill a politically-motivated end.

b. The Secretary Failed To Consider Important Aspects Of How Changes To The National Vaccine Schedule Would Impact The Health Care Industry.

The Directive is arbitrary and capricious because it failed to consider important issues relevant to the longstanding national and state statutory and regulatory framework surrounding decisions regarding the CDC's immunization schedules for adults and children. Agency action cannot ignore or fail to consider important aspects of the problem sought to be remedied. *State Farm*, 463 U.S. at 43. By issuing this Directive and changing the Schedules, the Secretary set into motion a policy that stands to disrupt multiple aspects of the American health care ecosystem.

The Schedules and their recommendations have wide-ranging effects far beyond who is able to be vaccinated and when. The complex landscape of federal and state laws that govern American health care rely on the Schedules to inform many aspects of operations. For example, while VFC providers are required to vaccinate eligible patients according to the Schedules, these providers are only required to stock vaccines designated as "routine."[55] The Directive removing the Covid vaccine from the routine child and adolescent immunization schedule, and the reclassification of the vaccine to SCDM, thus jeopardizes access to the vaccine for children in the

[55] CDC, VFC Operations Guide, at p. 82 (July 1, 2024), https://www.cdc.gov/vaccines-for-children/media/pdfs/2024/08/vfc-ops-guide_version-4.0_july-2024_low-res-508-rev-2.pdf.

VFC program. Further, the rescission of vaccination recommendations directly impacts whether the CDC is required to contract for the procurement and distribution of vaccines covered under the VFC program. *See* 42 U.S.C. § 1396s(e) ("The Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices."). Similarly, the Schedules affect health insurance cost-sharing obligations under the ACA. Children and pregnant women who once were able to access a vaccine free of charge or without difficulty will now face potential out-of-pocket expenses or an outright inability to receive Covid vaccinations because of the Directive.

The APA requires the Secretary to consider these reliance interests, the ways in which his action could necessitate changes throughout the nation's health care system, and to explain why such a sudden change in policy is warranted. *See FDA v. Wages & White Lion Invs., LLC*, 145 S.Ct. 898, 916-19 (2025). The Secretary has offered nothing indicating that HHS took into consideration *any* of these foreseeable, well-documented public health implications that the Directive directly impacts. This conduct is *precisely* why the APA dictates that, "[w]hen an agency changes course . . . it must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account.'" *Dep't. of Homeland Sec.*, 591 U.S. at 30 (cleaned up) (quoting *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 212 (2016)). Instead, the Directive stands to unleash significant consequences for the Association Plaintiffs, the Association Plaintiffs' members, and the patients whom they serve, including Jane Doe.

c. The Directive Fails Because It Is Contrary To Evidence.

Perhaps the most glaring flaw in the Directive is its conflict with real-world facts and evidence. The scientific and medical communities—and the CDC itself—all hold to and

promulgate evidence-based recommendations that directly contradict the thin rationale for changing the Schedules.

Determining if agency action is reasonable is measured by what the agency did rather than by what it might have done. *Am. Pub. Health Ass'n*, Case No. 1:25-cv-10814-WGY, ECF No. 163 at *84 (quoting *Green & Health Home Initiatives, Inc. v. E.P.A.*, 2025 WL 1697463, at *20 (D. Md. June 17, 2025)). Conclusory statements are an insufficient basis for agency action, *Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014) (quoting *Butte Cnty., Cal. v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010)), and the court's inquiry is limited to the agency's contemporaneous, then-existing explanation in light of the existing record, *Dep't of Comm.*, 588 U.S. at 780.

In his video announcing the recission and removal of well-established CDC vaccine recommendations, the Secretary proclaimed that there isn't "any clinical data to support the repeat booster strategy in children."[56] Commissioner Makary reiterated this assertion by stating "there's no evidence healthy kids need it today, and most countries have stopped recommending it for children."[57] None of these leaders, however, directed viewers to *any* evidence supporting these statements.[58] And a robust body of evidence directly contradicts these assertions and demonstrates the safety, efficacy, and importance of maternal and childhood vaccination against Covid.

To illustrate: the Secretary claimed that "the known risks associated with the use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine," and that vaccination during pregnancy poses potential risks to

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[56] *See* @SecKennedy, X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138.

[57] *Id.*

[58] *Id.*

both the pregnant woman and her unborn child.[59] There is no—nor has there ever been—any scientific, evidence-based analyses or peer-reviewed studies supporting either of these assertions. First, these propositions stand directly at odds with the research and findings underlying the professional guidelines that the Association Plaintiffs and their members have developed and followed to ensure safe, reliable care and treatment to their patients.[60] This is the same body of evidence that has come to shape and set the standard of care for these patients since the Covid vaccine became available. Second, the Secretary's assertions are contradicted by the CDC's own data, research, and fact sheets, demonstrating that the Directive and the Secretary's statements are also at odds with the very experts and professionals under his leadership charged with researching and analyzing these exact issues.

This tension between reality and the Secretary's words illustrates exactly the kind of incongruency that led the U.S. Supreme Court to overrule agency action under arbitrary and capricious review in *Department of Commerce v. New York*. *Department of Commerce*, and it is the same disconnect that moved courts to find against the government in similar proceedings. *See Dep't. of Comm.*, 588 U.S. at 785 (observing the incongruency between the stated reasons for agency action and the record before the Court); *Am. Pub. Health Ass'n*, Case No. 1:25-cv-10814-WGY, ECF No. 163 at *87. As the Supreme Court has explained, judicial review of agency action is deferential, but it is not bound by naivete. *Dep't. of Comm.*, 588 U.S. at 785 (quoting *United States v. Stanchich*, 550 F.2d 1294, 1300 (2nd Cir. 1977)). Just as in *Department of Commerce*, the Directive and the Secretary's statements ask this Court to accept contrived reasons empty of

[59] Ex. 5, Secretarial Directive.

[60] Ex. 20, Dr. Srinivas Decl. ¶ 5, 8; Ex. 19, Dr. Pavia Decl. ¶¶ 14–17, 24; Ex. 17, Dr. Goldman Decl. ¶¶ 9–11, 23, 27; Ex. 10, Dr. Kressly Decl. ¶¶ 18–22.

any concrete evidence. This Court should follow in the footsteps of others and decline to acquiesce to the blindness of the Secretary's wishes imposed on the public.

2. The Secretary's Action Was Not In Accordance With Law And Exceeds The Secretary's Authority.

The Directive removing the Covid vaccine from the Schedules is contrary to law and should be vacated pursuant to 5 U.S.C. § 706(2)(A). As described above, the process—if there even was one—that led to the Directive suffers from multiple flaws. First, the Secretary abandoned the long-established statutory and regulatory framework that governs how the ACIP conducts, reviews, and makes recommendations for the Schedules, subject to CDC approval, without providing any rationale for doing so. *See, e.g., Morton v. Ruiz,* 415 U.S. 199, 235 (1974). Second, the Secretary failed to provide any reasons for the change in HHS's position on the safety and efficacy of Covid vaccinations, which itself contradicts the FDA's determination that the vaccine is safe and effective. This alone does not pass muster under *State Farm* and subsequent caselaw because there is no rational connection between the Directive and the peer-reviewed, clinical evidence by the FDA when it approved the vaccine as safe and effective. Third, by failing to demonstrate any good reasoning for the change in policy, the Secretary ignores the basic teachings of the Supreme Court in *Fox Television Stations* and *Wages and White Lion Investments*.

Finally, by reversing the existing Covid vaccination recommendations without providing a justification based on clinical evidence or a consensus of professional medical opinion, the Secretary's action contravenes the plain intent of Congress to have the Secretary "increase awareness and knowledge of the safety and effectiveness of vaccines for the prevention and control of diseases, [and] combat misinformation about vaccines . . . ." 42 U.S.C. § 245. Unfounded by evidence-based science about vaccine safety and efficacy, the Directive furthers vaccine misinformation and will dangerously decrease the vaccination rate for Covid in children ages 6

months through 17 years and pregnant women, increasing the risk of infection, disease, and death in those populations.[61]

Because the Directive is not the result of properly-exercised Congressional authority, it is plainly contrary to law and must be set aside. *See e.g.*, *Health Ins. Ass'n of Am., Inc. v. Shalala*, 23 F.3d 412, 416 (D.C. Cir. 1994) (explaining that a court may not accept "the agency's policy judgments. . . if they conflict with the policy judgments that undergird the statutory scheme"); *Texas v. Becerra*, 89 F.4th 529, 541 (5th Cir. 2024) (upholding injunction against HHS enforcing guidance it promulgated beyond its statutory authority); *Tex. Med. Ass'n v. U.S. Dep't of Health & Human Servs.*, 110 F.4th 762, 774, 779–80 (5th Cir. 2024).

If there is any lodestar in administrative law, it is that agencies are bound by the laws they implement and cannot rewrite or ignore them. *See, e.g., West Virginia v. EPA,* 142 S. Ct. 2587, 2609 (2022) ("Agencies have only those powers given to them by Congress, and 'enabling legislation' is generally not an 'open book to which the agency [may] add pages and change the plot line.'" (quoting E. Gellhorn & P. Verkuil, *Controlling ChevronBased Delegations*, 20 Cardozo L. Rev. 989, 1011 (1999)); *City of Arlington v. FCC,* 569 U.S. 290, 297 (2013) ("No matter how it is framed, the question a court faces when confronted with an agency's interpretation of a statute it administers is always simply, whether the agency has stayed within the bounds of its statutory authority"). By abandoning the will of Congress, the Directive is plainly contrary to law.

D. Plaintiffs Will Suffer Irreparable Harm Absent Injunctive Relief

Plaintiffs are suffering, and will continue to suffer, irreparable harm absent relief from the Court vacating the Directive. As Americans watched the Covid pandemic unfold, Association

[61] *See* Ex. 19, Dr. Pavia Decl. ¶ 24; Ex. 17, Dr. Goldman Decl. ¶ 29; Ex. 15, Dr. Rouse Decl. ¶ 2; Ex. 16, Dr. Hopkins Decl. ¶ 33, 35.

Plaintiff members were the front-line workers serving our country and risking their own lives to prevent death and stop the deadly disease. Once vaccines against Covid were licensed and recommended for use ***by the ACIP***, Association Plaintiff members worked tirelessly to study and administer the vaccines, promote their efficacy at curbing severe illness and death, and set clinical guidelines recommending vaccination of their patients, like children and pregnant women, consistent with the evidence.[62] The Directive reverses the progress made, leaving some of our most vulnerable populations—children and pregnant women—afraid, misinformed, and at increased risk of preventable illness and death.[63]

Association Plaintiffs' members report that the Directive is undermining patient trust, interfering with the practice of medicine according to best practices, disrupting essential immunization schedules for patients, creating dangerous confusion in the clinical setting, and forcing doctors to choose between following HHS's recommendations or following the optimal standard of care to protect their patients.[64] Either option exposes them to a heightened risk of professional liability. Further, the Directive frustrates clinicians' and other public health members' ability to consult with individuals and their families or advise those communities regarding the effectiveness of vaccination at preventing serious illness and death.[65] Because of vaccine hesitancy and loss of trust that the Directive has created, Association Plaintiffs' members are required to

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[62] *See* Ex. 10, Dr. Kressly Decl. ¶¶ 20–21; Ex. 12, Dr. Jhaveri Decl. ¶¶ 6–7, Ex. 19, Dr. Pavia Decl. ¶¶ 14–17; Ex. 15, Dr. Rouse Decl. ¶¶ 10–13; Ex. 18, Dr. Benjamin Decl. ¶¶ 10–13; Dr. Goldman Decl. ¶¶ 9–11, 13–16.

[63] Ex. 20, Srinivas Dec. ¶ 7; Ex. 4, Jane Doe Decl. ¶ 7; Ex. 12, Dr. Jhaveri Decl. ¶¶ 9–11; Ex. 19, Dr. Pavia Decl. ¶¶ 23–30; Ex. 15, Dr. Rouse Decl. ¶¶ 8–11, 14; Ex. 18, Dr. Benjamin Decl. ¶¶ 19, 21–23; Ex. 17, Dr. Goldman Decl. ¶¶ 28–33; Ex. 13, Dr. O'Shea Decl. ¶¶ 5–6; Ex. 16, Dr. Hopkins Decl. ¶¶ 23–24, 33–35; Ex. 10, Dr. Kressly Decl. ¶¶ 12–14.

[64] Ex. 18, Dr. Benjamin Decl. ¶ 21; Ex. 12, Dr. Jhaveri Decl. ¶ 10; Ex. 15, Dr. Rouse Decl. ¶ 8; Ex. 17, Dr. Goldman Decl. ¶¶ 27–29; Ex. 13, Dr. O'Shea Decl. ¶¶ 4, 8–10; Ex. 10, Dr. Kressly Decl. ¶ 17.

[65] Ex. 18, Dr. Benjamin Decl. ¶ 22; Ex. 10, Dr. Kressly Decl. ¶ 12; Ex. 12, Dr. Jhaveri Decl. ¶11; Ex. 19, Dr. Pavia Decl. ¶¶ 24, 27–29; Ex. 17, Dr. Goldman Decl. ¶¶ 31, 33.

spend more time correcting vaccine misinformation with patients regarding the effectiveness of the Covid vaccines and other vaccines.[66]

Moreover, Jane Doe's impossible position, which forces her to gamble with her own and her baby's health, is putting needless stress and anxiety on her and other expecting mothers.[67] Pregnant persons are at greater risk for morbidity and mortality if they contract Covid, and contracting the disease while pregnant also puts the unborn child at risk for preterm birth and other complications, up to and including stillbirth or death.[68] Prohibiting Jane Doe, other pregnant women, and children across the U.S. from accessing the Covid vaccine irreparably endangers lives.[69] Therefore, the Directive must be vacated.

E. The Balance Of Hardships And The Public Interest Weigh In Favor Of An Injunction.

The balance of harms here unquestionably weighs in favor of the Plaintiffs and compels preliminary injunctive relief. *See Does 1–6 v. Mills*, 16 F.4th 20, 37 (1st Cir. 2021) (noting the balance of equities and the public interest "merge when the [g]overnment is the opposing party") (quoting *Nken v. Holder*, 556 U.S. 418, 435 (2009)).

First and foremost, "[c]ourts have consistently held that there is a strong public interest in health and safety." *Massachusetts v. Nat'l Insts. of Health*, 770 F.Supp.3d 277, 326 (D. Mass. 2025). Without injunctive relief, the Directive—an unscientific, arbitrary, and capricious decree made without the support of a scintilla of evidence or rationale—will remain in place along with the barriers the Directive creates to pregnant individuals and children accessing vaccines. As

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[66] Ex. 18, Dr. Benjamin Decl. ¶ 23; Ex. 10, Dr. Kressly Decl. ¶ 16; Ex. 16, Dr. Hopkins Decl. ¶¶ 23, 35.

[67] Ex. 4, Jane Doe Decl. ¶¶ 7, 10.

[68] *Id.* at ¶ 7; Ex. 18, Dr. Benjamin Decl. ¶ 17; Ex. 15, Dr. Rouse Decl. ¶ 6.

[69] Ex. 13, Dr. O'Shea Decl. ¶ 7; Ex. 18, Dr. Benjamin Decl. ¶ 14; Ex. 12, Dr. Jhaveri Decl. ¶ 12; Ex. 15, Dr. Rouse Decl. ¶¶ 1, 3.

discussed in more detail above, the Directive will reduce the number of pregnant individuals and children whose physicians recommend the vaccine to them. Of the group whose physicians recommend the vaccine notwithstanding the Directive, many will encounter difficulty accessing the vaccine because the Secretary's Directive has sown doubt as to pharmacists' authority to administer the vaccine. Like a matryoshka doll, the group is further diminished by the number of individuals whose health insurers refuse to pay for the vaccine under the Directive and for whom paying out of pocket for whatever price the pharmacy decides to charge is not feasible. As a result, the number of individuals vaccinated against Covid will decrease, which will result in increased rates of infection and an accompanying rise of severe symptoms and death among the entire population. Separate and apart from the actual health repercussions, the Covid pandemic taught us that disruption to public health is also a disruption to business and the economy, maintaining the stability of which are both squarely within the public interest.

The Directive also interferes with the important relationship of trust between physicians and their patients— a relationship that is so reliant on trust that it warrants its own exception to the hearsay rule under the Federal Rules of Evidence. *See* Fed. R. Evid. 803(4). Degrading the trust in the physician-patient relationship undermines the physician's ability to provide effective advice and treatment, harming both their reputations and their businesses while destroying health outcomes for their patients.

Additionally, the public has an "important interest" in ensuring that government agencies follow the law. *Neighborhood Ass'n of the Back Bay, Inc. v. FTA*, 407 F. Supp. 2d 323, 343 (D. Mass. 2005) ("[T]he public has an important interest in making sure government agencies follow the law."); *see also Clarke v. Office of Fed. Hous. Enter. Oversight,* 355 F. Supp. 2d 56, 66 (D.D.C. 2004) (noting a "substantial public interest" in ensuring that a federal agency "acts within the limits

of its authority"). And "[t]here is generally no public interest in the perpetuation of unlawful agency action." *Planned Parenthood of N.Y.C., Inc. v. HHS*, 337 F. Supp. 3d 308, 343 (S.D.N.Y. 2018).

Without an injunction, there will be nothing stopping the Secretary from continuing to make unfounded actions that disregard the boundaries of his delegated authority.

By contrast, no harm will befall the government if the Court issues injunctive relief. To the contrary, an injunction vacating the Directive would rid the government of an unlawful exercise of authority and would be a net positive for the government as well as the people it serves. *See Massachusetts v. Kennedy*, 1:25-cv-10814, at 29–30 (citing *R.I.L-R v. Johnson*, 80 F.Supp.3d 164, 191 (D.D.C. 2015) and *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 343 (D.C. Cir. 2016)).

IV. CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' motion for preliminary injunction and declaratory relief and enter an Order (1) declaring unlawful and setting aside the Directive as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law under the APA, vacating the Directive nationwide; (2) ordering the restoration of the Covid vaccine recommendations for healthy children ages six months to 17 years and pregnant women to the CDC immunization schedules posted on the CDC's website; (3) ordering the Secretary to announce on X that those immunizations are now reinstated to the CDC immunization schedules; and (4) entering a preliminary injunction 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-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women.

July 7, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed through the ECF system and served upon the following parties by Process Server on this 7th day of July 2025:

Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services

Marty Makary, in his official capacity as Commissioner of the Food and Drug Administration

Jay Bhattacharya, in his official capacity as Director of the National Institutes of Health

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