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 EVIDENTIARY HEARING AND ORAL ARGUMENT

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

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I. INTRODUCTION

With a Secretarial Directive dated May 19, 2025 (the "Directive"), United States Health and Human Services ("HHS") Secretary Robert F. Kennedy, Jr. (the "Secretary") recklessly disregarded the statutory and regulatory framework that governs the process for deciding which vaccines are listed on the Centers for Disease Control and Prevention ("CDC") immunization schedules (the "Schedules"). Without evidentiary support, the Directive rescinds and removes Covid-19 ("Covid") vaccine recommendations for children and pregnant individuals from the Schedules. He issued the Directive without following a process that HHS has followed for decades and without reasoned explanation. The Directive is a quintessential arbitrary and capricious agency action, is not in accordance with law, and violates the Administrative Procedure Act ("APA"). Accordingly, this Court should declare the Directive unlawful, vacate it in its entirety, and require the CDC to restore the Covid-19 vaccines to the Schedules for children and pregnant individuals.

II. BACKGROUND

A. Vaccine Approval and Recommendation Process

Two agencies within HHS, the U.S. Food and Drug Administration ("FDA") and the CDC, have differing responsibilities in the process that result in authorization and recommendation of vaccines for use in the United States.[1] The Center for Biologics Evaluation, housed in the FDA, reviews applications to market new vaccines for safety and effectiveness and decides whether to license vaccines for use. *See* 42 U.S.C. § 262(2); 21 C.F.R. § 601. Following FDA approval, the

[1] *See* Ex. 1, *The Vaccine Life Cycle: Safety at Every Phase*, CDC (infographic, 2020); *How Vaccines are Developed and Approved for Use*, CDC (Aug. 10, 2024), https://www.cdc.gov/vaccines/basics/how-developed-approved.html; Ex. 2, Plaintiffs' Federal Rule of Evidence 1006 Summary Exhibit (Summary of Covid Vaccine Approval and Recommendations). Pursuant to Federal Rule of Evidence 201, Plaintiffs request that the Court take judicial notice of the record attached hereto as Exhibit 1 and the records cited and referenced in the chart attached hereto as Exhibit 2, which consist of publicly available records and reports of the CDC and the FDA and are available on the CDC's or the FDA's websites. Should the Court deem it necessary, Plaintiffs will submit further briefing regarding this request for judicial notice.

Advisory Committee on Immunization Practices (the "ACIP"), housed in the CDC, is charged with preparing recommendations for whether and how vaccines are listed on the Schedules, which are then presented to the CDC Director for consideration and approval.[2] Once the CDC Director approves an ACIP recommendation, the CDC publishes the ACIP recommendation on its website and in the Morbidity and Mortality Weekly Report.[3] 45 C.F.R. § 147.130(a)(1)(ii). 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.[4]

Many federal and state public health statutes base vaccine requirements or cost-sharing prohibitions on ACIP recommendations. For example, the Vaccines for Children Program ("VFC") requires states to establish a pediatric vaccine distribution program that provides ACIP-approved vaccines free of cost to eligible children. 42 U.S.C. § 1396s(a)(1), (e). 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 [ACIP]." 42 U.S.C. § 300gg-13 (a)(2).

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[2] *The Advisory Committee on Immunization Practices Policies and Procedures*, CDC, at 1 (June 2022), https://www.cdc.gov/acip/downloads/Policies-Procedures-508_1.pdf; *Charter of the Advisory Committee on Immunization Practices*, CDC (Apr. 1, 2024), https://www.cdc.gov/acip/downloads/acip-charter.pdf; *see also* Ex. 2, Plaintiffs' Federal Rule of Evidence 1006 Summary Exhibit (Summary of Covid Vaccine Approval and Recommendations) (reflecting each Covid-related presentation made over the course of multiple ACIP meetings before the ACIP voted on various Covid vaccine recommendations). While the FDA's review is underway, a work group of the ACIP, which is an advisory committee subject to the Federal Advisory Committee Act, 5. U.S.C. § 1001, *et seq.*, reviews "all available scientific information about the vaccine so that they will be prepared to present information to ACIP about the vaccine once it licensed. At this point, the vaccine already has undergone several phases of testing for safety and efficacy with thousands of volunteers." *Role of the Advisory Committee on Immunization Practices in CDC's Vaccine Recommendations*, CDC (Sept. 17, 2024), https://www.cdc.gov/acip/about/role-in-vaccine-recommendations.html. After licensure, the ACIP "work group presents its findings to the entire ACIP at several meetings before ACIP members vote on whether to recommend the vaccine and who should receive the vaccine." *Id.*

[3] *The Advisory Committee on Immunization Practices Policies and Procedures*, CDC, at 9 (June 2022), https://www.cdc.gov/acip/downloads/Policies-Procedures-508_1.pdf.

[4] *See* Ex. 2, Plaintiffs' Federal Rule of Evidence 1006 Summary Exhibit (Summary of Covid Vaccine Approval and Recommendations); Ex. 3, *Interim Clinical Considerations for Use of mRNA COVID-19 Vaccines Currently Authorized in the United States*, CDC (December 30, 2020); *Advisory Committee on Immunization Practices Summary Report*, CDC, 67 (Feb. 28–Mar. 1, 2021), https://stacks.cdc.gov/view/cdc/113294.

B. The Directive

On May 27, 2025, the Secretary posted a video on his X social media account directing the removal of the Covid vaccine from the Schedules for "healthy children" and "healthy pregnant women."[5] This came as a shock to the ACIP members.[6] That same day, the Secretary issued the Directive, backdated to May 19, 2025,[7] instructing the CDC to remove these vaccines from the Schedules.[8] Like his X post, the Directive is devoid of any evidence supporting the Secretary's claim that "the known risks … do not outweigh the benefits of the vaccine" and is written in the first person, indicating that this was the Secretary's unilateral decision.[9]

The CDC's response to the Directive has left providers and patients with confusing, conflicting guidance. Although the CDC removed the Covid vaccine from its recommended vaccinations during pregnancy on the CDC's Adult Immunization Schedule,[10] the CDC's fact sheet "Vaccine Recommendations Before, During, and After Pregnancy" continues to recommend that, "[i]f you are pregnant, you should stay up to date on your COVID-19 vaccine."[11] Further, although the Directive rescinded the recommendation that children be vaccinated against Covid, the CDC instead changed the Covid vaccine from a "routine" recommendation to a "shared clinical decision-making" recommendation ("SCDM") on the Child and Adolescent Immunization Schedule.[12] While a "routine" recommendation is an unqualified endorsement of a vaccine, an SCDM designation actually has a chilling effect on vaccinations because it "cast[s] unwarranted

[5] *See* @SecKennedy, X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138.
[6] Ex. 4, Decl. of Jamie Loehr, MD, FAAFP, dated July 5, 2025 ("Dr. Loehr Decl.") at ¶ 10; Ex. 5, Decl. of Jane Doe, MD, dated July 6, 2025 ("Jane Doe, MD, Decl.") at ¶ 5.
[7] Ex. 6, *Secretarial Directive on the Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women* (May 19, 2025).
[8] *Id.*
[9] *Id.*
[10] Ex. 7, *Adult Immunization Schedule by Medical Condition and Other Indication*, CDC (May 29, 2025).
[11] Ex. 8, *Vaccine Recommendations Before, During, and After Pregnancy*, CDC (June 24, 2024).
[12] *See* Ex. 9, *Child and Adolescent Immunization Schedule by Age*, CDC (May 29, 2025); Ex. 10, *Child and Adolescent Immunization Schedule by Age*, CDC (July 2, 2025).

doubt on a vaccine that is FDA-approved, proven safe, and is essential for protecting [the] most vulnerable patients."[13] An SCDM designation also can cause difficulty in obtaining insurance coverage of the vaccination.[14]

C. The Directive's Harm

Plaintiff Jane Doe 1 is a doctor who is pregnant and works in a hospital.[15] She was "appalled" by the Secretary's proclamation that he was "pleased to make an announcement that will lead to more serious illness and death."[16] She knows that her pregnancy puts her at a greater risk of infection, which the Directive amplifies because the number of people with Covid infections who enter her hospital will rise.[17] This has increased her and her husband's level of anxiety and fear as first-time expectant parents.[18]

The Directive significantly impaired Plaintiff Jane Doe 2's ability to receive the Covid vaccine during her pregnancy. Her obstetrician wrote a prescription for her to receive a Covid vaccine, but a local pharmacist refused to administer the vaccine to her because the pharmacist feared she would lose her license if she did so.[19] When Jane Doe 2 informed her obstetrician's office about the pharmacist's refusal, she was advised that the practice could not help her because "the guidance is not to administer the Covid vaccine right now" and the practice "would revisit

[13] Ex. 11, Decl. of Mary Doherty-O'Shea Gallucci, MD, dated July 3, 2025 ("Dr. O'Shea Decl.") at ¶ 5.
[14] 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*, UHC Provider at 1 (Dec. 1, 2024), https://www.uhcprovider.com/content/dam/provider/docs/public/policies/comm-medical-drug/vaccines.pdf (only providing coverage for immunizations "subject to explicit the ACIP recommendations (e.g., 'should', 'shall', 'is'), and not permissive ('may') recommendations, for routine use").
[15] Ex. 5, Jane Doe, MD, Decl. ¶¶ 2–4.
[16] *Id.* at ¶ 5.
[17] *Id.* at ¶ 6.
[18] *Id.*
[19] Ex. 12, Decl. of Jane Doe 2, dated July 25, 2025 ("Jane Doe 2 Decl.") at ¶ 8.

this next season."[20] Her obstetrician later left a voicemail that "there are now conflicting guidelines and, therefore, conflicting practices being followed by community pharmacists."[21]

A chain pharmacy location advised Jane Doe 2 that "this is the first time a recommendation did not come from the [ACIP] and, therefore, this is a 'grey area,'" and she would need to schedule her vaccination when a "flexible" pharmacist "who would be willing to risk their license to vaccinate" her was available.[22] Even then, the pharmacy required Jane Doe 2 to attest that: "If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC."[23] When she asked the "flexible" pharmacist what this meant, he advised that the CDC's guidelines are unclear, but he "personally chooses to follow the recommendations of OB and pediatric groups."[24]

Given the confusion and fear caused by the Directive, seven medical and public health associations (the "Association Plaintiffs") have stepped up to challenge the Directive because of the harm it has caused to their members, the patients and clients for whom they care, and to the public health system in this country. The Directive, along with the Secretary's other actions and statements about vaccines (*see* First Am. Compl., ECF No. 63 ("FAC"), ¶¶ 43–53, 58–69), have harmed the ability of physicians to provide the requisite standard of care to their patients.[25] The Directive has put the Association Plaintiffs' members in a conflicting situation: either recommend the vaccine to healthy children and pregnant individuals consistent with the evidence and the

[20] *Id.* at ¶ 10.
[21] *Id.* at ¶ 13.
[22] *Id.* at ¶ 17.
[23] *Id.* at ¶ 20, Ex. F.
[24] *Id.* at ¶ 21.
[25] *See* Ex. 11, Dr. O'Shea Decl. ¶¶ 9, 17; Ex. 13, Decl. of Susan J. Kressly, MD, FAAP, dated July 3, 2025 ("Dr. Kressly Decl.") at ¶ 17; Ex. 14, Decl. of Ravi Jhaveri, MD, dated July 5, 2025 ("Dr. Jhaveri Decl.") at ¶ 10; Ex. 15, Decl. of Shannon Scott-Vernaglia, MD, dated July 7, 2025 ("Dr. Scott-Vernaglia Decl.") at ¶ 19; Ex. 16, Decl. of Regina LaRocque, MD, MPH, FIDSA, dated July 5, 2025 ("Dr. LaRocque Decl.") at ¶¶ 10–13.

standard of care in their disciplines; or, alternatively, comply with the Directive to avoid potential disciplinary action.[26]

As a member of Plaintiff Society for Maternal-Fetal Medicine ("SMFM") expressed:

> [The Directive] is currently undermining the patient-provider relationship, puts my decision-making as a physician at risk, and sows confusion among my patients about whether COVID-19 vaccination is necessary or advisable. . . . I practice in a region with historically low vaccine uptake, which makes clear and consistent public health messaging especially critical. . . . The Directive now places my clinical judgment in direct conflict with federal guidance, forcing me into an untenable position: either follow what I know to be the best for my patients, or align with a policy that contradicts established medical consensus. This erosion of trust is not just theoretical as it is already interfering with my ability to protect high-risk patients from a preventable and potentially deadly illness. . . . [S]everal of my patients have now begun to question other standard pregnancy vaccinations—such as Tdap and influenza—as a result of HHS's recent misinformation surrounding vaccine ingredients and recommendations for pregnant women.[27]

As a current member of Plaintiff American Academy of Pediatrics ("AAP") who is a pediatrician-owner of two medical practices in Michigan reports:

> This HHS directive is preventing me from complying with the AAP's standard of care for pediatricians. I am forced to either violate my duty to my patients or risk professional consequences, including medical malpractice liability. . . . The May 19 Directive is interfering with my ability to provide the standard of care recommended by the AAP, which is based on peer-reviewed research and a professional consensus as to best practices. I continue to recommend the COVID-19 vaccine to all pediatric patients, including the primary series for infants, but I do

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[26] *See* Presidential Make America Healthy Again Comm'n, *The MAHA Report*, at 65 (May 22, 2025), https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf ("Physicians who question or deviate from the CDC's vaccine schedule may face professional repercussions, including scrutiny from licensing boards and potential disciplinary action."); *See* Ex. 11, Dr. O'Shea Decl. ¶¶ 9–10; Ex. 13, Dr. Kressly Decl. ¶ 17; Ex. 14, Dr. Jhaveri Decl. ¶ 10; Ex. 17, Decl. of Caroline E. Rouse, MD, dated July 4, 2025 ("Dr. Rouse Decl.") at ¶¶ 8, 10; Ex. 18, Decl. of Jason M. Goldman, MD, MACP, dated July 28, 2025 ("Dr. Goldman Decl.") at ¶ 30; Ex. 19, Decl. of Georges C. Benjamin, MD, dated July 3, 2025 ("Dr. Benjamin Decl.") at ¶ 21; Ex. 20, Decl. of Andrew T. Pavia, MD, FAAP, FACP, FIDSA, dated July 4, 2025 ("Dr. Pavia Decl.") at ¶¶ 24–25; Ex. 21, Decl. of Carlene Pavlos, dated July 6, 2025 ("Pavlos Decl.") at ¶ 8; Ex. 22, Decl. of James D. Campbell, MD, MS, dated July 10, 2025 ("Dr. Campbell Decl.") at ¶¶ 21–23; Ex. 23, Decl. of Aaron Bornstein, MD, dated July 26, 2025 ("Dr. Bornstein Decl.") at ¶ 23; Ex. 24, Decl. of Brenda Anders Pring, MD, dated July 26, 2025 ("Dr. Anders Pring Decl.) at ¶ 13.

[27] Ex. 17, Dr. Rouse Decl. ¶¶ 8, 10, 14. Additionally, an SMFM maternal-fetal specialist in Texas who treats high-risk pregnant patients attests that the Directive is "creating dangerous confusion in the clinical setting, and forcing me to choose between following HHS's recommendations or expose myself to professional liability by following the standard of care that requires the recommendation of COVID-19 vaccines for pregnant women, which has been supported by scientific studies for years." Ex. 25, Decl. of Patrick S. Ramsey, MD, MSPH, dated July 29, 2025 ("Dr. Ramsey Decl.") at ¶ 2.

> so knowing that I am now potentially placing myself at odds with the federal directive . . . exposing myself to malpractice liability for recommending a vaccine that is FDA-approved and fully supported by pediatric standards of care.[28]

Physician members of Plaintiff American Public Health Association ("APHA") have informed its Executive Director that the Directive puts them in the position of providing an inferior standard of care by complying with the Directive, or risking their medical or other professional license by recommending vaccination contrary to the Directive.[29] "[T]his creates a professional conflict with the standard of public health practice required to control a disease outbreak in their community and the non-evidence based May 19 Secretarial Directive."[30] The Directive has caused tangible harm, which will only get worse unless and until the Directive is vacated.

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). When the government is a defendant in the suit, the final two factors merge. *Nken v. Holder*, 556 U.S. 418, 435–36 (2009).

[28] Ex. 11, Dr. O'Shea Decl. ¶¶ 4, 9. Similarly, an active member of Plaintiff American College of Physicians states, "Despite the Secretary's May 19, 2025 Directive, my practice is to provide the most optimal care possible for my patients, which includes giving the COVID vaccine to pregnant persons and children according to science." Ex. 26, Decl. of Robert H. Hopkins, Jr., MD, MACP, dated July 10, 2025 ("Dr. Hopkins Decl.") at ¶ 25.
[29] Ex. 19, Dr. Benjamin Decl. ¶ 21.
[30] *Id*. As the Assistant Health Commissioner for External Affairs at the Columbus, Ohio Department of Public Health explains, the Directive "is completely at odds with the mission, vision, and values of Columbus Public Health, and the standard of care Columbus Public Health holds itself to." Ex. 27, Decl. of J. Edward Johnson dated July 7, 2025 ("Johnson Decl.") at ¶ 23.

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." *Dep't of Com. v. New York*, 588 U.S. 752, 766 (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*. Here, the Jane Doe Plaintiffs have standing. Both are pregnant and therefore in a population group that the Directive targets, and the Directive has caused them both harm.[31] A decision vacating the Directive will redress the ongoing harm they face.[32]

An association plaintiff has standing to sue 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.'" *In re Fin. Oversight & Mgmt. Bd. for P.R.*, 110 F.4th 295, 308 (1st Cir. 2024) (quoting *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). "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)). "Actions seeking prospective relief have generally been held particularly suited to group representation." *Ass'n of Am. Univs. v. Nat'l Sci. Found*., 2025 WL 1725857, at *7 (D. Mass. June 20, 2025) (quoting *Camel Hair & Cashmere Inst. of Am., Inc. v. Associated Dry Goods Corp*., 799 F.2d 6, 12 (1st Cir. 1986)).

[31] Ex. 5, Jane Doe, MD Decl. ¶¶ 7, 9–11. Ex. 12, Jane Doe 2 Decl. ¶¶ 3, 8–23.
[32] *See* Ex. 5, Jane Doe, MD Decl. ¶¶ 9–11; Ex. 12, Jane Doe 2 Decl. ¶¶ 8–23.

The Association Plaintiffs here each have standing. The Directive frustrates the Associational Plaintiffs' purposes, and the most fundamental of the injuries that their members have suffered is the loss of trust that the Directive has caused patients to have in their providers, which has interfered with their ability to discharge the standard of care.[33] The first opinion in the AMA's Code of Medical Ethics provides:

> The practice of medicine, and its embodiment in the clinical encounter between a patient and a physician, is fundamentally a moral activity that arises from the imperative to care for patients and to alleviate suffering. ***The relationship between a patient and a physician is based on trust***, which gives rise to physicians' ethical responsibility to place patients' welfare above the physician's own self-interest or obligations to others, to use sound medical judgment on patients' behalf, and to advocate for their patients' welfare.[34]

Thus, "[a]t its core, the doctor-patient relationship represents a fiduciary relationship in which, by entering into the relationship, the physician agrees to . . . provide the highest standard of care" as "[p]oor outcomes . . . flow from an impaired doctor-patient relationship."[35] The Directive directly harms the physician-patient relationship and damages the goodwill between them, which hinders the members' abilities to carry out the full scope of their medical obligations. *See Ross-Simons of Warwick, Inc. v. Baccarat, Inc*., 102 F.3d 12, 20 (1st Cir. 1996) ("By its very nature injury to goodwill and reputation is not easily measured or fully compensable in damages. Accordingly, this kind of harm is often held to be irreparable."); *Fairfield Cnty. Med. Ass'n v. United Healthcare of New England, Inc*., 557 F. App'x 53, 56 (2d Cir. 2014) (affirming district court determination that

[33] *See* Ex. 13, Dr. Kressly Decl. ¶¶ 13, 15; Ex. 11, Dr. O'Shea Decl. ¶ 6; Ex. 20, Dr. Pavia Decl. ¶¶ 2,8; Ex. 14, Dr. Jhaveri Decl. ¶ 11; Ex. 17, Dr. Rouse Decl. at ¶¶ 2,8; Ex. 18, Dr. Goldman Decl. ¶¶ 33, 35; Ex. 19, Dr. Benjamin Decl. ¶¶ 21–23; Ex. 28, Decl. of Jenifer Leaf Jaeger, MD, MPH, FAAP, dated July 15, 2025 ("Dr. Jaeger Decl.") at ¶¶ 6, 11.

[34] *Code of Medical Ethics: Opinion 1.1.1 Patient-Physician Relationships*, AMA https://code-medical-ethics.ama-assn.org/ethics-opinions/patient-physician-relationships (last visited July 24, 2025) (emphasis added).

[35] *See* Fallon E Chipidza et al., *Impact of the Doctor-Patient Relationship*, 17 Primary Care Companion CNS Disorders 5 (Oct. 22, 2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4732308/.

plaintiffs faced irreparable harm and therefore had associational standing where declarants described a disruption of the physician-patient relationship) (non-precedential).

The Directive also harms the Association Plaintiffs because it places its physician members in a conflicting situation: either follow the unsupported, baseless Directive, in which case members would be providing inferior care to their patients; or adhere to their profession's standard of care and recommend the vaccine, but then expose themselves to disciplinary action.[36] Indeed, the Secretary's own "MAHA Report" warns: "Physicians who question or deviate from the CDC's vaccine schedule may face professional repercussions, including scrutiny from licensing boards and potential disciplinary action."[37] This alone establishes the irreparable injury to physician members of the Association Plaintiffs. *See Richmond Med. Ctr. for Women v. Gilmore*, 11 F. Supp. 2d 795, 809 (E.D. Va. 1998) (finding irreparable injury as a result of government action when physicians are "constrained to alter their medical advice to, and their medical care of, their patients, contrary to their best professional medical judgments."); *see also Mayor and City Council of Balt. v. Azar*, 392 F. Supp. 3d 602, 618 (D. Md. 2019) (forcing plaintiffs to "contravene their ethical obligations to provide patient-centered, nondirective care" constitutes irreparable harm).

Finally, the "threats to public health and safety alone constitute irreparable harm that support an injunction." *See, e.g.*, *Colorado v. U.S. Dep't of Health & Hum. Servs*., 2025 WL 1426226, at *20 (D.R.I. May 16, 2025) (internal citation omitted). Association Plaintiffs report that the Directive is causing an increased public health risk in members' communities.[38]

Association Plaintiffs, therefore, have standing.

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[36] *See* Ex. 11, Dr. O'Shea Decl. ¶¶ 9–10; Ex. 13, Dr. Kressly Decl. ¶ 17; Ex. 14, Dr. Jhaveri Decl. ¶ 10; Ex. 17, Dr. Rouse Decl. ¶¶ 8, 10; Ex. 18, Dr. Goldman Decl. ¶ 30; Ex. 19, Dr. Benjamin Decl. ¶ 21; Ex. 20, Dr. Pavia Decl. ¶¶ 24–25; Ex. 21, Pavlos Decl. ¶ 8; Ex. 24, Dr. Anders Pring Decl. ¶ 13.

[37] Presidential Make America Healthy Again Comm'n, *The MAHA Report*, at 65 (May 22, 2025), https://www.whitehouse.gov/wp-content/uploads/2025/05/MAHA-Report-The-White-House.pdf.

[38] *See* Ex. 17, Dr. Rouse Decl. ¶¶ 13–14; Ex. 19, Dr. Benjamin Decl. ¶¶ 23–24; Ex. 21, Pavlos Decl. ¶¶ 5, 8; Ex. 25, Dr. Ramsey Decl. ¶¶ 14–15; Ex. 28, Dr. Jaeger Decl. ¶ 12.

2. Ripeness

"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* ("*NIH I*"), 770 F. Supp. 3d 277, 303 (D. Mass. 2025). An agency action is final if it (1) marks the consummation of the government's decision-making process and is not "merely tentative or 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) (internal quotation marks omitted)). Because Plaintiffs seek equitable relief enjoining final agency action, the APA provides for judicial review in the district court. *See* 5 U.S.C. §§ 702, 704; *e.g., Bowen v. Massachusetts*, 487 U.S. 879 (1988).

The Directive is neither tentative nor subject to further review. Instead, it is a definitive statement of a change in policy from which legal consequences have flowed. The change to the Schedules per the Secretary's Directive immediately affected multiple federal and state statutes, including which vaccines are covered under various federal statutes, such as the ACA and the VFC program. Further, some health insurance plans can now deny coverage of Covid vaccines for children and pregnant women because of the Secretary's unilateral change to the Schedules. With schools starting around the country next month and the upcoming respiratory virus season arriving shortly thereafter (*see* FAC ¶¶ 10, 40), the Directive's impact is imminent and ripe for adjudication.

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

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

An agency's action is arbitrary and capricious in violation of the APA (*see* 5 U.S.C. § 706(2)(A)) 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). 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." *NIH I*, 770 F. Supp. 3d at 304 (quoting *Penobscot Air Servs., Ltd. v. FAA*, 164 F.3d 713, 720 (1st Cir. 1999) (internal quotation marks omitted)). Conclusory statements are an insufficient basis for agency action. *Amerijet Int'l, Inc. v. Pistole*, 753 F.3d 1343, 1350 (D.C. Cir. 2014).

Further, although political considerations may influence agency actions, this cannot substitute or displace the requirement for reasoned decision-making. *See Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 16, 39–40 (2020) (Thoams, J.; Alito, J.; and Gorsuch, J. concurring) (observing that engaging in reasoned decision-making is a necessary component to agency action). Indeed, 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)). Here, the evidence substantially reflects that the Directive is arbitrary and capricious.

a. The Directive Lacks Reasoned Decision-Making And An Explanation For The Change In Position.

At bottom, arbitrary and capricious review is a search for "a satisfactory explanation" for an agency's action. *Am. Pub. Health Ass'n v. Nat'l Inst. of Health* ("*NIH II*"), 2025 WL 1822487, at *15 (D. Mass. July 2, 2025) (quoting *Ohio v. Env't Prot. Agency*, 603 U.S. 279, 292 (2024)). The Directive fails to meet this low bar.

The Directive is devoid of citations to a single peer-reviewed study and rejects, without explanation, the years' worth of data, peer-reviewed studies, and evidence the ACIP has presented

and used to inform its multitude of CDC-approved recommendations regarding Covid vaccines.[39] Indeed, at the April 2025 ACIP meeting, the CDC reported that healthy children and pregnant women were very much still at risk from Covid and presented a wealth of uncontroverted data on the safety and efficacy of Covid vaccines for these populations. FAC ¶ 4. However, in his video announcing the Directive six weeks later, the Secretary falsely proclaimed that there isn't "any clinical data to support the repeat booster strategy in children."[40] In response, less than a month after the announcement of the Directive, CDC employees *again* presented inconvertible evidence contradicting the Directive's mandates.[41] This tension between reality and the Secretary's words is precisely the type of incongruent agency action that is subject to being overruled under arbitrary and capricious review. There is no satisfactory explanation for this agency action or a rational connection between the objective facts and the Directive's rescission and removal of Covid vaccine recommendations. *Little Sisters of the Poor Saints Peter and Paul Home v. Pennsylvania*, 591 U.S. 657, 682–83 (2020). Judicial review of agency action is deferential, but it is not bound by naiveté. *Dep't. of Com.*, 588 U.S. at 785 (observing the incongruency between the stated reasons for agency action and the record before the Court).

For these same reasons, the Directive also fails arbitrary and capricious review because it did not articulate or explain the sudden 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." *Fed. Commc'ns*

[39] *See* Ex. 2, Plaintiffs' Federal Rule of Evidence 1006 Summary Exhibit (Summary of Covid Vaccine Approval and Recommendations); Ex. 11, Dr. O'Shea Decl. ¶¶ 1, 4, 9; Ex. 14, Dr. Jhaveri Decl. ¶¶ 7, 10; Ex. 17, Dr. Rouse Decl. ¶ 8; Ex. 19, Dr. Benjamin Decl. ¶¶ 17, 18, 21.
[40] *See* @SecKennedy, X (May 27, 2025, 10:16 AM), https://x.com/SecKennedy/status/1927368440811008138.
[41] *See* FAC ¶ 93; Ex. 29, Decl. of Charlotte Moser, MS, dated July 6, 2025 ("Moser Decl.") at ¶ 11; Lakshmi Panagiotakopoulos, *Use of 2025–2026 COVID-19 Vaccines: Work Group Considerations*, CDC ACIP Meeting, at 11, 53 (April 15, 2025), https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/05-Panagiotakopoulos-COVID-508.pdf.

Comm'n v. Fox Television Stations, Inc., 556 U.S. 502, 515 (2009) (emphasis in original). While the Secretary may have acknowledged the former, he has not addressed the latter.

In issuing the Directive, the Secretary ignored HHS's longstanding practices for evaluating the safety and efficacy of a vaccine before making its recommendations without any "reasoned analysis for the change." *See State Farm*, 463 U.S. at 42. Neither the Directive nor the Secretary's announcement describe *why* this change in agency policy is occurring. This change rests entirely on conclusory assertions that "healthy kids" and "healthy pregnant women" don't need the Covid vaccine.[42] 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), and "devoid of data or any independent explanation," *Rhode Island v. Trump*, 2025 WL 1303868, at *11 (D. Mass. May 6, 2025).

Agency action must be reasonable and reasonably explained to withstand scrutiny under the arbitrary and capricious standard. *Ohio v. Env't Prot. Agency*, 603 U.S. at 292; *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021). While arbitrary and capricious review is narrow, it demands that an agency engage in *some* reasoned decision making. *See NIH I*, 770 F. Supp. 3d at 306; *NIH II*, 2025 WL 1822487, at *15. Here, there was none. Rather than being a reasoned decision, the Directive is mere *ipse dixit*, contrary to evidence, and should be vacated. *See Nat'l Tire Dealers & Retreaders Ass'n, Inc. v. Brinegar*, 491 F.2d 31, 40 (D.C. Cir. 1974).

b. The Secretary Failed To Consider Important Aspects Of How Changes To The CDC's Immunization Schedules Would Impact Healthcare Delivery Nationwide.

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 the Directive and changing the Schedules, the

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

Secretary set into motion a policy that disrupts multiple parts of the American healthcare ecosystem. The Schedules and their recommendations have wide-ranging effects far beyond when and to whom a vaccine may be administered. The complex landscape of federal and state laws that govern American healthcare 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."[43] The Directive removing the Covid vaccine from the routine Child And Adolescent Immunization Schedule, and the reclassification of the vaccine to SCDM, jeopardizes access to the vaccine for children in the VFC program. Similarly, the Schedules affect health insurance coverage and cost-sharing obligations under the ACA. Children and pregnant women who were previously able to receive the 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 necessary consequential changes throughout the nation's healthcare system, and to explain why such a sudden change in policy is warranted. *See Data Mktg. P'ship, LP v. U.S. Dep't of Lab.*, 45 F.4th 846, 860 (5th Cir. 2022) ("The Supreme Court has made clear that when it comes to arbitrary-and-capricious review, 'the Government should turn square corners in dealing with the people.'" (quoting *Dep't of Homeland Sec.*, 591 U.S. 1, 24 (2020))). Nothing indicates that HHS took into consideration *any* of the foreseeable public health implications Plaintiffs' declarants describe. Such conduct is *precisely* why the APA dictates that, "when an agency changes course, it must 'be cognizant that longstanding policies may have engendered serious reliance interests that must be

[43] CDC, VFC Operations Guide, at 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.

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)).

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

The Directive is contrary to law and should be vacated pursuant to 5 U.S.C. § 706(2)(A). Since 1964, Congress and state legislatures have incorporated the ACIP's vaccine recommendations into laws covering vaccines. The ACA, the VFC program, the Immigration and Nationality Act, Medicare Part D, the Veterans Health Administration, Tricare/Military Health System, and the Inflation Reduction Act (prohibiting cost sharing for individuals covered by the Medicaid and CHIP programs of "approved vaccines recommended by the Advisory Committee on Immunization Practices"), among others, explicitly rely on the ACIP's vaccine recommendations, not unilateral decisions of the HHS Secretary. FAC ¶¶ 40.a.–f. The Directive is not in accordance with these laws. Through the decades, Congress and state legislatures have created an intertwined, complex statutory and regulatory framework that incorporates reliance on the vaccine recommendations of agencies and advisory committees comprised of true subject-matter experts tasked with developing those recommendations based on rigorous, evidence-based analyses. The Secretary ignored this framework when he issued the Directive. *See e.g.*, *Morton v. Ruiz,* 415 U.S. 199, 235 (1974) ("Where the rights of individuals are affected, it is incumbent upon agencies to follow their own procedures. Even where the internal procedures are possibly more rigorous than otherwise would be required."); *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) (upholding injunction against multiple agencies that imposed substantive standards for arbitration beyond their delegated authority).

At the end of December 2020, the President signed a new law that requires the Secretary to "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. The Directive does the exact opposite. 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. Env't Prot. Agency*, 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.'") (internal citation omitted). The Directive rewrites many laws and, therefore, must be vacated.

D. Plaintiffs Will Suffer Irreparable Harm Absent Injunctive Relief

Plaintiffs are suffering. They will continue to suffer irreparable harm absent relief from the Court vacating the Directive. As Americans watched the Covid pandemic unfold, Association Plaintiff members were the front-line workers serving our country and risking their own lives to prevent death and stop the deadly disease. At the same time, the FDA, the ACIP, and the CDC assiduously worked through the rigorous, multi-level evaluation process to determine the safety and efficacy of each Covid vaccine before recommending it for administration to the public.[44] Once these Covid vaccine recommendations were issued, Association Plaintiff members worked tirelessly to study and administer the vaccine, vouch for the vaccine's efficacy at curbing severe illness and death, and set clinical guidelines recommending vaccination of their patients, including children and pregnant women, consistent with the evidence developed and evaluated during this

[44] *See* Ex. 1, *The Vaccine Life Cycle: Safety at Every Phase*, CDC (infographic, 2020); Ex. 2, Plaintiffs' Federal Rule of Evidence 1006 Summary Exhibit (Summary of Covid Vaccine Approval and Recommendations).

vaccine recommendation process.[45] The Directive reverses this progress, leaving some of our most vulnerable populations, children and pregnant women at increased risk of illness and death.[46]

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 clinical settings, and forcing doctors to choose between following the Directive or the optimal standard of care.[47] Either option exposes them to a heightened risk of professional liability. Further, the Directive frustrates clinicians' ability to consult with individuals and their families or advise those communities regarding the effectiveness of vaccination at preventing serious illness and death.[48] The Directive is damaging the foundation of the fiduciary relationship between patient and physician—trust. This loss of trust has and will lead to poor outcomes for patients, physicians, and communities.[49]

Finally, the Jane Doe Plaintiffs, who are pregnant, face a heightened risk of contracting Covid because of the Directive. Worse, because of the confusion the Directive has caused in the vaccine infrastructure, they face doctors, nurses, and pharmacists who refuse to administer the Covid vaccine because they fear losing their licenses if they administer the vaccine in contravention of the Directive.

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

[46] Ex. 5, Jane Doe, MD, Decl. ¶ 7; Ex. 11, Dr. O'Shea Decl. ¶¶ 5–6; Ex. 13, Dr. Kressly Decl. ¶¶ 12–14; Ex. 14, Dr. Jhaveri Decl. ¶¶ 9–11; Ex. 17, Dr. Rouse Decl. ¶¶ 8–11, 14; Ex. 18, Dr. Goldman Decl. ¶¶ 28–34; Ex. 19, Dr. Benjamin Decl. ¶¶ 19, 21–23; Ex. 20, Dr. Pavia Decl. ¶¶ 23–30; Ex. 26, Dr. Hopkins Decl. ¶¶ 23–24, 33–35; Ex. 30, Decl. of Sindhu K. Srinivas, MD, MSCE, dated July 6, 2025 ("Dr. Srinivas Decl.") at ¶¶ 7–12; Ex. 31, Decl. of Shetal Shah, MD, dated July 28, 2025 ("Dr. Shah Decl.") at ¶¶ 15–20.

[47] *See* Ex. 11, Dr. O'Shea Decl. ¶¶ 4, 8–10; Ex. 13, Dr. Kressly Decl. ¶ 17; Ex. 14, Dr. Jhaveri Decl. ¶ 10; Ex. 15, Dr. Scott-Vernaglia Decl. ¶ 19; Ex. 17, Dr. Rouse Decl. ¶ 8; Ex. 18, Dr. Goldman Decl. ¶¶ 30–31; Ex. 19, Dr. Benjamin Decl. ¶ 21.

[48] Ex. 13, Dr. Kressly Decl. ¶ 12; Ex. 14, Dr. Jhaveri Decl. ¶ 11; Ex. 18, Dr. Goldman Decl. ¶¶ 33–35; Ex. 19, Dr. Benjamin Decl. ¶ 22; Ex. 20, Dr. Pavia Decl. ¶¶ 24, 27–29; Ex. 21, Pavlos Decl. ¶¶ 3–5.

[49] Ex. 13, Dr. Kressly Decl. ¶ 16; Ex. 19, Dr. Benjamin Decl. ¶ 23; Ex. 26, Dr. Hopkins Decl. ¶¶ 23, 35.

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, "[c]ourts have consistently held that there is a strong public interest in health and safety." *NIH I*, 770 F. Supp. 3d at 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 adequate explanation—will remain in place along with the barriers the Directive creates to children and pregnant individuals accessing vaccines. The Directive, as shown above, has already reduced the number of children and pregnant individuals receiving not just a vaccine against Covid, but also other vaccines. Access to vaccines has already dwindled due to the Directive. More health insurers will refuse to pay for the vaccine because of the Directive, which will lead either to patients facing the choice of paying hundreds of dollars for a vaccine that was free, or not getting vaccinated. 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 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

physician-patient relationship undermines physicians' ability to provide effective advice and treatment, harming both their reputations, their businesses, and their patients' lives.

Finally, the public has an "important interest" in ensuring that government agencies follow the law. *Neighborhood Ass'n of the Back Bay, Inc. v. Fed. Transit Admin.*, 407 F. Supp. 2d 323, 343 (D. Mass. 2005); *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"); *Planned Parenthood of N.Y.C., Inc. v. U.S. Dep't of Health & Hum. Servs*., 337 F. Supp. 3d 308, 343 (S.D.N.Y. 2018) ("[t]here is generally no public interest in the perpetuation of unlawful agency action." (internal citation omitted)). Based on his recent testimony before Congress,[50] the actions and attitude he has displayed with regard to vaccines, *see* FAC ¶¶ 46–54, and his stacking of the HHS and the ACIP with those who align with his views on vaccines, *id*. at ¶¶ 55–80, the Secretary is poised to make more harmful vaccine decisions. Vacatur of the Directive is the only means for deterring the Secretary from further unlawful action.

By contrast, injunctive relief does not harm the Government. Rather, 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 NIH I*, 770 F. Supp. 3d at 326.

IV. CONCLUSION

For the foregoing reasons, the Court should grant Plaintiffs' motion for preliminary injunction and declaratory relief and expedited consideration enter an Order consistent with the proposed order filed contemporaneously herewith.

[50] The Secretary's testimony was disingenuous at best. He testified that "we're not depriving anybody of choice if a pregnant woman wants the Covid-19 vaccine she can get it—no longer recommending it because there was no science supporting that recommendation." C-Span, *Health and Human Services Secretary Kennedy Testifies on 2026 Budget Request, Part 1*, at 01:15:25–01:15:48 (June 24, 2025), https://www.c-span.org/program/house-committee/health-and-human-services-secretary-kennedy-testifies-on-2026-budget-request-part-1/661456. This is simply not true. *See* Ex. 25, Dr. Ramsey Decl. ¶¶ 11–13 and studies cited therein and attached thereto.

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I hereby certify that this document was filed through the ECF system and served upon the following parties by email on this 29th day of July 2025:

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