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-WGY Hon. William G. Young Magistrate Judge Hon. M. Page Kelley

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FOR LACK OF SUBJECT-MATTER JURISDICTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Other Authorities

I. INTRODUCTION

On May 27, 2025, the Secretary of Health and Human Services (the "Secretary") issued a "Secretarial Directive" (the "Directive") that injected chaos, confusion, and disruption into the American healthcare system that has caused concrete harm to all of the Plaintiffs. The Directive has created barriers to accessing the Covid-19 vaccine that has caused the Individual Plaintiffs financial and physical injuries. The Directive has caused financial harm to members of the Associational Plaintiffs by, *inter alia*, forcing them to work extra time for which there is neither a Current Procedural Terminology ("CPT") code to bill their time, nor a Health Care Common Procedure Coding System ("HCPCS") code that is reimbursed by health plans; *i.e.*, with no mechanism to get paid for the extra work time that the Directive has created for the Associational Plaintiffs' members, the Directive is forcing them to work for free. Plaintiff, the American Academy of Pediatrics ("AAP"), has had to divert significant resources to try to mitigate the damage that the Directive has caused to its members, to the patients whom its members care for, and to the organization; thereby establishing organizational standing not only for itself but all of the non-Individual Plaintiffs (hereafter, the "Associational Plaintiffs").

Plaintiffs have filed with this Memorandum declarations from the Jane Doe Plaintiffs and members of the Associational Plaintiffs that show the harm that is befalling them—and the American healthcare system—***now***. Defendants' motion should be denied, and this case should proceed to a trial on the merits so that the Court can hear and see how dire the circumstances are that warrant the Directive being vacated.

II. STATEMENT OF FACTS

A. The Individual Plaintiffs

In July 2025, Jane Doe 1, an M.D., visited her obstetrician who counseled her that because of the uncertainty the Directive had created, she (the obstetrician) was deviating from the standard

of care and recommending that Jane Doe consider trying to get a version of the Covid-19 vaccine that was developed for the 2024–2025 respiratory season earlier than 34 weeks gestation. *See* Ex. 1, Decl. of Jane Doe 1 ("JD1 Decl."), at ¶ 3. Getting the vaccine after 34 weeks gestation enhances the chances that antibodies generated by the vaccine will be passed onto the fetus and thereby protect the child during the first six months of life when the child is not eligible to get the Covid-19 vaccine. *Id.* Jane Doe 1 had heard of insurance carriers not covering the Covid-19 vaccine for pregnant women because of the Directive. *Id.* at ¶ 14. As a medical trainee with significant student loan debt and a baby on the way, she could not afford to pay hundreds of dollars out of pocket for the Covid-19 vaccine. *Id.* at ¶ 15. The stress of deciding whether to accept substandard protection and the concomitant stress of potentially having to pay out of pocket for the Covid-19 vaccine caused Jane Doe 1 to suffer loss of sleep, headaches, and fatigue, all of which affected her productivity at work. *Id.* at ¶¶ 9, 16. On top of all of this, Jane Doe 1 contracted Covid-19 on or about September 1, 2025. *Id*. at ¶ 10.

Jane Doe 2 also is pregnant and likewise encountered significant barriers to accessing the Covid-19 vaccine. *See* Ex. 2, Decl. of Jane Doe 2 ("JD2 Decl."), at ¶¶ 3, 7. When she tried at multiple pharmacies and at her own obstetrician's office to get the Covid-19 vaccine, pharmacists and her doctor's office outright refused to give her the vaccine because to do so was contrary to the new Centers for Disease Control and Prevention ("CDC") guidance. *Id.* at ¶¶ 7–10, 28. On June 4, 2025, Jane Doe 2 left work and drove to a local pharmacy, only to be denied a vaccine by the pharmacist. *Id.* at ¶ 10. The round trip of approximately 13 miles cost her $1.30 at a minimum. *Id.* at ¶¶ 11–14. Jane Doe 2 also spent hours making calls and sending messages back and forth between her physician's office, pharmacies, and a local urgent care because these providers were confused and uncertain due to the Directive as to whether they could administer the Covid-19

vaccine to a pregnant woman. *Id.* at ¶¶ 16–20, 23–24. This time that she spent trying at multiple locations to get the vaccine diverted Jane Doe 2 from focusing on the responsibilities of her job and reduced her productivity: harms that are directly traceable to the Directive. *Id.* at ¶¶ 14–15.

After she tried but was unable to get a Covid-19 shot in June, Jane Doe 2 was exposed to Covid-19 after a July 4 celebration. *Id.* at ¶ 25. The stress of possibly contracting Covid-19 shortly after she was unable to get the booster exacerbated her underlying anxiety disorder and prenatal depression, caused clinically significant sleep disturbances, and caused her to require dental intervention to address increased tooth-grinding. *Id.* at ¶ 26. Jane Doe 2 still suffers from anxiety, depression, and sleep disturbances as a result of being denied the Covid-19 vaccine. *Id.*

On August 14, 2025, a pharmacist denied Jane Does 3's teenage sons, Jimmy and Timmy Doe, Covid-19 vaccines because the Directive removed the recommendation that teenagers receive routine Covid-19 vaccinations. *See* Ex. 3, Decl. of Jane Doe 3 ("JD3 Decl.") at ¶¶ 4, 12–15. That August 14 encounter injured Timmy Doe, who is neurodivergent and suffers from severe anxiety, Attention-Deficit Hyperactivity Disorder ("ADHD"), and a needle phobia. *Id.* at ¶¶ 6–7. Timmy Doe had a full-blown panic attack at the pharmacy on August 14 that manifested in hyperventilating, shaking, crying, and clenching his teeth. *Id.* at ¶¶ 5–6, 13–14. When Jane Doe 3 made a second attempt to get the Covid-19 vaccine for her sons on September 12, Timmy had another anxiety attack that manifested with similar symptoms. *Id.* at ¶¶ 19–21. Had Timmy Doe not been denied the vaccine because of the Directive, Jane Doe 3 and Timmy would not have had to try a second time to get the vaccine, and Timmy would not have had to suffer another anxiety attack. *Id.* at ¶ 22. These injuries are directly traceable to the Directive. Jane Doe 3 also suffered an economic injury because her expenses for the electricity to charge her car on August 14, 2025,

resulted in no benefit at all when she was unable to obtain vaccinations for herself and her children. *Id.* at ¶ 25.

B. The Associational Plaintiffs

The Directive has harmed and continues to harm the Associational Plaintiffs and their members. AAP member Dr. Suzanne Berman, a pediatrician who co-owns the only pediatric practice in her rural Western Appalachia county and neighboring counties in Tennessee, has been harmed by the Directive. Ex. 4, Decl. of Suzanne Berman ("Berman Decl."), at ¶¶ 1, 6–7. Seventy-five percent of Dr. Berman's practice are vulnerable children enrolled in Medicaid or the Children's Health Insurance Program ("CHIP") who rely on the Vaccines for Children ("VFC") program to get vaccinated without out-of-pocket costs. *Id*. at ¶¶ 6, 10–11. She must stock the Covid-19 vaccine at hundreds of dollars per dose because her practice's isolated location means that there are few, if any, other nearby locations that stock the vaccine in her area. *Id.* at ¶¶ 11–12. The Directive, however, has reduced uptake of the vaccine, which will leave her with unused vaccine that she cannot be reimbursed for or may be unable to return to the manufacturer and to get her money back. *Id.* at ¶¶ 13–17. Further, while she and her colleagues regularly counsel parents on their child's care, the move from a clear recommendation to shared clinical decision making ("SCDM") has resulted in a material increase in the frequency and duration of counseling parents of patients about the Covid-19 vaccine-time for which her practice is not paid when parents decline the vaccine. *Id*. at ¶¶ 17–18.

Similarly, Dr. Margie Andreae, an AAP member and pediatrician in Michigan; Dr. Mary-Cassie Shaw, an AAP member and pediatrician in North Carolina; and Dr. Thomas Boyce, a pediatric infectious disease specialist and member of the Infectious Disease Society of America ("IDSA"), have incurred financial harm because the Directive has required all of them to spend more time explaining the safety and effectiveness of the Covid-19 vaccine during preventative

visits, time for which there is no CPT code or HCPCS code that they can use to bill such time when the vaccine is declined. *See* Ex. 5, Decl. of Margie Andreae ("Andreae Decl."), at ¶¶ 10–14; Ex. 6, Decl. of Mary-Cassie Shaw ("Shaw Decl."), at ¶¶ 6–7; Ex. 7, Decl. of Thomas Boyce ("Boyce Decl."), at ¶¶ 9–11.

On August 19, 2025, the AAP released its annual immunization schedule that, for the first time in decades, materially diverged from the CDC's immunization schedule. *See* Ex. 8, Decl. of Molly O'Shea ("O'Shea Decl."), at ¶ 6. That same day, the Secretary posted a statement on X that not only was false and gratuitously disparaging of the AAP, but also threatened any doctor who "diverge[d] from the CDC's official list" with liability because they, according to the highest-ranking health official in the country, "are not shielded from liability under the 1986 Vaccine Injury Act." *Id.* at ¶ 7, Ex. C. Dr. Molly O'Shea, a pediatrician in Michigan who co-owns two practices and is a member of the AAP, took the Secretary's threat seriously and contacted her insurance agent about her malpractice coverage if she administered the Covid-19 vaccine contrary to the "CDC's official list." *Id.* at ¶¶ 1–2, 7–8. Her insurance agent told her: "my practices are not able to give the Covid vaccine or a prescription for the Covid vaccine to any healthy children because, if we do, we are likely not to be covered under our policy, and the carrier would likely not pay for defense counsel to defend us, in the event of a lawsuit over our decision to give the Covid vaccine to a child." *Id.* at ¶ 8.

Then there are the operational harms to the associations. In his declaration, the Chief Executive Officer of the AAP, Mark Del Monte, lists the many initiatives and activities that the AAP has been forced to implement to try to counteract the damage that the Directive has caused. *See* Ex. 9, Decl. of Mark Del Monte ("Del Monte Decl."), at ¶¶ 1, 4–9. Multiple different teams of AAP employees from multiple departments have been forced to divert many hours from other

AAP initiatives to spend that time on a myriad of activities aimed at dispelling the confusion and chaos that the Directive has injected into the American healthcare system. *Id.* at ¶¶ 7–9. The Directive has required Dr. James Lewis, a member of the American Public Health Association and the Health Officer of Snohomish County Health Department in Everett, Washington, to divert many of his working hours to efforts to change local and state laws, and internal policies that are tied to Advisory Committee on Immunization Practices ("ACIP") recommendations and CDC guidance. *See* Ex. 10, Decl. of James Lewis ("Lewis Decl."), at ¶¶ 5–8. Dr. Lewis is engaging in these efforts because the Directive and other actions emanating from the Secretary, the ACIP, and the CDC have caused him and his colleagues to lose trust in the decisions of the Secretary and his advisors. *Id.* at ¶ 5.

III. ARGUMENT

A. The Applicable Legal Standard

1. General Principles

Plaintiffs have standing when they can satisfactorily answer Justice Scalia's memorable question: "What's it to you?"[1] Put differently, Plaintiffs have standing when they have a "personal stake" in the dispute. *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 379 (2024); *accord*, *Am. Ass'n of Univ. Professors v. Rubio*, 780 F.Supp.3d 350, 374 (D. Mass. 2025). Standing requires a concrete and particularized injury in fact that is actual or imminent, fairly traceable to defendants' conduct, and likely redressable. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992). Injuries are "concrete" when they actually exist, *Lyman v. Baker*, 954 F.3d 351, 360 (1st Cir. 2020), and injuries are "particularized" when they affect the plaintiffs "in a personal and individual way," *Lujan*, 504 U.S. at 560 n.1. *See also Mass. Lobstermen's Ass'n, Inc. v. Nat'l Marine Fisheries*

[1] Antonin Scalia, *The Doctrine of Standing as an Essential Element of the Separation of Powers*, 17 Suffolk U. L. Rev. 881, 882 (1983).

Serv., 2024 WL 2194260, at *4 (D. Mass. Apr. 16, 2024) ("To a lobster fisherman who had planned to fish in the relevant waters, the closure of those waters is a concrete, particularized, and actual injury."), *rev'd on other grounds, sub nom. Mass. Lobstermen's Ass'n, Inc. v. Menaches*, 127 F.4th 398 (1st Cir. 2025). Injuries are imminent where the threatened harm is "certainly impending" as opposed to conjectural or "too speculative." *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013); *accord Victim Rights Law Ctr. v. Cardona*, 552 F.Supp.3d 104, 123 (D. Mass. 2021), *order clarified on other grounds by Victim Rights Law Ctr. v. Cardona*, 2021 WL 3516475 (D. Mass. Aug. 10, 2021).

The quantum of injury need not be great; "[i]t is a bedrock proposition that a relatively small economic loss—even an identifiable trifle—is enough to confer standing." *Massachusetts v. U.S. Dep't of Health and Hum. Servs.*, 923 F.3d 209, 222 (1st Cir. 2019)*; see also Am. Ass'n of Univ. Professors*, 780 F.Supp.3d at 379.

An injury is traceable to the actions of a defendant where the plaintiff can show a "sufficiently direct causal connection between the challenged action and the identified harm." *Victim Rights Law Ctr.*, 552 F.Supp.3d at 123 (quoting *Dantzler, Inc. v. Empresas Berríos Inventory & Operations, Inc.*, 958 F.3d 38, 47 (1st Cir. 2020)). Traceability "does not mean that plaintiffs must show to a scientific certainty that defendant's actions, and defendant's actions alone, caused the precise harm suffered by plaintiffs. The fairly traceable requirement is not equivalent to a requirement of tort causation." *Conservation Law Found. v. Am. Recycled Materials, Inc.*, 2017 WL 2622737, at *3 (D. Mass. June 16, 2017) (cleaned up) (quoting *Interfaith Cmty. Org. v. Honeywell Int'l, Inc.*, 399 F.3d 248, 257 (3d Cir. 2005)); *see also Conservation Law Found., Inc. v. Academy Express, LLC*, 129 F.4th 78, 90 (1st Cir. 2025) ("A plaintiff can satisfy traceability by showing 'that the defendant's conduct is one among multiple causes' of the alleged

injury" (quoting 13A Charles Alan Wright, Arthur R. Miller & Edward H. Cooper, Fed. Practice & Procedure § 3531.5 (3d ed. 2008))). Indirect relationships can be sufficiently traceable even if the causal link depends on the action of a third party. *See Bennett v. Spear*, 520 U.S. 154, 168–69 (1997), *abrogated on other grounds as recognized in Teva Pharms. USA, Inc. v. Azar*, 369 F.Supp.3d 183, 200–201 (D.D.C. 2019). The predictable reaction of another party to a government action or the downstream effects of that action are sufficient to establish standing. *Diamond Alt. Energy, LLC v. EPA*, 145 S.Ct. 2121, 2134, 2136–37 (2025)*; Dep't of Com. v. New York*, 588 U.S. 752, 768 (2019).

As to redressability, the plaintiff "need only show that a favorable ruling could potentially lessen its injury." *Antilles Cement Corp. v. Fortuno*, 670 F.3d 310, 318 (1st Cir. 2012).

"At the pleading stage, the Court applies to questions of standing the same plausibility standard used to evaluate a motion under Rule 12(b)(6); the Plaintiffs, therefore, need not definitely prove their injury or disprove defenses but need only plausibly plead on the face of their complaint facts supporting standing." *Am. Pub. Health Ass'n v. Nat'l Insts. of Health*, 2025 WL 1548611, at *6 (D. Mass. May 30, 2025) (cleaned up) (quoting *In re Fin. Oversight & Mgmt. Bd. for P.R.*, 110 F.4th 295, 307–08 (1st Cir. 2024)), *appeal docketed*, Case No. 25-1611 (1st Cir. June 24, 2025). As long as one plaintiff has standing, the litigation continues. *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007); *Comfort v. Lynn Sch. Comm.*, 418 F.3d 1, 11 (1st Cir. 2005) (en banc), *abrogated on other grounds by Parents Involved in Cmty. Schools v. Seattle School Dist. No. 1*, 551 U.S. 701 (2007).

2. Associational Standing

Associations have associational standing to sue on behalf of their members if (1) the members have standing to sue in their own right; (2) the interests the organization seeks to protect are germane to the organization's purpose; and (3) neither the claim asserted, nor the relief

requested requires the individual members to participate in the lawsuit. *Hunt v. Wash. State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977); *Am. Pub. Health Ass'n*, 2025 WL 1548611 at *7 (D. Mass. May 30, 2025); *see also, e.g., Mass. Lobstermen's Ass'n, Inc.*, 2024 WL 2194260, at *5 (holding that the Lobstermen Association had associational standing to challenge fishing regulations because the association existed to protect lobstermen and to advocate for the lobstering industry and the new rule was a threat to the industry). Where the relief requested is only injunctive in nature, individual members of an association are not required to participate in the lawsuit for an organization to exercise associational standing. *Mass Lobstermen's Ass'n, Inc.*, 2024 WL 2194260 at *5 (citing *Sexual Minorities Uganda v. Lively*, 960 F.Supp.2d 304, 326 (D. Mass. 2013)).

An association may also have standing "solely as the representative of its members even in the absence of injury to itself, in certain circumstances." *Camel Hair & Cashmere Inst. of Am., Inc. v. Associated Dry Goods Corp.*, 799 F.2d 6, 10 (1st Cir. 1986) (citing *Warth v. Seldin*, 422 U.S. 490, 511 (1975)).

3. Organizational Standing

Organizational standing exists when the challenged conduct causes "concrete and demonstrable injury to the organization's activities" together with a "consequent drain on the organization's resources" which is "more than simply a setback to the organizations' abstract social interests." *Am. Ass'n of Univ. Professors*, 780 F.Supp.3d at 379 (quoting *Havens Realty Corp. v. Coleman*, 455 U.S. 363, 379 (1982)). If the members of an organization are injured, the organization has standing even if it has not suffered an independent injury. 13A Charles Alan Wright, Arthur R. Miller & Edward H. Cooper Fed. Practice and Procedure § 3531.9.5 (3d ed.).

"[O]nly a perceptible impairment of an organization's activities is necessary for there to be an injury in fact[.]" *Louis v. Saferent Sols., LLC*, 685 F.Supp.3d 19, 32 (D. Mass. 2023); *see also New York v. U.S. Dep't of Homeland Sec.*, 969 F.3d 42, 60–63 (2d Cir. 2020) (holding that

organizations had standing to challenge regulation because the regulation at issue caused the organizations to divert resources to mitigate the impact of a regulation on members and individuals they serve); *The Presbyterian Church (U.S.A.) v. United States*, 870 F.2d 518, 521–22 (9th Cir. 1989) (holding that the plaintiff church established organizational standing because it alleged that surveillance by the Immigration and Naturalization Service caused a decline in attendance and participation in programs).

B. The Individual Plaintiffs Have Standing

All three individual plaintiffs have suffered concrete injuries traceable to the Directive and redressable by this Court.

In July, shortly after the Directive was issued, Jane Doe 1, a pregnant doctor who practices in a hospital, was faced with the decision of whether to get the 2024–2025 Covid-19 vaccine instead of waiting for the 2025–2026 Covid-19 vaccine because she and her obstetrician were concerned that the Directive would reduce access to any Covid-19 vaccines and that payers might not cover the new Covid-19 vaccine due to the Directive. JD1 Decl. at ¶¶ 3–5. Plus, she contracted Covid-19.[2] *Id.* at ¶ 10. All of this exacerbated the stress of being pregnant, which manifested in her suffering loss of sleep, headaches, and fatigue, all of which affected her productivity at work. *Id.* at ¶¶ 9, 16. The stress that the Directive caused Jane Doe 2 to suffer because she was unable on multiple occasions to get the Covid-19 vaccine manifested in exacerbating her anxiety disorder, prenatal depression, and her clinically significant sleep disturbances, and also led her to require dental intervention to address increased tooth-grinding. JD2 Decl. at ¶¶ 26, 31. Jane Doe 3 had to witness her neurodivergent child have another anxiety attack when they tried for a second time to

[2] Defendants argue that Jane Doe 1's fear of contracting Covid is "pure conjecture" and "speculative." (ECF No. 103 at 10). That Jane Doe 1 contracted Covid on or about September 1, 2025 (JD1 Decl. at ¶ 10) shows that it was not conjecture or speculation that Jane Doe 1 would contract Covid; rather, it was predictable and foreseeable.

get the Covid-19 vaccine because they were refused the first time due to the Directive. JD3 Decl. at ¶¶ 5–7, 13–14. These physical injuries are sufficient for Article III standing. *TransUnion, LLC v. Ramirez*, 594 U.S. 413, 425 (2021) ("[C]ertain harms readily qualify as concrete injuries under Article III. . . . If a defendant has caused physical or monetary injury to the plaintiff, the plaintiff has suffered a concrete injury in fact under Article III."); *Tignor v. Dollar Energy Fund, Inc.*, 745 F.Supp.3d 189, 201 (W.D. Pa. 2024) (fear, anxiety, and stress were sufficient, concrete injuries).

Jane Does 1 and 2 also spent hours talking with their medical providers, pharmacies, and urgent care locations, and sifting through insurance documents, to research whether and where they could get the Covid-19 vaccine and whether the shot would be covered by insurance. JD1 Decl. at ¶¶ 3–4, 12–14; JD 2 Decl. at ¶¶ 8–11, 15–24. This was time that they could have spent performing their jobs, a harm that is directly traceable to the Directive. *See, e.g.*, *Webb v. Injured Workers Pharmacy, LLC*, 72 F.4th 365, 377 (1st Cir. 2023) (holding that the time the plaintiffs spent responding to a data breach was a concrete legal injury where the time would otherwise have been put to profitable use).

The Jane Does suffered financial loss in their repeated attempts to get the Covid-19 vaccine after the Directive. JD1 Decl. at ¶¶ 13–15; JD2 Decl. at ¶¶ 9, 11–15; JD3 Decl. at ¶¶ 15, 25. Though small, $1.30 or less is sufficient to satisfy Article III standing. *Van v. LLR, Inc.*, 61 F.4th 1053, 1064 (9th Cir. 2023) ("Any monetary loss, even one as small as a fraction of a cent, is sufficient to support standing"); *cf. Adams v. Watson*, 10 F.3d 915, 924 (1st Cir. 1993) (holding that plaintiffs had standing and rejecting defendant's argument that class members' share of aggregate injury was minimal).

Finally, although Jane Doe 2 and Jimmy and Timmy Doe were able to get the Covid-19 vaccine, their injuries are not solely in the past. The harms they suffered are capable of repetition,[3] and if the Motion to Dismiss is granted, would evade review. *See e.g.*, *Roe v. Wade*, 410 U.S. 113, 125 (1973) ("Pregnancy provides a classic justification for a conclusion of nonmootness. It truly could be 'capable of repetition, yet evading review.'"), *overruled on other grounds by Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022); *see also S. Pac. Terminal Co. v. Interstate Commerce Comm'n*, 219 U.S. 498, 515 (1911); C. Wright, A. Miller, & E. Cooper, Fed. Practice & Procedure § 3533.8 (3d ed. 2025); *Mangual v. Rotger-Sabat*, 317 F.3d 45, 60–61 (1st Cir. 2003), appeal after remand, 383 F.3d 1 (1st Cir. 2004).

C. The Associational Plaintiffs Have Standing

The Associational Plaintiffs have Article III standing because they satisfy each of the *Hunt* elements: (1) their members have standing in their own right; (2) their interests at issue are germane to the associations' respective purposes; and (3) neither the claim asserted, nor the relief requested, require the individual members to participate in the lawsuit. *See Hunt*, 432 U.S. at 343. Further, all of the Associational Plaintiffs have demonstrated concrete, redressable injuries traceable to the Directive and redressable by this Court.

1. First *Hunt* Element: The Associational Plaintiffs' Members Have Standing in Their Own Right

The members of the Association Plaintiffs have standing in their own right as individuals whom the Directive has harmed. Those injuries include the additional uncompensated time that Association members have had to spend because of the Directive and the likelihood of having to eat the cost of purchasing vaccine doses that go unused due to the Directive's suppression of

[3] Jane Does 1 and 2 could become pregnant again, and Jane Doe 3's son is likely to have another panic attack if they are faced with repeat difficulty in getting the Covid-19 vaccine.

vaccine uptake. *See* Ex. 5, Andreae Decl. at ¶ 14 ("losing about $150/day" in uncompensated time because of "vaccine refusal rates tied to the Directive"); Ex. 4, Berman Decl. at ¶¶ 15–16, 19 (likely not to be reimbursed or to be able to return vaccine doses that cost $104.54/dose or $847/dose). These financial losses are more than a trifle, and "a relatively small economic loss—even an identifiable trifle—is enough to confer standing." *Adams*, 10 F.3d at 924.

The Secretary's threat of legal liability for administering vaccines contrary to CDC guidance also demonstrates sufficient harm. *See* Ex. 8, O'Shea Decl. at ¶¶ 7–8, Ex. C; *see also 303 Creative LLC v. Elenis*, 600 U.S. 570, 597 (2022) (holding that a wedding website designer, who declared she would not design a website for a same-sex couple, had standing, even though she had not yet been asked to design a website by a same-sex couple, based on the credible threat of legal consequences if she refused). To be sure, these harms satisfy the standard for injury in fact because they demonstrate a "personal stake" in the dispute. *All. for Hippocratic Med.*, 602 U.S. at 379.

In addition, the inability to prescribe or administer the Covid-19 vaccine or to practice medicine consistent with professional judgment or training are precisely the types of harms that the court in *Washington v. Trump*, 2025 WL 659057 (W.D. Wash. Feb. 28, 2025) held sufficient to establish standing. There, physicians challenged executive orders restricting access to gender-affirming care. The District Court concluded that individual physicians had standing to challenge parts of the order because it prevented them from delivering medically appropriate care and forced them to violate their ethical obligations to patients—even though the order had yet to be enforced, and the alleged injury had not yet actually materialized. *See id*. at *4–5.

The Directive has already created harm, which demonstrates a "substantial probability" of further injury if the Directive is not vacated. *See Adams*, 10 F.3d at 924 (noting that "the meaning of the term 'imminent' depends on the particular circumstances" and that government actions can

have "intractable, long-term consequences"). A party is not required to wait until it is "too late" for purposes of Article III standing. *Rental Hous. Ass'n of Greater Lynn, Inc. v. Hills*, 548 F.2d 388, 389 (1st Cir. 1977). To the contrary, courts have long held that a party who reasonably anticipates harm may bring suit and satisfy Article III's requirements. *Id.*; *see also Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 153–55 (2010) (holding that alfalfa farmers' allegations that their organic and conventional alfalfa crops would be infected with a generally engineered gene if the Animal and Plant Health Inspection Service deregulated the engineered gene were sufficient to establish Article III standing to challenge the deregulation order because they would have to conduct testing to determine if their crops were contaminated before continuing to market their product as non-genetically-engineered alfalfa). Plaintiffs have demonstrated through the declarations filed with this Opposition that they have already suffered harm and that the likelihood of future harm is high.[4]

Association Plaintiffs' members have satisfied the burden of stating a plausible claim of redressability because a ruling and preliminary injunction in their favor would relieve them of the harms caused by the Directive. *See, e.g.*, *Am. Ass'n of Univ. Professors*, 780 F.Supp.3d at 378–79. To establish redressability, a plaintiff "need only show that a favorable ruling *could potentially* lessen its injury." *Antilles Cement Corp.*, 670 F.3d at 318 (emphasis added). The relief Plaintiffs seek is redressable. It will: (1) obviate the need to dedicate time and resources to navigating confusing changes in law and policy not supported by or in conflict with established science (*see* Ex. 9, Del Monte Decl. at ¶¶ 4–9; Ex. 10, Lewis Decl. at ¶¶ 5–8.); (2) relieve Plaintiff

[4] *See, e.g.*, Ex. 1, JD1 Decl. at ¶¶ 9, 15–16; Ex. 2, JD2 Decl. at ¶¶ 14–15, 26; Ex. 3, JD3 Decl. at ¶¶ 5–6, 13–14, 19–22; Ex. 4, Berman Decl. at ¶¶ 13–18; Ex. 5, Andreae Decl. at ¶¶ 10–14; Ex. 6, Shaw Decl. at ¶¶ 6–7; Ex. 7, Boyce Decl. at ¶¶ 9–10; Ex. 8, O'Shea Decl. at ¶¶ 6–8; Ex. 9, Del Monte Decl. at ¶¶ 4–9; Ex. 10, Lewis Decl. at ¶¶ 5–8; *see also* ECF 99, Second Amended Complaint for Declaratory and Injunctive Relief at ¶¶ 45–82 (detailing Defendants' changes to the healthcare and immunology landscape that Plaintiffs have been forced to endure).

organizations' members from spending more time counseling patients experiencing unfounded episodes of vaccine hesitancy, thereby affording their practices the opportunity to see and treat more patients (*see* Ex. 4, Berman Decl. at ¶¶ 10, 12–14, 17–19; Ex. 5, Andreae Decl. at ¶¶ 10–16; Ex. 6, Shaw Decl. at ¶¶ 6–8; Ex. 7, Boyce Decl. at ¶¶ 9–11); (3) reduce the risk of having to eat the cost of purchasing a supply of Covid-19 vaccine doses; and (4) provide clarity to Association Plaintiffs' members on their ability to administer the Covid-19 vaccine, thereby reducing the risk of threatened liability that Association Plaintiffs' members face for prescribing or administering vaccines in a manner that is inconsistent with the Directive, as suggested by the Secretary himself. *See* Ex. 8, O'Shea Decl. at ¶¶ 7–8, Ex. C; *see, e.g.*, *Washington*, 2025 WL 659057, at *4–5.

2. Second *Hunt* Element: The Interests The Association Plaintiffs Seek Are Germane to Each Organization's Purpose

The second element of associational standing under *Hunt* requires that the interests an organization seeks to protect via litigation are germane to its organizational purpose. 432 U.S. at 343; *see also United Food & Commercial Workers Union 751 v. Brown Group, Inc.*, 517 U.S. 544, 555–56 (1996). Since Defendants' motion does not contest a failure to satisfy the second *Hunt* criterion, they have conceded this point. *See, e.g.*, *New England Fishermen's Stewardship Ass'n v. Raimondo*, 761 F.Supp.3d 141, 197 (D. Maine 2024), *appeal docketed*, Case No. 25-1212 (1st Cir. Mar. 7, 2025). Moreover, it is beyond cavil that the interests the Associational Plaintiffs seek to protect are germane to their purpose of supporting their members' efforts to protect and enhance public health through reliance on peer-reviewed, evidence-based, authentic science supported by data that has been analyzed, studied, debated, and voted on by credible subject-matter experts.

3. Third *Hunt* Element: Neither The Claim Asserted Nor The Relief Requested Requires The Participation Of Individual Members Of The Association Plaintiffs In The Lawsuit

The third *Hunt* criterion states that an organization has standing when "neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." 432 U.S. at 343. Individual members are not required to participate if the relief requested will "inure to the benefit of those members of the [Associations] actually injured." *Housatonic River Initiative v. EPA*, 75 F.4th 248, 265–66 (1st Cir. 2023) (quoting *Warth*, 422 U.S. at 515); *see also Playboy Enters., Inc. v. Pub. Serv. Comm'n of P.R.*, 906 F.2d 25, 35–36 (1st Cir. 1990)*; North End Chamber of Com. v. City of Boston*, 761 F.Supp. 3d 269 (D. Mass. 2024), *appeal docketed*, Case No. 25-1063 (1st Cir. Jan. 17, 2025).

Here, the relief requested will inure to the Association Plaintiffs' members by restoring their ability to practice medicine and engage in initiatives to support public health according to peer-reviewed evidence and professional experience. *See Am. Ass'n of Univ. Professors*, 780 F.Supp.3d at 378–79. Further, vacating the Directive and restoring the recommendations to the CDC immunization schedules that pregnant women and children receive the Covid-19 vaccine will significantly reduce, if not eliminate, the amount of uncompensated time and wasted Covid-19 vaccine stock that medical practices are experiencing because of the Directive.

4. The Associational Plaintiffs Plausibly Allege Injuries In Fact That Are Concrete And Imminent

The Association Plaintiffs have suffered a direct, immediate, and concrete injury as a result of the Secretary's Directive. The Supreme Court's recent decision in *Diamond Alternative Energy* controls here: "[t]he government generally may not target a business or industry through stringent and allegedly unlawful regulation, and then evade the resulting lawsuits by claiming that the targets of its regulation should be locked out of court as unaffected bystanders." 145 S.Ct. at 2142. In that case, the Supreme Court determined that a group of fuel producers had standing to challenge an EPA regulation requiring a reduction in the manufacture of gasoline-powered vehicles. The Court

applied a traditional causation and redressability analysis and determined that the regulations raised the "'familiar' circumstance where government regulation of a business 'may be likely' to cause injuries to other linked businesses." *Id.* at 2136 (quoting *All. for Hippocratic Med.*, 602 U.S. at 384). As a result, the fuel producers had standing due to the likely downstream effects of the regulation. *Id.*

Here, as in *Diamond Alternative Energy*, the downstream negative effects of the Directive's regulation of pediatricians, maternal-fetal specialists, and other members of the Associational Plaintiffs who care for children or pregnant women, are predictable and—as the declarations filed herewith demonstrate—have already occurred. Further, the negative impact of the Directive gets worse by the day. Covid-19 cases are rising around the country and are anticipated to rise during the respiratory disease season in the fall,[5] but the Directive erects a barrier to access for individuals seeking the Covid-19 vaccine that can prevent illness, hospitalization, or death. The Directive forces health care providers to spend more time counseling patients on the Covid-19 vaccine in the face of past and anticipated increases in Covid-19 cases, but this is time for which they are often not compensated. The Directive will also in all likelihood result in unused vaccine doses for practices like Dr. Suzanne Berman's in Tennessee, the cost of which her medical practice will likely have to bear at least partially.

The Directive also injures the Associations' members by putting them on the horns of a dilemma: administer the Covid-19 vaccine contrary to CDC guidance and be exposed to liability (according to the Secretary) that may not be covered under the providers' malpractice insurance policy (*see* Ex. 8, O'Shea Decl. at ¶¶ 7–8); or act against their conscience and ethics and either not

[5] The current CDC statistics are available at: https://www.cdc.gov/covid/php/surveillance/index.html (Accessed Sept. 23, 2025). The CDC's projections for Covid-19 for the respiratory disease season are available at: https://www.cdc.gov/cfa-qualitative-assessments/php/data-research/season-outlook25-26.html (accessed Sept. 25, 2025).

administer the vaccine or advise patients not to get the Covid-19 vaccine, inconsistent with the applicable standard of care, and thereby potentially be exposed to liability under state medical malpractice laws. *See, e.g., Cain v. Niemela*, 2020 WL 4249161, at *6 (Mich. Ct. App. July 23, 2020) ("A plaintiff in a medical malpractice action must establish, among other elements, the applicable standard of care governing the defendant doctor's actions and that the defendant doctor breached that standard." (quotation marks omitted) (quoting *Elher v. Misra*, 878 N.W.2d 790, 795 (Mich. 2016)); *Palandjian v. Foster*, 842 N.E.2d 916, 920 (Mass. 2006) ("To prevail on a claim of medical malpractice, a plaintiff must establish the applicable standard of care and demonstrate both that a defendant physician breached that standard, and that this breach caused the patient's harm.").

Thus, the Directive, buttressed by the Secretary's threat, put providers in an intractable conflict situation: either comply with federal guidance or comply with their applicable standard of care governed by state law that is inconsistent with federal guidance. Either option exposes them to potential liability that is traceable to the Directive. *See, e.g., Boggs v. Boggs*, 520 U.S. 833, 844 (1997) ("In the face of this direct clash between state law and the provisions and objectives of ERISA, the state law cannot stand. . . . where compliance with both federal and state regulations is a physical impossibility"); *Denny's, Inc. v. Cake*, 364 F.3d 521, 527 (4th Cir. 2004) (where a state law conflicts with an ERISA plan, "the plan's fiduciary faces a Hobson's choice: obey the state law, and risk violating the provisions of the plan and hence ERISA, or disobey the state law and then raise ERISA preemption as a defense in a state enforcement action and risk breaking the law.") (cleaned up).

D. AAP Has Established Organizational Standing

AAP has put forth sufficient facts to establish of organizational standing. Because of the confusion and uncertainty that the Directive has caused about the Covid-19 vaccine, AAP has been

forced to update FAQs, policy statements, and other guidance on the Covid-19 vaccine; update its own immunization schedule to reflect guidance contrary to the CDC's current immunization schedules; conduct multiple webinars that have taken hours to prepare to try to dispel the confusion that the Directive has caused; answer individual inquiries from many of the AAP's 67,000 members about what they and AAP should recommend to patients about the Covid-19 vaccine; engage in ongoing advocacy with payers about Covid-19 coverage; hold multiple meetings with other professional societies to try to achieve alignment and consensus on how to address the damage caused by the Directive; and much more. Multiple AAP teams of employees have spent many hours on these efforts that could have been spent on other public health initiatives that the AAP would like to pursue. The Directive has caused AAP to divert significant resources from other core activities and has harmed their members. *Havens*, 455 U.S. at 379; *Ass'n of Univ. Professors*, 780 F.Supp.3d at 379 ("Organizational standing allows an organization to sue when, like an individual, it has 'alleged a personal stake in the outcome of the controversy,' because the challenged actions have caused 'concrete and demonstrable injury to the organization's activities,' with a 'consequent drain on the organization's resources' that is 'more than simply a setback to the organizations' abstract social interests.'" (quoting *Havens*, 455 U.S. at 379)); *Alianza Americas v. DeSantis*, 727 F. Supp. 3d 9, 47 (D. Mass. 2024) ("[A]n advocacy organization can establish that it suffered an injury by showing that 'its mission has been frustrated by the challenged conduct and it has expended resources to combat it.'" (quoting *Equal Means Equal v. Dep't of Ed.*, 450 F. Supp. 3d 1, 7 (D. Mass. 2020))).

"So long as one plaintiff has standing to seek a particular form of global relief, the court need not address the standing of other plaintiffs seeking the same relief." *Comfort*, 418 F.3d at 11. Accordingly, as the AAP has stated a plausible injury claim to establish organizational standing,

the Court need not address whether the other Associational Plaintiffs satisfy the elements of organizational standing doctrine.

IV. CONCLUSION

Based on the foregoing facts, arguments, and authorities, Defendants' Motion to Dismiss should be denied in its entirety.

Dated: September 24, 2025

Respectfully submitted,

By: *James J. Oh*
James J. Oh (*admitted pro hac vice*)
Kathleen Barrett (*admitted pro hac vice*)
Carolyn O. Boucek (*admitted pro hac vice*)
Lydia Pincsak (*admitted pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
227 W. Monroe Street, Suite 4500
Chicago, IL 60606
Tel: 312.499.1400
Fax: 312.845.1998
Email: joh@ebglaw.com
kbarrett@ebglaw.com
cboucek@ebglaw.com
lpincsak@ebglaw.com

Elizabeth J. McEvoy (BBO No. 683191)
EPSTEIN BECKER & GREEN, P.C.
One Financial Center, Suite 1520
Boston, MA 02111
Tel: 617.603.1100
Fax: 617.249.1573
Email: emcevoy@ebglaw.com

Richard H. Hughes IV (*admitted pro hac vice*)
Stuart M. Gerson (*admitted pro hac vice*)
Robert Wanerman (*admitted pro hac vice*)
William Walters (*admitted pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
1227 25th Street, N.W., Suite 700
Washington, DC 20037

Tel: 202.861.0900
Fax: 202.296.2882
Email: rhhuges@ebglaw.com
sgerson@ebglaw.com
rwanerman@ebglaw.com
wwalters@ebglaw.com

Marguerite Stringer (*admitted pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
6000 Poplar Avenue, Suite 250
Memphis, TN 38119
Tel: 901.712.3200
Fax: 615.691.7715
Email: mstringer@ebglaw.com

Jeremy A. Avila (*admitted pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
57 Post Street, Suite 703
San Francisco, CA 94104
Tel: 415.398.3500
Fax: 415.398.0955
Email: javila@ebglaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 24th day of September 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

Jim O'Neill, in his official capacity as Acting Director Centers for Disease Control and Prevention

c/o Leah Belaire Foley, US Attorney
Michael L. Fitzgerald
Office of the US Attorney for the District of Massachusetts
1 Courthouse Way, Suite 9200
Boston, Massachusetts 02210
michael.fitzgerald2@usdoj.gov

c/o Isaac Belfer
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044-0386
Isaac.C.Belfer@usdoj.gov

/s/ James J. Oh
James J. Oh

EXHIBIT 1

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

DECLARATION OF JANE DOE, MD

I, Jane Doe, MD, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am currently 34 weeks pregnant.

2. I have talked with my obstetrician about my interest in receiving a covid-19 vaccine during my pregnancy to protect me and Baby Doe. My obstetrician strongly endorsed my decision to get a covid-19 vaccine and instructed me to wait until I was at least 34 weeks pregnant to ensure the best chance of maximally protecting Baby Doe from the upcoming respiratory season, especially because Baby Doe will be ineligible to get a covid-19 vaccine for her first respiratory season.

3. My physician counseled me that, because of the Secretary's May 28, 2025 Directive rescinding the recommendation that healthy children and pregnant women receive routine covid-19 vaccines, there has been such confusion in the medical community about who is eligible for the

covid-19 vaccine and, as a result, her patients have been having difficulty getting the vaccine at the point in their pregnancies that afforded them maximal protection. In July 2025, my obstetrician told me that because of the uncertainty about whether I would be able to actually access the covid-19 vaccine at the point in my pregnancy that would be maximally beneficial for my baby, she was deviating from her recommendation that I follow the standard of care and recommended, instead, I could consider trying to get a version of the covid-19 vaccine that was developed for the 2024–2025 respiratory season earlier than she would normally recommend.

4. My obstetrician counseled me that even if I could access a 2024–2025 covid-19 vaccine and my insurance agreed to cover me getting that covid-19 vaccine before my pregnancy progressed to 34 weeks, if I wanted to get a 2025–2026 covid-19 vaccine when it came out in the fall of 2025 when I would be at least 34-weeks pregnant, my insurance carrier would likely deny my insurance claim on an updated 2025–2026 covid-19 vaccine because I will have received some form of covid-19 vaccine too recently.

5. My reasonable belief that I will encounter difficulty accessing a covid-19 vaccine as a pregnant individual once I am 34 weeks pregnant is based on the information provided to me by my obstetrician. My obstetrician openly told me that the medical advice she gave me this summer is different advice than she would have given me without the Secretary's Directive.

6. Now that the Directive has rescinded the recommendation that healthy pregnant women receive the covid-19 vaccine, I am now forced to gamble with my baby's life and my family's finances insofar as I have been faced with the decision whether to try to get a 2024–2025 vaccine and risk jeopardizing the protection to my baby girl or waiting with hope that we can get a 2025–2026 vaccine to better protect her with the knowledge that if we wait, we may not be able

to get any protection. I am not a betting person, and Mr. Kennedy is asking me to bet my firstborn child.

7. The magnitude of the dilemma the Secretary's Directive puts me in is augmented by the fact that, under the Secretary's Directive, my daughter will not be able to receive a covid-19 vaccine at all until she is at least six months old—after her first respiratory viral season—and she will be unable to receive a covid-19 vaccine as a routine matter after she is born until she becomes an adult.

8. I need to try to give her the maximum protection I can while she's still in the safest place for her: my womb. The Secretary's Directive is forcing me to risk my baby's health and deprives me of my fundamental right as her mother to make the best decisions for my daughter, and my fundamental right to direct my personal medical decisions.

9. I have lost many hours of sleep worrying for my daughter's health and specifically about what decision I should make, now that I have been faced with the decision to either accept suboptimally timed old vaccine which, paying out of pocket for a second updated vaccine, or waiting and risking my baby losing her only best chance to be protected against this deadly virus. My health is suffering as a result of the stress of this decision; specifically, I am losing sleep and am suffering headaches and fatigue. I am fatigued and getting headaches at work because of the stress of the barriers to accessing the vaccine the Directive has caused, and my fatigue and headaches are negatively affecting my productivity at work.

10. Agonizing over the decision whether to wait to get the 2025–2026 vaccine or accept the suboptimally timed old vaccine, I actually contracted the covid-19 virus on September 1, 2025.

11. Even though I have now contracted the covid-19 virus during my pregnancy, my obstetrician has counseled me that the covid-19 vaccine is still the best way to protect my baby so

I am still looking to get vaccinated and I am currently still faced with the decision when to get the 2024–2025 covid-19 vaccine or wait for the 2025–2026 covid-19 vaccine to become available in my community, and the attendant current risks that poses to my health, my baby's future, and my right to make the best decisions for her as her mother.

12. I have learned of pregnant women being denied the covid-19 vaccine because of the Directive, and as a result of learning that, I have called several pharmacies and my employer's employee health resources to try to figure out if I can get a covid-19 vaccine during my pregnancy to protect myself and my baby. So far, I have spent significant time sorting out their various answers which ranged from being unable to tell me if I am eligible for the vaccine as a pregnant woman based on the Directive, and that I *should* be able to get it if I make an appointment, but the pharmacies I called could not make any guarantees that I would be able to get the vaccine there as a pregnant person. I have also reviewed news articles to try to get some insight where I might be successful in getting a covid-19 vaccine, so I can best plan my attempt to get a vaccine for the highest chance of success. Today.com has reported that, even if my pregnancy does not render me ineligible for the new 2025–2026 covid-19 vaccine categorically, I won't be able to get the new 2025–2026 covid-19 vaccine in Massachusetts where I work, and I'll need a prescription in Connecticut where I live. *Are the New COVID Vaccines Available, and Can You Get One? It Depends, Experts Say.* TODAY.COM (Sept. 10, 2025) https://www.today.com/health/coronavirus/covid-vaccine-2025-2026-rcna228529.

13. I have made calls to doctor's offices, pharmacies, and other individuals in my quest to get a covid-19 vaccine in between patient appointments, at times when I would otherwise be putting my efforts to profitable use.

14. Even if I can convince a pharmacy to administer the covid-19 vaccine to me despite the Secretary's Directive, I am far from sure that my insurance will pay for it. I have heard of insurance carriers rescinding coverage for the covid-19 vaccine for pregnant women based on the Secretary's Directive. Because I am not privy to the internal workings of my insurer, I will not be guaranteed advance notice if my insurance carrier changes the policy to deny coverage for the covid-19 vaccine before I am able to get the vaccine (even if I call an hour before I receive the vaccine, that information can be stale by the time the pharmacy can administer the vaccine).

15. My husband and I have significant educational debt, and on a medical trainee's salary with a baby on the way, I cannot afford to pay out-of-pocket for whatever the pharmacy wants to charge for a covid-19 vaccine. Some pharmacies in my area are charging more than two hundred dollars for a single covid-19 vaccine out of pocket. *See Immunizations*, CVS (last accessed Sept. 15, 2025) *https://www.cvs.com/immunizations/covid-19-vaccine*.

16. I have ruminated over whether or not the covid-19 vaccine will be actually or functionally available to me to protect myself and my baby and it has caused significant stress to myself and my baby by proxy. As a result of the stress, I feel about not being able to get a covid-19 vaccine because of the barriers the Directive has caused, I am losing sleep and suffering stress-induced headaches and fatigue. I am sure that these symptoms and the underlying stress induced by the Directive caused compromised my immune system and left me more susceptible to contracting covid-19 when I did. These physical symptoms are a burden on me and my baby and are negatively affecting my productivity at work, which is already reduced by the burden of coordinating with pharmacies and doctor's offices to plan to obtain the covid-19 vaccine during the remainder of my pregnancy. I would not be suffering any of these symptoms if not for the Directive.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on September 23, 2025

/s/ Jane Doe I

Jane Doe, M.D.

EXHIBIT 2

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

DECLARATION OF JANE DOE 2

I, Jane Doe 2, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old.

2. I reside in Massachusetts.

3. I am almost 37 weeks pregnant.

4. I had planned to receive a Covid booster this summer.

5. I saw the announcement that the Secretary of the Department of Health and Human Services ("Secretary") made on X on May 27, 2025, rescinding the recommendation that healthy pregnant individuals and children ages 6 months–17 years get the Covid vaccine.

6. I have been vaccinated against Covid and have received Covid vaccine boosters. However, as a pregnant woman, I am now at greater risk for morbidity and mortality and severe illness if I contract Covid. If I contract Covid while pregnant, that puts my unborn child at risk for

preterm birth and other complications, up to and including stillbirth or death. The Secretary's change to the Covid immunization schedule has significantly raised my level of anxiety, and my inability to locate a health care practitioner able to administer the vaccine to me has caused great distress. I am joining this lawsuit because reversing the Secretary's directive will personally benefit me, as well as all other individuals who are also expecting.

7. On May 30, 2025, following news of the Secretary's removal of the recommendation for the Covid vaccine for pregnant women, I attended a pre-scheduled, routine 20-week prenatal checkup. At this time, I asked my OB/GYN about the CDC recommendations for the Covid booster. She recommended that I be vaccinated against Covid and wrote a prescription for me which she sent to a chain pharmacy. She also documented this interaction in my prenatal report, which states, "Unclear where new CDC guidelines are coming from, unclear if data based. At this time, pregnancy still considered [high risk] for Covid infection and complications and vaccine recommended."[1]

8. On June 4, 2025 I scheduled a vaccination appointment with a chain pharmacy specifically for the Covid vaccine.

9. On June 4, 2025, I drove 6.5 miles in my 2018 Honda CR-V to a national chain pharmacy in the middle of my workday to my local pharmacy.

10. However, upon arrival at the pharmacy, as I was filling out my paperwork to receive the vaccine, the pharmacist on staff asked me whether I was pregnant. After I confirmed that I was, she refused to administer the Covid vaccine to me. The pharmacist stated that she could no longer administer the Covid vaccine due to the new CDC recommendations. She said that she could lose

[1] A true and correct redacted copy of the May 30, 2025 prenatal report is attached hereto as **Exhibit A**.

her license, even though she acknowledged the prescription for the Covid vaccine sent by my provider on May 30, 2025.

11. After being denied the covid-19 vaccine, I drove another 6.5 miles back to my home in my 2018 Honda CR-V.

12. My 2018 Honda CR-V gets approximately 31 miles per gallon. *2018 Honda CR-V*, UNITED STATES DEPARTMENT OF ENERGY (Last visited Sept. 16, 2025) https://www.fueleconomy.gov/feg/PowerSearch.do?action=noform&path=1&year1=2018&year2=2018&make=Honda&baseModel=CR-V&srchtyp=ymm&pageno=1&rowLimit=50.

13. A gallon of regular gasoline cost on average $3.11 in Massachusetts the first week of June 2025. *Weekly Massachusetts All Grades All Formulations Retail Gasoline Prices*, U.S. ENERGY INFORMATION ADMINISTRATION (last visited Sept. 16, 2025) https://www.eia.gov/dnav/pet/hist/LeafHandler.ashx?n=pet&s=emm_epm0_pte_sma_dpg&f=w.

14. Based on my 13-mile drive to and from the pharmacy on June 4, 2025 in my 2018 Honda CR-V which gets 31 miles to the gallon, and that gas prices in my area were $3.11 that week, I burned $1.30 in gas going to and returning from the pharmacy on June 4, 2025. My only purpose in going to the pharmacy that day was to be vaccinated against covid-19.

15. If I did not go to the pharmacy for my covid-19 vaccine on June 4, 2025, I would have devoted that time to my work.

16. Upon being denied the covid-19 vaccine on June 4, 2025, I immediately contacted my OB/GYN's office where I spoke with the on-call nurse to alert them that the chain pharmacy was not able to provide me with the vaccine—this caught them off-guard. The nurse reviewed the conflicting guidance between CDC and the American College of Obstetricians and Gynecologists (ACOG) and determined that they could not administer the vaccine to me either, also citing

concerns that their medical license could be at jeopardy. I also looked at the CDC website for guidance, and it stated that pregnant women should receive the Covid vaccine. I sent a message to my OB/GYN via the practice's medical portal with this information to get confirmation that this was indeed accurate.[2]

17. On June 11, 2025, having received no response to my June 4, 2025 portal message, I called my OB/GYN's office because their lack of responsiveness was uncharacteristically slow. The on-call nurse said that my portal message was sent to the Chair of Maternal Health for the practice who then spoke to the Chief Medical Officer (CMO) for the practice. The nurse explained to me that the CMO said that the guidance is not to administer the Covid vaccine right now and that they would revisit this next season. The nurse suggested I follow up with an urgent care and further stated that "it's a dead end with us" because the practice no longer carries the Covid vaccine and would no longer administer it.

18. A few minutes after this phone call, the on-call nurse sent me a message via the practice's medical portal which included an email from the Medical Director and CMO of the hospital regarding the current Covid vaccine status.[3] The CMO's email states:

> There's probably a lot of education that needs to take place this season. The CDC no longer recommends [the Covid vaccine] for children or pregnant women but there is no prohibition against giving it. The CDC now admits to the use of the word may. I can ask if perhaps the urgent cares can keep U.S. stock. But the new vaccine strain is not yet out.

---

[2] A true and correct redacted copy of my June 4, 2025, portal message to my OB/GYN practice is attached hereto as **Exhibit B.**

[3] A true and correct redacted copy of the June 11, 2025, portal message from my OB/GYN practice is attached hereto as **Exhibit C.**

19. On June 11, 2025, immediately following this phone call and portal message, I called a local urgent care clinic. This clinic informed me they do not stock the vaccine and did not know if they would be ordering more stock. They also stated that it had been a while since anyone asked for the Covid vaccine.

20. On June 13, 2025, my OB/GYN called and left a voicemail following up on the portal messages from June 4, 2025 and June 11, 2025. She communicated that as an office practice and hospital, the practice was looking into the concerning reality that my experience at the chain pharmacy had unveiled: that there are now conflicting guidelines and, therefore, conflicting practices being followed by community pharmacies. She also shared that the practice follows materials from ACOG which strongly supports Covid vaccination during pregnancy.

21. On June 25, 2025, I had my 24-week checkup where I saw a nurse midwife. When I asked again about the Covid vaccine, she said that the practice "supports" me getting the vaccine but does not administer or carry it themselves. She said that the practice had no plans to order the vaccine and to check with the in-house pharmacy.

22. Following this appointment, I called the in-house pharmacy and was told that they also do not stock the Covid vaccine. I followed up with my OB/GYN practice to let them know the situation. [4]

[4] A true and correct redacted copy of my June 25, 2025, portal message to my OB/GYN practice is attached hereto as **Exhibit D**.

23. On June 26, 2025, I received a message via the practice's medical portal from a certified nurse midwife stating that she had called another location of the chain pharmacy which confirmed that they had the Covid vaccine in stock and sent a prescription directly to them.[5]

24. On July 6, 2025, I followed up with the other chain pharmacy location identified by the nurse midwife. My conversation with the pharmacist was confusing. She stated that certain "flexible" pharmacists would administer the Covid vaccine while others would not. When I asked whether it was the chain pharmacy's policy to allow individual pharmacists to determine which vaccines they could administer, she said that normally all pharmacists are on the same page regarding vaccine recommendations but that this is the first time a recommendation did not come from the Advisory Committee on Immunization Practices (ACIP) and, therefore, this is "a grey area." She said to schedule an appointment when a more "flexible" pharmacist, who would be willing to risk their license to vaccinate me, is on staff on July 23. I have scheduled an appointment with this pharmacist for July 23 and hope to receive the vaccine that day. However, I am nervous that should the pharmacist staffing schedule change, I will not be able to receive the vaccine yet again.

25. On July 7, 2025, I learned that a close acquaintance tested positive for Covid earlier that day. This acquaintance had stayed in my home from July 3 until July 6 to celebrate Independence Day, meaning that I and my unborn baby were unknowingly exposed to this deadly illness.

---

[5] A true and correct redacted copy of the June 26, 2025, portal message from my OB/GYN practice is attached hereto as **Exhibit E.**

26. The stress of being vulnerable to covid-19 and having unknowingly exposed by unborn baby to covid-19 because the Directive blocked my ability to be vaccinated in June of 2025 exacerbated my underlying anxiety disorder and prenatal depression. I have suffered clinically-significant sleep disturbances as a result of this stress, and I required a dental intervention to address stress-induced tooth-grinding because I am so stressed about having access to covid-19 vaccines and being vulnerable to the disease personally and for my baby. I still suffer from anxiety, depression, and clinically-significant sleep disturbances as a result of being denied the covid-19 vaccine between June 2025 and July 2025.

27. On July 23, 2025, I finally received a COVID-19 vaccination at a national chain pharmacy. The scheduling process was conducted over the phone. I was told I would be seen during a time when a "flexible" pharmacist was on duty.

28. When I arrived at the pharmacy on July 23, 2025, the pharmacist presented me with an attestation form that I was required to sign in order to receive the Covid-19 vaccine. The form included the following statement: "If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC."[6] I was confused by this statement because, on the one hand, pharmacists and my own doctor's office had refused to give me the vaccine because it was supposedly against current recommendations from the CDC and what Secretary Kennedy said in his announcement on X on May 27. On the other hand, I am aware that on the same day that I went to the flexible pharmacist who gave me the Covid shot, the CDC website states:

> "If you are pregnant or were recently pregnant, you are:

[6] A true and correct copy of the attestation form is attached hereto as **Exhibit F.**

- More likely to get very sick from COVID-19 compared to those who are not pregnant.
- More likely to need hospitalization, intensive care, or the use of a ventilator or special equipment to breathe if you do get sick from COVID-19. Severe COVID-19 illness can lead to death.
- At increased risk of complications that can affect your pregnancy and baby including, preterm birth or stillbirth.

COVID-19 vaccination remains the best protection against COVID-19-related hospitalization and death for you and your baby. CDC recommendations align with those from professional medical organizations including the American College of Obstetricians and Gynecologists, Society for Maternal Fetal Medicine, and American Society for Reproductive Medicine."

But then, the CDC website also has a prominently displayed banner stating: "COVID recommendations have recently been updated for some populations. This page will be updated to align with the updated immunization schedule."[7]

29. Since the CDC's current eligibility guidelines conflict with the Secretary's directive, I had to ask the pharmacist during my visit for clarification on that section of the attestation. The pharmacist agreed that the guidelines were unclear. He told me that, in cases like this, he personally chooses to follow the guidance of obstetric and pediatric professional organizations. Relying on his assurance, I signed the attestation and received the vaccine.

30. I am surprised that a major pharmacy chain permits this level of ambiguity and discretion among its pharmacists regarding federal vaccination guidelines.

31. During the two-month period from May 30, 2025 until July 23, 2025, I have personally experienced and witnessed the chaos, confusion, and stress that the Secretary's directive has caused for me, doctors and pharmacists as to whether the Covid vaccine can be given to

[7] A true and correct copy of the CDC website as of July 24, 2025 is attached hereto as **Exhibit G.**

pregnant individuals like me. I am grateful that I was finally able to find a "flexible" pharmacist who gave me the vaccine when others would not. I am very concerned for other pregnant individuals who are all in the same position as I have been—receiving conflicting and inconsistent guidance from the country's top public health official, from the CDC website, from my own doctor's office, and from the multiple pharmacists from whom I attempted to get the vaccine. It is clear to me that the Secretary's directive is the direct cause of this chaos and confusion. I sincerely hope for all pregnant individuals in this country that this situation gets fixed and clarified so that women who are pregnant do not have to experience what I experienced. That is why I submit this declaration and join this lawsuit.

32. All of the facts set forth in this declaration are based on my personal knowledge.

33. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath.

34. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

9/23/2025

Executed on September __, 2025.

/s/ Jane Doe 2

JANE DOE 2

EXHIBIT A

OB/GYN Prenatal Report

Notes

Visit Date: 05/30/25 Last Updated by: [redacted]

35yo G2P0 at 20w1d for routine prenatal care.

No vaginal bleeding, leaking, discharge, dysuria or abdominal pain.

Endorses fetal flutters.

Prenatal chart and labs reviewed.

Level II reviewed, limited anatomy, otherwise normal EFW 22%tile. Needs 4 week f/u, scheduled for 6/27.

Rash in inferior abdominal fold, not c/w yeast. Advised to keep dry and use topical hydrocortisone. Given ABD pads.

Patient inquiring about Covid vaccine booster. Discussed recent CDC recommendations against Covid vaccination in health kids and pregnant women.

Unclear where new CDC guidelines are coming from, unclear if data based. At this time, pregnancy still considered HR for Covid infection and complications and vaccine recommended.

Increased daily water intake and PNVs encouraged.

PTL/SAB precautions reviewed.

FU in 4 weeks

EXHIBIT B

1:44 pm ***

Hi Dr. [redacted],
Unfortunately today I was refused a vaccination for the Covid vaccine, with the pharmacist citing their license would be in jeopardy, and insisting they had to follow CDC guidelines.

I spoke to [redacted] and the care team and [redacted] and it sounds like I'm the first person to experience this, but she reiterated they can't write a letter or administer the vaccine either for the same reasons- licenses would be in jeopardy.

Can you confirm this is all accurate and do you have any advice on how I can access the vaccine both you & ACOG recommend? The CDC website doesn't actually look like it's been updated, it still states pregnant women should get vaccinated against COVID.

Thanks,
[redacted]

EXHIBIT C

9:32 am

COVID vaccine

From [redacted] on
June 11, 2025 at 9:32 am

Hi [redacted],

Here is the most recent email from our medical director anf hospital CMO regarding the current COVID vaccine status:

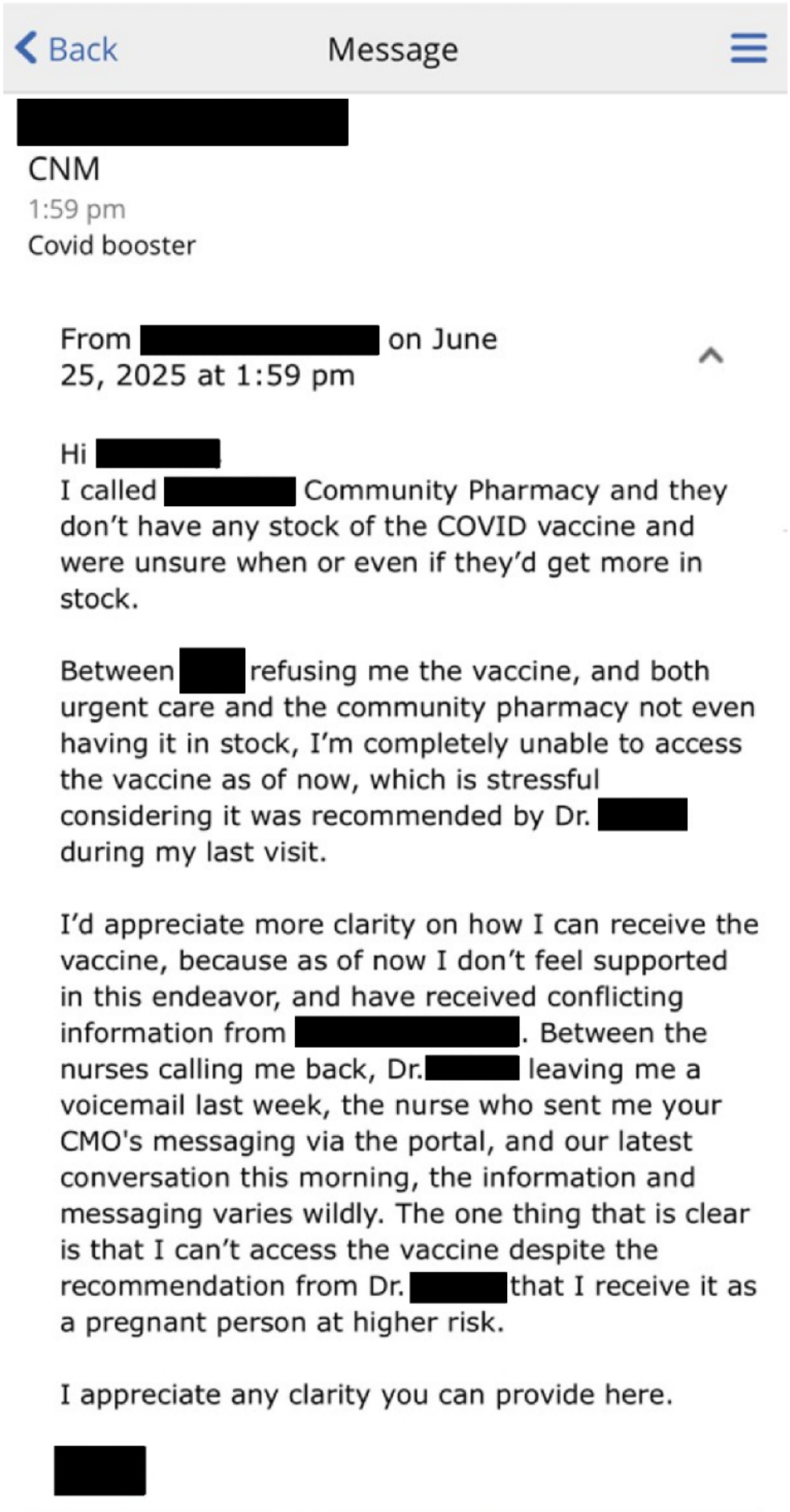
His response "There's probably a lot of education that needs to take place this season. The CDC no longer recommends COVID for children or pregnant women but there is no prohibition against giving it. The CDC now admits to the use of the word may. I can ask if perhaps the urgent cares can keep U.S. stock. But the new vaccine strain is not yet out."

So, with that being said I would hold off for now until we get back to URI season and we have a better plan in place to help our patients access vaccination if it is desired.

Thank you,

[redacted]

EXHIBIT D



Back Message

[redacted]

CNM

1:59 pm

Covid booster

From [redacted] on June 25, 2025 at 1:59 pm

Hi [redacted]

I called [redacted] Community Pharmacy and they don't have any stock of the COVID vaccine and were unsure when or even if they'd get more in stock.

Between [redacted] refusing me the vaccine, and both urgent care and the community pharmacy not even having it in stock, I'm completely unable to access the vaccine as of now, which is stressful considering it was recommended by Dr. [redacted] during my last visit.

I'd appreciate more clarity on how I can receive the vaccine, because as of now I don't feel supported in this endeavor, and have received conflicting information from [redacted]. Between the nurses calling me back, Dr. [redacted] leaving me a voicemail last week, the nurse who sent me your CMO's messaging via the portal, and our latest conversation this morning, the information and messaging varies wildly. The one thing that is clear is that I can't access the vaccine despite the recommendation from Dr. [redacted] that I receive it as a pregnant person at higher risk.

I appreciate any clarity you can provide here.

[redacted]

EXHIBIT E

Back Message

[redacted] CNM
10:00 am
Covid booster

From [redacted], CNM on
June 26, 2025 at 10:00 am

Hi [redacted],

I just called [redacted] on [redacted] - the pharmacy tech that I spoke with said that they have the COVID vaccine in stock and they do not require any special documentation to administer the COVID vaccine in pregnancy. Just in case, I have also ordered the vaccine to the [redacted] pharmacy.

Our in-house pharmacy advised that there is a website that can help you identify alternative local vaccine access locations - vaxassist.com.

Please feel free to reach out with any questions or concerns.

[redacted] CNM

*** From [redacted] on June 25, 2025 at 1:59 pm ***

Hi [redacted],
I called [redacted] Community Pharmacy and they don't have any stock of the COVID vaccine and were unsure when or even if they'd get more in stock.

Between [redacted] refusing me the vaccine, and both urgent care and the community pharmacy not even having it in stock, I'm completely unable to access the vaccine as of now, which is stressful

EXHIBIT F

CONSENT FOR SERVICES: I have received/read (or had read to me) the Vaccine Information Statement(s), Vaccine Information Fact Sheet(s) and/or Patient Fact Sheet(s) regarding the vaccine(s). I understand the benefits/risks of vaccination. I voluntarily assume full responsibility for any reactions/consequences that may result. I understand I should remain in the vaccine administration area for 15 minutes, or longer if directed, after vaccination to be monitored for potential adverse reactions. In the event of side effects, I understand I should call the pharmacy, my doctor, or 911. I certify the information provided regarding eligibility for the vaccine is accurate and request the vaccine be given to me/the person previously named for whom I am authorized to make this request. If I am signing on behalf of another individual (including a minor), I attest I have the authority to do so. The following must have consent of a parent or guardian: Patients in Alabama/Nebraska under 19 yrs old; patients in South Carolina under 16 yrs old; and patients under 18 yrs old in all other states. If I am receiving a COVID-19 vaccine dose, I attest I am eligible for that dose according to current recommendations from the CDC. State of Georgia only: I verify a pharmacist asked for my health history and whether I had a physical exam in the past year. Health care providers did not identify conditions(s) that would mean I should not receive vaccine(s)

AUTHORIZATION TO REQUEST PAYMENT: I authorize [redacted] to release information to Medicare, Medicaid or any other third party payer as needed and to request payment of authorized benefits to be made on my behalf to [redacted], I certify the information provided about my Medicare, Medicaid or other coverage is correct

ACCEPTANCE OF FINANCIAL RESPONSIBILITY: Notwithstanding anything previously set forth, I agree I am responsible for and will promptly pay on demand any and all obligations to [redacted] Pharmacy including all self-pay balances as well as charges for services not covered or disallowed by my insurance carrier (for non-COVID-19 vaccines)

DISCLOSURE OF RECORDS: I understand [redacted] may be required to or may voluntarily disclose my health information with respect to this vaccine to my healthcare providers, my insurance plan, health systems and hospitals, and/or state or federal registries. I understand [redacted] will use and disclose my health information as set forth in the [redacted] Notice of Privacy Practices (copy is available in-store, online or by requesting a paper copy from the pharmacy team). State of California only: I agree to have the California Immunization Registry (CAIR) share my immunization data with the health care providers, agencies or schools. State of Florida only: Students 18-23 may opt out of the immunization registry by notifying pharmacy prior to administration

Date: _____

X _____

Signature of patient to receive vaccine or person authorized to make the request (parent/guardian)

EXHIBIT G

COVID-19

COVID-19 Vaccination for Women Who Are Pregnant or Breastfeeding

For Everyone
SEPT. 10, 2024 •

COVID-19 VACCINE RECOMMENDATIONS

COVID-19 vaccine recommendations have recently been updated for some populations. This page will be updated to align with the updated immunization schedule. Learn more.

WHAT TO KNOW

- Everyone ages 6 months and older is recommended to get the updated COVID-19 vaccine, including if you are pregnant, breastfeeding a baby, trying to get pregnant now, or might become pregnant in the future.
- COVID-19 vaccination during pregnancy is safe and effective.
- COVID-19 vaccines are not associated with fertility problems in women or men.
- Infants ages 6 months and older are recommended to get the updated COVID-19 vaccine even if born to mothers who were vaccinated or had COVID-19 before or during pregnancy.
- If you are pregnant or were recently pregnant, you are more likely to get very sick from COVID-19, compared to those who are not pregnant. Additionally, if you have COVID-19 during pregnancy, you are at increased risk of complications that can affect your pregnancy and your baby from serious illness from COVID-19.

Recommendations during and after pregnancy

If you are pregnant or were recently pregnant, you are:

- More likely to get very sick from COVID-19 compared to those who are not pregnant.
- More likely to need hospitalization, intensive care, or the use of a ventilator or special equipment to breathe if you do get sick from COVID-19. Severe COVID-19 illness can lead to death.
- At increased risk of complications that can affect your pregnancy and baby including, preterm birth or stillbirth.

COVID-19 vaccination remains the best protection against COVID-19-related hospitalization and death for you and your baby. CDC recommendations align with those from professional medical organizations including the American College of Obstetricians and Gynecologists, Society for Maternal Fetal Medicine, and American Society for Reproductive Medicine.

Pregnant and have questions about COVID-19 vaccine?

If you would like to speak to someone about the COVID-19 vaccination during pregnancy, you can talk to your healthcare provider. You can also contact MotherToBaby, whose experts can answer questions in English or Spanish. This service is free and confidential.

To reach MotherToBaby:

- **Call:** 1-866-626-6847
- **Text:** 1-855-999-3525 (standard messaging rates may apply)

Safety and effectiveness of COVID-19 vaccination during pregnancy

Studies including hundreds of thousands of people around the world show that COVID-19 vaccination before and during pregnancy is safe, effective, and beneficial to both the pregnant woman and the baby. The benefits of receiving a COVID-19 vaccine outweigh any potential risks of vaccination during pregnancy. Data show:

- **COVID-19 vaccines do not cause COVID-19, including in pregnant women or their babies.** None of the COVID-19 vaccines contain live virus. They cannot make anyone sick with COVID-19, including pregnant women or their babies. Learn more about how vaccines work.
- **It is safe to receive an mRNA COVID-19 vaccine (Moderna or Pfizer-BioNTech), before and during pregnancy.** Both vaccines show no increased risk for complications like miscarriage, preterm delivery, stillbirth, or birth defects [1] [2].
- **mRNA COVID-19 vaccines during pregnancy are effective.** They reduce the risk of severe illness and other health effects from COVID-19. COVID-19 vaccination might help prevent stillbirths and preterm delivery [1] [2] [3] [4].
- **COVID-19 vaccination during pregnancy builds antibodies that can help protect the baby.** [4] [5]
- **Receiving mRNA COVID-19 vaccines during pregnancy can help protect babies younger than age 6 months from hospitalization due to COVID-19.** [6] [7] [8]
- Most babies hospitalized with COVID-19 were born to pregnant women who were not vaccinated during pregnancy [6] [7] [8].

Recommendations if you are breastfeeding

CDC recommends that women who are breastfeeding a baby, and infants 6 months of age and older, get vaccinated and stay up to date with their COVID-19 vaccines.

Vaccines are safe and effective at preventing COVID-19 in women who are breastfeeding a baby. Available data on the safety of COVID-19 vaccination while breastfeeding indicate no severe reactions after vaccination in the breastfeeding mother or the breastfed child. [9] There has been no evidence to suggest that COVID-19 vaccines are harmful to either women who have received a vaccine and are breastfeeding or to their babies. [10]

Studies have shown that mothers who are breastfeeding a baby and have received mRNA COVID-19 vaccines have antibodies in their breast milk, which could help protect their babies. [9] [10]

CDC also recommends COVID-19 vaccines for children aged 6 months and older.

Possible side effects

Pregnant women have not reported different side effects from women who are not pregnant after vaccination with mRNA COVID-19 vaccines (Moderna and Pfizer-BioNTech vaccines) [1] [2].

- Fever during pregnancy, for any reason, has been associated with adverse pregnancy outcomes.
- Fever in pregnancy may be treated with acetaminophen as needed, in moderation, and in consultation with a healthcare provider.
- Learn more about possible side effects and rare severe allergic reactions after receiving a COVID-19 vaccine.

Recommendations if you would like to have a baby in the future

CDC recommends that women who are trying to get pregnant now or might become pregnant in the future, as well as their partners, stay up to date and get the updated COVID-19 vaccine. COVID-19 vaccines are not associated with fertility problems in women or men.

Common questions

Expand All

What are the long-term effects on the baby if I get a COVID-19 vaccine during pregnancy?

Scientific studies to date have shown no safety concerns for babies born to mothers who were vaccinated against COVID-19 during pregnancy. Based on how these vaccines work in the body, experts believe they are unlikely to pose a risk for long-term health effects. CDC continues to monitor, analyze, and disseminate information from women vaccinated during all trimesters of pregnancy to better understand effects on pregnancy and babies.

When should I get the updated COVID-19 vaccine during pregnancy?

CDC and professional medical organizations, including the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine, recommend COVID-19 vaccination at any point in pregnancy. COVID-19 vaccination can protect you from getting very sick from COVID-19. Keeping yourself as healthy as possible during pregnancy is important for the health of your baby.

Which COVID-19 vaccine should I receive if I am pregnant?

You can choose which updated COVID-19 vaccine to get.

Can I get a COVID-19 vaccine at the same time as other vaccines?

Children, teens, and adults, including pregnant women, may get a COVID-19 vaccine and other vaccines, including a flu vaccine, at the same time.

Resources

For Healthcare and Public Health

- Considerations for the Use of COVID-19 Vaccines in the United States
- Management of Anaphylaxis after COVID-19 Vaccination
- COVID-19 Clinical and Professional Resources
- Clinic Poster: Protect yourself and your baby from COVID-19 PDF

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases; Coronavirus and Other Respiratory Viruses Division

REFERENCES

1. Fleming-Dutra KE, Zauche LH, Roper LE, Ellington SR, Olson CK, Sharma AJ, Woodworth KR, Tepper N, Havers F, Oliver SE, Twentyman E, Jatlaoui TC. Safety and Effectiveness of Maternal COVID-19 Vaccines Among Pregnant People and Infants. Obstet Gynecol Clin North Am. 2023 Jun;50(2):279-297. Safety and Effectiveness of Maternal COVID-19 Vaccines Among Pregnant People and Infants - ScienceDirect
2. Prasad, S., Kalafat, E., Blakeway, H. et al. Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy. Nat Commun 13, 2414 (2022). Systematic review and meta-analysis of the effectiveness and perinatal outcomes of COVID-19 vaccination in pregnancy | Nature Communications
3. Schrag SJ, Verani JR, Dixon BE, et al. Estimation of COVID-19 mRNA Vaccine Effectiveness Against Medically Attended COVID-19 in Pregnancy During Periods of Delta and Omicron Variant Predominance in the United States. JAMA Netw Open. 2022;5(9):e2233273. doi:10.1001/jamanetworkopen.2022.33273
4. Piekos SN, Price ND, Hood L, Hadlock JJ. The impact of maternal SARS-CoV-2 infection and COVID-19 vaccination on maternal-fetal outcomes. Reprod Toxicol. 2022;114:33-43. The impact of maternal SARS-CoV-2 infection and COVID-19 vaccination on maternal-fetal outcomes - ScienceDirect
5. Yang YJ, Murphy EA, Singh S, et al. Association of Gestational Age at Coronavirus Disease 2019 (COVID-19) Vaccination, History of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Infection, and a Vaccine Booster Dose With Maternal and Umbilical Cord Antibody Levels at Delivery. Obstetrics & Gynecology: 2021. DOI: https://doi.org/10.1097/AOG.0000000000004693
6. Halasa NB, Olson SM, Staat MA, et al. Maternal Vaccination and Risk of Hospitalization for Covid-19 among Infants. N Engl J Med. 2022;387(2):109-119. doi:10.1056/NEJMoa2204399

7. Hamid S, Woodworth K, Pham H, et al. COVID-19–Associated Hospitalizations Among U.S. Infants Aged <6 Months — COVID-NET, 13 States, June 2021–August 2022. MMWR Morb Mortal Wkly Rep 2022;71:1442–1448. DOI: http://dx.doi.org/10.15585/mmwr.mm7145a3
8. Simeone RM, Zambrano LD, Halasa NB, et al. Effectiveness of Maternal mRNA COVID-19 Vaccination During Pregnancy Against COVID-19–Associated Hospitalizations in Infants Aged <6 Months During SARS-CoV-2 Omicron Predominance — 20 States, March 9, 2022–May 31, 2023. MMWR Morb Mortal Wkly Rep 2023;72:1057–1064. DOI: http://dx.doi.org/10.15585/mmwr.mm7239a3
9. Muyldermans J, De Weerdt L, De Brabandere L, Maertens K, Tommelein E. The Effects of COVID-19 Vaccination on Lactating Women: A Systematic Review of the Literature. Front Immunol. 2022;13:852928. Published 2022 Apr 8. doi:10.3389/fimmu.2022.852928
10. Drugs and Lactation Database (LactMed) [Internet]. Bethesda (MD): National Library of Medicine (US); 2006-. COVID-19 Vaccines. [Updated 2022 Sep 19]. Available from: https://www.ncbi.nlm.nih.gov/books/NBK565969/

SOURCES

- National Center for Immunization and Respiratory Diseases (NCIRD), Division of Viral Diseases

EXHIBIT 3

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

DECLARATION OF JANE DOE 3

I, Jane Doe 3, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old.

2. I reside in the state of Washington.

3. I am immunocompromised, which places me at a substantially increased risk of severe illness, hospitalization, or death if I contract Covid.

4. I am the mother of two minor children, sons ages 16 (Jimmy) and 13 (Timmy).

5. Both of my sons are neurodivergent.

6. Jimmy and Timmy both have anxiety disorders and attention deficit hyperactivity disorder ("ADHD") and Jimmy also has autism.

7. In addition to his underlying anxiety and ADHD, Timmy Doe has a severe needle phobia.

8. I hold a Master's degree in Public Health and Epidemiology and a Bachelor of Science (major in biology and minors in chemistry and mathematics).

9. My children and I have followed public health guidance throughout the Covid pandemic, including receiving recommended vaccinations. This year, both my sons again wanted to receive the Covid booster before school starts on August 27, 2025, so they would be fully protected at the start of the school year.

10. I saw the announcement that the Secretary of the Department of Health and Human Services ("Secretary") made on X on May 27, 2025, ordering the Centers for Disease Control and Prevention ("CDC") to remove from its immunization schedules the recommendation that healthy pregnant individuals and children ages 6 months–17 years get the Covid vaccine (the "Directive"). As an immunocompromised parent, this decision alarmed me and my children. They do not want to contract Covid or risk passing it to me, and they expressly wanted the vaccine before school began.

11. On August 8, 2025, I personally received a Covid vaccine from a national pharmacy chain. I scheduled that appointment online and was vaccinated without issue that day.

12. I used the same pharmacy's online scheduling system to book Covid vaccination appointments for both of my sons for August 14, 2025. The system accepted their birthdates and allowed me to select the Covid vaccine for each child.

13. On the night of August 13, 2025, anticipating his vaccine appointment, Timmy Doe suffered an anxiety attack.

14. Before entering the pharmacy on August 14, 2025, Timmy Doe had a panic attack including hyperventilating, crying, clenching his teeth, shaking, and other physical symptoms of his anxiety and needle phobia.

15. I drove my electric vehicle to the chain pharmacy on August 14, 2025 with my two sons at the time of their scheduled vaccine appointment. I checked in with pharmacy technician at the pharmacy counter, and my children sat in the seats behind me. After checking in with the pharmacy technician, she got the pharmacist (a female with short dark hair) who came to the counter to speak with me.

a. The pharmacist stated that the new vaccine is coming out in September and I said, we don't know that. The pharmacist then asked if my children previously received the vaccine, and I said yes. The pharmacist responded, "then why do you need it?" I explained to the pharmacist that "I wanted my children protected before school started, and as it takes up to two weeks to obtain the full effect of the Covid vaccine, I wanted them to receive the vaccine now."

b. The pharmacist then took out her phone and started scrolling through something on her screen. The pharmacist then looked up from her phone and told me, "I cannot give them the Covid vaccine because they are not in the eligible age group." When I asked, "what is the eligible age group?," the pharmacist replied, "either over 60 or 65 is the eligible age group." The pharmacist then ended the conversation by stating that she would not vaccinate my sons because they are not in the eligible age group.

16. As a result of being turned away by the pharmacist, my children remained unvaccinated until September 12, 2025. Until they could be vaccinated, both boys were deeply upset—they were fearful of catching what they call the new Covid strain's "razor-blade throat" and even more fearful of infecting me given my compromised immune system.

17. I have experienced firsthand the confusion, anxiety, and disruption caused by the Secretary's Directive. Before the Directive, my children were eligible for and received the Covid vaccine. I encountered absolutely no issues getting my children the Covid vaccine last year. After

the Directive, my children were refused vaccination at a national pharmacy chain, leaving them and me more vulnerable to the virus.

18. The denial of vaccination for my children is a direct consequence of the Directive. Vacating that Directive would immediately benefit me and my children by restoring their ability to receive the vaccine and reduce our risk of severe illness. I am joining this lawsuit because I and my children have suffered, and continue to suffer, personal harm as a result of the Directive. I therefore urgently seek relief that will protect my children and me from the ongoing threat of Covid.

19. I made a second appointment for Jimmy and Timmy to be vaccinated against covid-19 at a local national chain pharmacy for September 12, 2025. I told my sons about their appointment the night before on September 11, 2025.

20. On September 11, 2025, anticipating his vaccine appointment for the following day, Timmy Doe had another anxiety attack.

21. Routine is very important to Timmy as a neurodivergent individual and it is critical to the success of his coping mechanisms for his mental health struggles. When we were denied the covid-19 vaccine because of the Directive, his routine around vaccinations was disrupted, and now he cannot readily rely on clear expectations what a vaccine appointment will look like, which exacerbates his anxiety and phobia symptoms, and contributed to triggering and exacerbating the severity of his anxiety attack on September 11, 2025.

22. Timmy Doe's anxiety attack on September 11, 2025 was caused, at least in part, by the disruption of his expectations about what a vaccine appointment entails because we were denied the vaccine during the August 14, 2025 appointment.

23. School started for Timmy Doe on August 27, 2025. Because the pharmacist denied him the covid-19 vaccine on August 14, 2025 due to the Directive, he was not vaccinated when school started. One of his classes had a celebrating involving food, and Timmy, fearing contracting covid-19 and giving it to his immunocompromised mother, did not feel comfortable taking his mask off to enjoy the class treat. As a result, he was unable to participate fully in the celebration and suffered an element of social ostracism. Had he received the vaccine on August 14, 2025 as planned, he would have participated in the class event and avoided the social ostracism.

24. All of the facts set forth in this declaration are based on my personal knowledge. If called upon to testify as to the facts stated herein as a witness, I could and would competently testify under oath to the truth of these facts.

25. Prior to driving my electric vehicle to the pharmacy on August 14, 2025, I charged my electric vehicle at my home. My electric bill is higher than it would have been had I not driven to the pharmacy and back on August 14, 2025 for my sons' vaccine appointment. The only reason I went to the pharmacy that day was to get my sons vaccinated against covid-19.

I declare under penalty of perjury under the laws of the United States of America and the State of Washington that the foregoing is true and correct.

Executed on September 9/23/2025, 2025 in the state of Washington.

/s/ Jane Doe 3

Jane Doe 3

EXHIBIT 4

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

DECLARATION OF DR. SUZANNE BERMAN

I, Dr. Suzanne Berman, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old, reside in Tennessee, and currently co-own Plateau Pediatrics, located in Crossville, Tennessee. I primarily manage the business and compliance aspects of the practice.

2. I completed medical school at the University of Tennessee, Memphis in 1998. I completed my residency in pediatrics at Southern Illinois University in 2001.

3. I am board-certified in pediatrics.

4. I am member of the American Academy of Pediatrics (AAP).

5. Ten clinicians, including physicians and nurse practitioners, currently practice at Plateau Pediatrics.

6. Many of the children we treat are medically complex or fragile, including former premature infants, children with G-tubes, and children requiring ventilators. These children require specialty care that family practitioners often cannot provide.

7. Given our large population of Medicaid patients, Plateau Pediatrics has long participated in the Vaccines for Children ("VFC") program, which requires us to stock both federally supplied vaccines and private stock vaccine formulations. We are therefore required to purchase and maintain private stock of Covid-19 vaccines.

8. When the Centers for Disease Control and Prevention ("CDC") classifies a vaccine as routine, that means that the patient should get the vaccine. In other words, when a vaccine is classified as routine, the default is to get the vaccine, or, put another way, it is assumed or presumed that the patient will get the vaccine as a matter of following the ordinary standard of care for the patient. I have been comfortable with recommending that my patients receive a vaccine recommended as routine because credible doctors, scientists, and other subject-matter experts on vaccines, infectious diseases, epidemiology, and public health have done thorough, comprehensive analysis of the evidence on the vaccine and concluded with a high degree of confidence that the vaccine is highly effective at preventing disease and saving lives with minimal risk to the patient.

9. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025, and have read the related May 19 "Secretarial Directive" ("Directive") confirming what the Secretary said in the video. Although I understood the Secretary to be instructing the CDC in that video to remove the recommendation entirely that healthy children receive the Covid-19 vaccine, I learned that the Covid-19 recommendation was not entirely removed from the CDC immunization schedule but was changed to a "Shared Clinical Decision Making" recommendation, or SCDM. I and my colleagues

considered this change from "routine" to "SCDM" to be a downgrading of the CDC's recommendation and discouraging parents to permit the vaccine for their children.

10. The downgrading to SCDM has the downstream effect of discouraging parents to agree to vaccinate their children with the Covid vaccine, which will cause financial harm to my practice. Plateau Pediatrics serves approximately 8,800 active patients. The practice is located in a rural area of Western Appalachia, and roughly 75% of our patients are enrolled in Medicaid or CHIP (Children's Health Insurance Program).

11. We are the only pediatric practice in our county, which has a population of approximately 60,000 to 70,000 people. While some family medicine physicians in the county see children, we are the only pediatricians. Several neighboring counties have no pediatric practices. As a result, our practice provides essential pediatric care for families across multiple counties in Tennessee.

12. Our practice does not require patients to be vaccinated in order to remain in our care because the practice serves a population with a high level of skepticism of vaccines. If my practice were to require patients to be vaccinated, these families would have no alternative options for pediatric care. Yet, I and my colleagues nonetheless still try to convince parents to vaccinate their children. If we are successful in convincing a skeptical parent to give the Covid-19 vaccine to their child, Plateau Pediatrics must have the Covid-19 vaccine in stock when parents decide to vaccinate their child so that the vaccine can be administered immediately, before the parent leaves the practice and possibly changes his or her mind.

13. Covid-19 vaccination counseling is reimbursed only if the vaccine is actually administered to the patient. Medicaid reimbursement rates for Covid-19 vaccine administration range from as low as $15 per dose to approximately $40 per dose, depending on the payer.

Commercial payers typically reimburse in the same range. These payments do not cover the full cost of time and overhead involved.

14. Additionally, under the VFC program, our practice receives no payment for the vaccine product. We are only permitted to bill for the administration of the vaccine, which typically results in reimbursement of $15 to $40 depending on the Medicaid plan.

15. In August, our practice made a substantial investment in the Covid-19 vaccine when we bought 10 doses of the Pfizer vaccine at a cost of $1,045.37. We have ordered more doses, but they have not yet arrived. It is unclear whether we will be able to return any or all of the unused Pfizer vaccine. We cannot expect that vaccine manufacturers will allow full return of unused vaccine. For example, the 2025-2026 flu vaccine return policy only permits a credit for <=15% of unused doses, down from 30% in previous years.

16. Because only the Moderna Covid vaccine is authorized for children six months to 11 years old, we can only order the Moderna vaccine for this age group at a cost of $847.10 per dose. However, because we are not existing Moderna customers, there is no guarantee that we can return any unused or expired doses for a credit. The likelihood of my practice losing money on the Moderna vaccine is substantial because the likelihood that my practice will have unused 2025-2026 Moderna vaccine is high.

17. Counseling patients and families regarding the Covid-19 vaccine has become increasingly difficult in our practice because of the Secretary's Directive to the CDC to downgrade the recommendation of the Covid-19 vaccine from routine to SCDM. What the Directive practically did was to flip a switch from on to off. Before the Directive, the switch was set to on in that the presumption or default was that everyone should (not must) get the Covid-19 vaccine for their children. The Directive flipped the switch to off by downgrading the Covid-19 vaccine to

SCDM, which has led to an increasing number of parents starting with the presumption or default that their child should not get the Covid-19 vaccine. The vaccination numbers at my clinic this year show this flip of the switch. In the four and a half months before the Directive, my practice administered 44 vaccines to patients. Since May 2025, our practice has administered only seven Covid-19 vaccinations to pediatric patients. Many of the parents who declined the vaccine for their children have cited the change in the CDC's immunization schedule and/or other misinformation they heard from the Secretary.

18. The Directive's flipping of the recommendation to SCDM has and will result in continuing financial loss to my clinic. Shared decision making requires more time spent on counseling between physician and parent on the individual circumstances of the patient's health, medical history, family situation, and environmental/epidemiological milieu. As this year's Covid-19 vaccine uptake numbers at my clinic show, after the Directive, an increasing number of these discussions have resulted in refusal of the vaccine. In such cases, we are not reimbursed for the time spent counseling the parents or for the vaccine product that we had purchased.

19. My practice is likely to have unused 2025-2026 vaccine doses that we will be unable to return to the manufacturer and get our money back. The Directive has increased the financial risk of stocking Covid-19 vaccines because it has discouraged uptake of the vaccine. Nonetheless, my practice continues to stock the vaccine. We believe it is important to try to protect our patients, staff, and community from Covid as much as possible, even if my practice ends up eating some of the cost of stocking the vaccine.

20. Financial loss to the clinic affects me personally because I am a co-owner of Plateau Pediatrics.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Tennessee, that the foregoing is true and correct.

Executed on September 22, 2025 in Crossville, Tennessee.

/s/ Suzanne Berman, MD, FAAP

Dr. Suzanne Berman

EXHIBIT 5

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

DECLARATION OF DR. MARGIE ANDREAE

I, Dr. Margie Andreae, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old, reside in Michigan, and currently practice part time at the Pediatric Clinic of the Canton Health Center, located in Canton, Michigan.

2. I am the Professor Emerita of Pediatrics and former Chief Medical Officer for Revenue Cycle and Billing Compliance for the University of Michigan Medical Center.

3. I completed medical school at the University of Michigan Medical School in 1991. I completed my residency in pediatrics at William Beaumont Hospital in 1995.

4. I am board-certified in pediatrics.

5. I am fellow of the American Academy of Pediatrics ("AAP").

6. When the Centers for Disease Control and Prevention ("CDC") classifies a vaccine as routine, that means that the patient should get the vaccine. A routine recommendation means that the vaccine has proven over the years to be highly effective at preventing disease and saving

lives with minimal risk to the patient and, therefore, should be administered as a standard part of medical care for children. In short, a routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine.

7. During my more than three decades of taking care of children, I have paid close attention to the CDC's childhood immunization schedule, the process that is followed by the Food and Drug Administration ("FDA") to authorize a vaccine for use in the United States, and the process that the Advisory Committee on Immunization Practices ("ACIP") and the CDC follow to arrive at recommendations as to how vaccines should be used by different population groups in the United States. Up until this year, I have trusted the process that has resulted in vaccines being listed on the CDC's childhood immunization schedule. Up until this year, the FDA's Center for Biologics Evaluation and Research ("CBER") has been staffed with highly-qualified, non-partisan experts who have followed the science and made trustworthy, evidence-based decisions on whether to authorize a vaccine for use in the United States. Up until this year, the ACIP has likewise been staffed with highly-qualified, non-partisan experts who have followed the science and voted, based on the evidence, on how vaccines should be recommended for use for different population groups in the United States. Both CBER and the ACIP operated without undue influence from political appointees at either FDA or CDC before this year. Based on the trustworthy process that used to exist, I have had no hesitation in advising providers and patients that a child should receive a vaccine that is a "routine" recommendation on the CDC schedules, including receiving the Covid-19 vaccine. And most parents of my patients did not hesitate to get their children the Covid-19 vaccine, which is an outlier considering that pediatric uptake of Covid vaccines is waning.

8. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025. I also learned that the Secretary issued a written "Secretarial Directive" ("Directive") that instructed the CDC to remove the recommendation that children ages six months to 17 years receive the Covid-19 vaccines from the CDC's childhood immunization schedule. I was very concerned when I learned this, especially because the Secretary has not identified any evidence or data that he relied upon to issue the Directive.

9. Although I understood the Secretary to be instructing the CDC to remove the recommendation entirely that children receive the Covid-19 vaccine, I learned that the Covid-19 recommendation was not removed from the CDC immunization schedule but instead was changed to a "Shared Clinical Decision Making" recommendation, or SCDM. I and my colleagues considered this change from "routine" to "SCDM" to be a downgrading of the CDC's recommendation and sending a message to parents discouraging them to vaccinate their children with the Covid-19 vaccine.

10. The effect of downgrading the recommendation of the Covid-19 vaccine for children to SCDM is to require me and my colleagues to spend more time counseling patients about the safety and effectiveness of the Covid-19 vaccine. Counseling is, of course, part of a doctor's job, but we usually are paid for it. Before the Directive was issued, when the Covid-19 vaccine was a routine recommendation, I spent very little time counseling on the Covid-19 vaccine because there was very little to debate about the safety and effectiveness of the Covid-19 vaccine. However, the Directive has contributed to the confusion and distrust about the Covid-19 vaccine. This confusion and distrust requires me to spend more time building trust with my patients and

telling them the truth about the Covid-19 vaccine to correct the misinformation the Secretary has spread about the Covid-19 vaccine, as in his video on X.

11. In pediatric practice, patients rarely come in solely for vaccines. Most vaccinations occur during scheduled well visits. For infants and toddlers, there are multiple well visits each year; for older children, there is typically an annual visit.

12. A standard well visit averages about twenty minutes, covering a wide range of preventive care tasks. No additional reimbursement is available for the extra time we are now spending on vaccine-specific counseling during these visits.

13. Health care providers like myself bill payers for their professional services using Current Procedural Terminology (CPT) codes. Each code is tied to a patient care service and are used to document and receive reimbursement for medical encounters.

14. Vaccine administration has its own family of CPT codes, with the codes tying compensation of doctors to actual administration of the vaccine during a well visit. The Directive has caused me to spend more time during well visits discussing the Covid-19 vaccine with parents, who are increasingly declining the Covid-19 vaccine for their children. There is no billable code that I can use to compensate me for the additional time now spent counseling parents who refuse the vaccine. While no billable code existed before the Directive for such encounters, the difference now is that the Directive has caused me to spend significantly more time in unbillable counseling on the Covid-19 vaccine. On average, I spend about five minutes counseling each patient who refuses a vaccine, and I see about three such patients per day. This adds up to 15 minutes per day spent on non-reimbursable vaccine counseling. This is a significant opportunity cost because I could use this time to see an additional patient which could be reimbursed $150. In other words, due to increased vaccine refusal rates tied to the Directive, I am losing about $150/day.

15. Unlike other vaccines subject to shared decision-making, such as the MenB vaccine, the COVID-19 directive was issued without publication of supporting data in the CDC's Morbidity and Mortality Weekly Report (MMWR). Normally, MMWR provides clinicians with the evidence base to guide patient counseling and serves as the trigger for payer coverage. No such data or guidance accompanied this change, leaving physicians without a clear basis to counsel patients, which also contributes to the increased amount of time spent on unbillable counseling time on the Covid-19 vaccine.

16. The lack of evidence to support the Directive has also caused a shift of the burden to physicians to research and interpret data that was previously synthesized and communicated by ACIP. In other words, the ACIP did the deep work to synthesize, analyze, and interpret the data to arrive at sound recommendations with regard to vaccines. Before the current ACIP, I trusted the recommendations that came out of the ACIP. Now, I do not trust the Directive or, for that matter, recommendations from the current ACIP. This has further complicated the counseling process.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Michigan, that the foregoing is true and correct.

Executed on September 23, 2025 in Canton, MI.

Dr. Margie Andreae

/s/ Dr. Margie Andreae

EXHIBIT 6

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-WGY District Judge: William G. Young Magistrate Judge: M. Page Kelley

DECLARATION OF MARY-CASSIE SHAW, MD, FAAP

I, Mary-Cassie Shaw, declare, pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am over 18 years old and reside in Raleigh, North Carolina.

2. I earned a Doctor of Medicine degree from the East Carolina University Brody School of Medicine.

3. I am a Fellow of the American Academy of Pediatrics ("AAP") and a member of the North Carolina Pediatric Society.

4. I have been a practicing pediatrician at Oberlin Pediatrics in Raleigh since 2003.

5. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025, and have read the related May 19 "Secretarial Directive" ("Directive") confirming what the Secretary said in the video. I disagree with the decisions announced in the May 27 video and in the Directive to remove recommendations

from the Centers for Disease Control and Prevention's ("CDC's") immunization schedules that pregnant women and children receive the COVID-19 vaccine.

6. Those decisions have personally affected my job and caused disruption at Oberlin Pediatrics. The Directive has caused chaos and confusion at my practice on whether we can administer the COVID-19 vaccine to children and whether we can get it. This has resulted in me and my colleagues at the practice, including providers and staff, having to spend time that we did not spend before calling drug stores, the health department, other pediatric offices, hospitals, to see if we can get the COVID-19 vaccine from them. This time is not time we can bill and be paid for.

7. After the Directive, I have had to have longer, more in-depth conversations with parents about the safety and effectiveness of the COVID-19 vaccine, conversations that we did not have to have before the Directive. I and my practice are not being compensated for this extra time. Many of these conversations have been about dispelling disinformation that the Secretary has spread about the COVID-19 and other vaccines. For example, I have had to tell patients that any trace amount of aluminum in vaccines is not dangerous and that there is ten times more aluminum in breast milk than there is in a dose of a vaccine. Ninety-nine percent of these discussions about vaccines are in preventative visits for which there is no CPT code that I can use to bill this time. I and my colleagues are frustrated with the Directive causing us to work this additional time for free.

8. The Directive has also contributed to patients dropping out of my practice. I had a Mom with eight children, all of whom I have seen since they were born. She came in with her husband, and both expressed concern about aluminum in vaccines. They have since disappeared and not brought any of their children in to my practice when they were due for their next preventative visits. They have not transferred practices, because if they had, we would have

received a request for the children's medical records. This is not the only example of which I am aware of families simply dropping out of the healthcare system because of their mistrust of the COVID-19 and other vaccines The Directive has caused financial harm to my practice by contributing to patients dropping out of my practice.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. §1746, and the laws of the State of North Carolina, that the foregoing is true and correct.

Executed on September 23, 2025 in Raleigh, North Carolina.

/s/ _____

Mary-Cassie Shaw, MD, FAAP

EXHIBIT 7

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

DECLARATION OF DR. THOMAS BOYCE

I, Dr. Thomas Boyce, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old, reside in Wisconsin, and currently practice as a pediatric infectious disease specialist in a large, rural healthcare system, which has 60 locations in 32 counties in Wisconsin and serves about 310,000 patients, including 46,500 children.

2. I completed medical school at the University of Michigan in 1990. I completed my residency in pediatrics at University of Wisconsin in 1993. I completed my fellowship in pediatric infectious diseases at Vanderbilt University Medical Center in 1999.

3. I am board-certified in pediatric infectious diseases and pediatrics.

4. I am member of the Infectious Diseases Society of America (IDSA) and the Pediatric Infectious Diseases Society (PIDS).

5. As a pediatric infectious disease physician, my primary duty is to consult with providers and patients about infectious diseases, which includes consulting about vaccination against infectious diseases with parents of pediatric patients.

6. In the past, when the CDC classified a vaccine as routinely recommended, that meant that the patient should get the vaccine. A routine recommendation meant that the vaccine has proven over the years to be highly effective at preventing disease and saving lives with minimal risk to the patient and, therefore, should be administered as a standard part of medical care for children. In short, a routine recommendation indicates that unless there is a specific contraindication to administering that vaccine, the patient should receive the vaccine.

7. During my more than three decades of practicing as an infectious disease specialist, I have, until this year, trusted the process that has resulted in vaccines being listed on the CDC immunization schedules as routinely recommended. Up until this year, the Food and Drug Administration's Center for Biologics Evaluation and Research ("CBER") has been staffed with highly-qualified, non-partisan experts who have followed the science and made trustworthy, evidence-based decisions on whether to authorize a vaccine for use in the United States. Up until this year, the CDC's Advisory Committee on Immunization Practices ("ACIP") has likewise been staffed with highly-qualified, non-partisan experts who have followed the science and voted, based on the evidence, on how vaccines should be recommended for administering to different population groups in the United States. Based on this trustworthy process, I have had no hesitation in advising providers and patients that a child should receive a vaccine that is a "routine" recommendation on the CDC schedules, including receiving the Covid-19 vaccine.

8. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025. Although I understood the

Secretary to be instructing the CDC in that video to remove the recommendation entirely that children receive the Covid-19 vaccine, I subsequently learned that the Covid-19 recommendation was not entirely removed from the CDC immunization schedule but was changed to a "Shared Clinical Decision Making" recommendation, or SCDM. I and my colleagues considered this change from "routine" in past years to "SCDM" this year to be a downgrading of the CDC's recommendation and essentially discouraging receipt of the vaccine in that population.

9. The effect of the Directive's change to SCDM has been to impose an additional requirement on providers to engage in a discussion as to the benefits and risks of the Covid-19 vaccine with parents of pediatric patients that was not required before the Directive. This is problematic, because there are no new data on either safety or efficacy on which to base a change in the level of recommendation. Because of the misinformation and disinformation about the Covid-19 vaccine that the Secretary and others have spread, and because of the disruption and chaos that has occurred at the CDC and with the ACIP since the Secretary took office, the SCDM requirement has resulted in much lengthier discussions with patients about the Covid-19 vaccine than before the Directive was issued. The Secretary's Directive and other actions have sown confusion and caused parents of pediatric patients to lose trust in the advice of their physicians with respect to the Covid-19 and other vaccines. This in turn has created more work for me to explain that the Covid-19 vaccine has always been and continues to be safe to give to their children.

10. This extra work caused by the Directive is work for which I am not paid. Health care providers like myself bill payers for their professional services using Current Procedural Terminology (CPT) codes. Each code is tied to a patient care service visit that is used to document and receive reimbursement for medical encounters. I am unaware of any CPT code that I or other pediatricians (whether subspecialists or primary care providers) can use to bill the extra time that

we now must spend engaging in SCDM with parents of children. I have not been able to bill payers for this extra time engaging in SCDM about the Covid-19 vaccine. The Directive is making me and other pediatricians at my institution and throughout the country do work for free.

11. During the last month, I estimate that I have spent an average of about 1.5 hours per day engaging in SCDM with primary care providers and the parents of children about the Covid-19 and other vaccines. This has amounted to about 7.5 extra hours of work per week for me that the Directive has required for which I am not compensated. This does not include extra time that I have spent creating institutional guidelines and participating in meetings to discuss the changes in Covid-19 vaccine recommendations to colleagues and leaders within my institution.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Wisconsin, that the foregoing is true and correct.

Executed on September 19, 2025 in Marshfield, Wisconsin.

/s/ Thomas G. Boyce, MD, MPH

Dr. Thomas Boyce

EXHIBIT 8

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

DECLARATION OF DR. MOLLY O'SHEA, MD

I, Dr. Molly O'Shea, M.D., (aka Mary Doherty-O'Shea Gallucci) declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am a graduate of the University of Michigan Medical School and completed residency at Children's Hospital of Michigan. I am a board-certified pediatrician and the owner of two pediatric practices in Michigan with locations in Bloomfield Hills (Oakland County) and Washington Township (Macomb County). I have practiced pediatrics for over 30 years. I care for children from birth through adolescence, including newborns.

2. I am a member of the American Academy of Pediatrics (AAP).

3. I saw the video that the Secretary posted on his official X account on May 27, 2025 that ordered the CDC to remove the recommendation that all children between the ages of 6 months and 17 years routinely get the Covid-19 vaccine. When I saw that video, I expected that the CDC would change its immunization schedule consistent with the Secretary's stated intent and consistent with a document titled the "Secretarial Directive On Pediatric Covid-19 Vaccines For

Children Less Than 18 Years of Age and Pregnant Women" dated May 19, 2025 (the "Directive"), and completely remove the recommendation that children get the Covid-19 vaccine from the CDC schedule.

4. However, on or about May 30, 2025, the CDC changed its immunization guidance with regard to children and the Covid-19 vaccine from routine vaccination for all children to "Shared Clinical Decision Making" ("SCDM") without explanation. When the CDC categorizes a vaccine on its immunization schedule as "routine," not only does it mean that the group of people in the category *should* get the vaccine, but in any health care setting the default decision is to vaccinate. In the past, when the Advisory Committee on Immunization Practices has recommended and the CDC has adopted SCDM for a vaccine, it has provided an explanation and published guidance on how to engage in SCDM with patients. For example, after the ACIP recommended SCDM for the Meningococcal B vaccine, the CDC published the guidance attached hereto as Exhibit A on how providers could engage in SCDM with patients. No explanation was given, however, for why the CDC listed the Covid-19 vaccine for children as SCDM, and the CDC published no guidance for providers on how to engage in SCDM with parents about the Covid-19 vaccine.

5. I and other providers at my practices were confused not only by the Directive itself, which came out of the blue and was supported with no evidence, but also by the CDC's subsequent decision to list the Covid-19 vaccine for children as SCDM without explanation or guidance. My colleagues and I took the Directive and subsequent listing of the Covid-19 vaccine for children as SCDM to be an effort by the Secretary to discourage parents and caregivers from giving their children the Covid-19 vaccine. As a board-certified pediatrician who has been practicing for more than 30 years, I wholeheartedly and vehemently disagree with the Directive and his other actions

to discourage vaccines. I am appalled that he has taken this action especially after he testified before Congress earlier this year that "I don't think people should be taking medical advice from me." Covid illness is currently on the rise. Yet, his Directive, which is de facto medical advice, will, unfortunately and very likely, lead to more illness and death.

6. The AAP released on August 19, 2025, its own immunization schedule that differs from the immunization schedules that are posted on the Centers for Disease Control and Prevention ("CDC") website. One difference between the AAP's schedule and the Secretary's schedule is that the AAP recommends the Covid-19 vaccine for children 18 years or younger without qualification. See Exhibit B, attached hereto. In addition, the AAP strongly recommends children 6 months to 2 years receive the Covid vaccine in the hope that they will develop immunity from vaccine rather than from natural illness. Data show that this age group is at high risk for complications from infection including hospitalization and death. In addition, data show that receiving vaccine before natural illness decreases the risk of other Covid complications including long Covid. AAP publishes its own immunization schedule annually before the Fall respiratory virus season, and the AAP's schedule has traditionally aligned with the CDC's immunization schedule. However, this year, the release of AAP's immunization schedule differed significantly from the CDC's schedule, including with respect to the Covid-19 vaccine.

7. The release of AAP's immunization schedule on August 19, 2025 apparently caught the attention of the Secretary, who posted that same day on his official X account the post attached hereto as Exhibit C. When I read this post, I became particularly concerned about what the Secretary said in the last paragraph: "AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act." I took the Secretary's statement as a threat to me, to the doctor-

members of the AAP, and to any other providers that if they make vaccine recommendations that are inconsistent with the CDC's "official list," the Secretary would cause legal or disciplinary action to be taken against those providers. I have heard that the Secretary has a team of lawyers around the country who file or participate in litigation to pursue their anti-vaccine agenda.

8. The Secretary's threat was unsettling to me and my colleagues, so much so that I contacted my practices' insurance agent about my practices' coverage under our malpractice insurance policy. My insurance agent told me that my practices are not able to give the Covid vaccine or a prescription for the Covid vaccine to any healthy children because, if we do, we are likely not to be covered under our policy, and the carrier would likely not pay for defense counsel to defend us, in the event of a lawsuit over our decision to give the Covid vaccine to a child. The Secretary's Directive is thus exposing me to liability, as confirmed by my insurance agent, for doing my job consistent with the standard of care and consistent with my conscience.

9. I have seen the government's argument that there can be no harm to me when it is my job to counsel patients on the Covid-19 vaccine. That argument is bewildering and galling in the face of the Secretary's threat that he or his allies will go after doctors who advise their patients divergently from the CDC's "official list." I wonder how the Secretary or his allies would take it if they were exposed to legal or professional liability for following their conscience and doing the right thing. Being in this position is emotionally distressing to me.

10. My outside advisors have also counseled me that families who get the Covid vaccine for their "healthy" children may not be reimbursed by insurance and will have to pay out of pocket for the Covid vaccine. The cost to purchase the vaccine for my two practices will be about $113 - $120 per dose before excise taxes, shipping, and other costs, which I will have to charge to my patients, if they can afford it. For those who cannot afford the vaccine but really want

it, I may have to eat the cost. Right now, I am unable to purchase any doses of the Covid vaccine. I have heard that the CDC will not release any supply of the 2025-2026 Covid vaccine until after the next ACIP meeting, which is scheduled for September 18 and 19. Unlike years past, I will not be purchasing Covid vaccine to vaccinate any patient at my practices who wants it. We will be purchasing Covid vaccine for our children who meet FDA and CDC criteria. This feels morally wrong and compromises my duty as a pediatrician. I am stuck though. Should my colleagues or I, even through shared decision making, give Covid vaccine to a healthy child and that child experiences an adverse event, our potential liability will be too large to bear. Further, I am at a materially higher risk of liability for providing the vaccine to a healthy child, which is considered to be administering the vaccine "off label," because the Secretary has warned that diverging from the CDC's official list does not shield me from liability under the 1986 Vaccine Injury Act. The idea that pediatricians can employ SCDM and give the Covid-19 vaccine to anyone who wants it is misleading and a fallacy.

11. Even if I were able to purchase the 2025-2026 Covid vaccine, for healthy children I am likely to lose money because the Directive, which forces me and my colleagues to engage in SCDM, has resulted and will result in fewer parents vaccinating their children, much more time spent obtaining informed consent, and leftover vaccine which is often difficult to return. I have already seen the impact of the downgrade of the recommendation for the Covid-19 vaccine for children from routine to SCDM. Since the Directive, fewer parents are getting their children vaccinated for anything, including Covid-19, than was the case before the Directive. The vaccine conversations are much longer and more difficult. The change in vaccine uptake and more time with each family is already resulting in financial harm to my practice that can be directly tied to the Directive because I typically am not able to bill for and therefore am not paid for the extra

counseling time that the Directive has forced me to engage in. The Directive is making make me provide extra counseling on the Covid-19 vaccine for free.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of Michigan, that the foregoing is true and correct.

Dated: September 19, 2025

Molly O'Shea, MD, FAAP

Dr. Molly O'Shea, MD

EXHIBIT A

Shared Clinical Decision-Making

Meningococcal B Vaccination

All adolescents and young adults who are at increased risk for serogroup B meningococcal disease should receive Meningococcal B (MenB) vaccine. This includes patients with anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, or complement inhibitor use.

Shared clinical decision-making (SCDM) is recommended regarding MenB vaccination for healthy people 16–23 years of age. SCDM recommendations are meant to be flexible and informed by the characteristics, values, and preferences of the individual patient and the clinical discretion of the health care provider.

When you decide to discuss MenB vaccination with people 16–23 years of age:

Remember:

- MenB vaccine is not routinely recommended for all people in this age group.
- The vaccine series provides short-term protection against most strains of serogroup B meningococcal bacteria circulating in the United States.

Consider:

- Serogroup B meningococcal disease is an uncommon but deadly disease. In recent years, between 20 and 50 cases occurred each year in 16- through 23-year-old people in the United States.
- A low risk of exposure or infection does not mean a person cannot get a MenB vaccine. It is just one potentially important consideration in SCDM.
- Serogroup B meningococcal disease cases most commonly affect young adults who attend a four-year university, are freshmen, live in on-campus housing, or participate in sororities or fraternities.
- MenB vaccines are safe and effective, but they only offer short-term protection (1 to 2 years) to those who get vaccinated.

How to vaccinate:

- If you and your patient decide MenB vaccination is appropriate, administer a 2-dose series of a MenB vaccine, one each at month 0 (the first vaccine appointment) and 6 months later.
  - To optimize rapid protection (e.g., for students starting college in less than 6 months), a 3-dose series (0, 1–2, 6 months) may be administered.
- MenB-4C and MenB-FHbp are not interchangeable.
- MenB vaccines should not be administered to a person who has had a severe allergic reaction (e.g., anaphylaxis) to a:
  - Previous dose of MenB vaccine
  - Component of the vaccine
- In pregnant women, delay vaccination until after pregnancy unless the patient is at increased risk and the benefits of vaccination outweigh the potential risks.

Additional information:

CDC Child and Adolescent Immunization Schedule by Age:
www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

CDC Adult Immunization Schedule by Age:
www.cdc.gov/vaccines/hcp/imz-schedules/adult-age.html

CDC Meningococcal Vaccine Recommendations:
www.cdc.gov/meningococcal/hcp/vaccine-recommendations/index.html

EXHIBIT B

Red Book® Online

AAP Immunization Schedule

September 9, 2025

The American Academy of Pediatrics' Recommended Child and Adolescent Immunization Schedule can be found here.

Recommended Child and Adolescent Immunization Schedule for Ages 18 Years or Younger

United States 2025

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN®

Vaccines and Other Immunizing Agents in the Child and Adolescent Immunization Schedule*

Monoclonal antibody	Abbreviation(s)	Trade name(s)
Respiratory syncytial virus monoclonal antibody	RSV-mAb	Beyfortus Enflonsia
Vaccine	**Abbreviation(s)**	**Trade name(s)**
COVID-19 vaccine	1vCOV-mRNA	Comirnaty mNEXSPIKE Spikevax
	1vCOV-aPS	Nuvaxovid
Dengue vaccine	DEN4CYD	Dengvaxia
Diphtheria, tetanus, and acellular pertussis vaccine	DTaP	Daptacel Infanrix
Haemophilus influenzae type b vaccine	Hib (PRP-T)	ActHIB Hiberix
	Hib (PRP-OMP)	PedvaxHIB
Hepatitis A vaccine	HepA	Havrix Vaqta
Hepatitis B vaccine	HepB	Engerix-B Recombivax HB
Human papillomavirus vaccine	HPV	Cardasil 9
Influenza vaccine (inactivated, egg-based)	IIV3	Multiple
Influenza vaccine (inactivated, cell-culture)	ccIIV3	Flucelvax
Influenza vaccine (recombinant)	RIV3	Flublok
Influenza vaccine (live, attenuated)	LAIV3	FluMist
Measles, mumps, and rubella vaccine	MMR	M-M-R II Priorix
Meningococcal serogroups A, C, W, Y vaccine	MenACWY-CRM	Menveo
	MenACWY-TT	MenQuadfi
Meningococcal serogroup B vaccine	MenB-4C	Bexsero
	MenB-FHbp	Trumenba
Meningococcal serogroup A, B, C, W, Y vaccine	MenACWY-TT/MenB-FHbp	Penbraya
	MenACWY-CRM/MenB-4C	Penmenvy
Mpox vaccine	Mpox	JYNNEOS
Pneumococcal conjugate vaccine	PCV15	Vaxneuvance
	PCV20	Prevnar 20
Pneumococcal polysaccharide vaccine	PPSV23	Pneumovax 23
Poliovirus vaccine (inactivated)	IPV	Ipol
Respiratory syncytial virus vaccine	RSV	Abrysvo
Rotavirus vaccine	RV1	Rotarix
	RV5	RotaTeq
Tetanus, diphtheria, and acellular pertussis vaccine	Tdap	Adacel Boostrix
Tetanus and diphtheria vaccine	Td	Tenivac Tdvax
Varicella vaccine	VAR	Varivax
Combination vaccines (use combination vaccines instead of separate injections when appropriate)		
DTaP, hepatitis B, and inactivated poliovirus vaccine	DTaP-HepB-IPV	Pediarix
DTaP, inactivated poliovirus, and Haemophilus influenzae type b vaccine	DTaP-IPV/Hib	Pentacel
DTaP and inactivated poliovirus vaccine	DTaP-IPV	Kinrix Quadracel
DTaP, inactivated poliovirus, Haemophilus influenzae type b, and hepatitis B vaccine	DTaP-IPV-Hib-HepB	Vaxelis
Measles, mumps, rubella, and varicella vaccine	MMRV	ProQuad

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit when indicated. The use of trade names is for identification purposes only and does not imply endorsement by the AAP.

Updated September 9, 2025

How to use the child and adolescent immunization schedule

1. Determine recommended vaccine by age (Table 1)
2. Determine recommended interval for catch-up vaccination (Table 2)
3. Assess need for additional recommended vaccines by medical condition or other indication (Table 3)
4. Review vaccine types, frequencies, intervals, and considerations for special situations (Notes)
5. Review contraindications and precautions for vaccine types (Appendix)
6. Review new or updated American Academy of Pediatrics (AAP) guidance (Addendum)

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov (Accessed August 11, 2025) or 800-822-7967
- For RSV-mAb products, clinically significant adverse events to MedWatch Adverse Event Report Program at www.accessdata.fda.gov/scripts/medwatch/index.cfm (Accessed August 11, 2025). If co-administered with other products, then report to VAERS.

Questions or comments

Submit a question or comment to www.aap.org/en/forms/immunization-schedule-questions.

Helpful information

- **Best practices for immunization (including contraindications and precautions):** www.aap.org/immunization and www.immunize.org
- ***Red Book: 2024–2027 Report of the Committee on Infectious Diseases* (33rd Edition):** www.aapRedBook.org
- **Vaccine information statements:** www.immunize.org/vaccines/vis/about-vis

View online at AAP.org/ImmunizationSchedule

Article type: Resources
Topics: Vaccine/Immunization

The Child and Adolescent Immunization Schedule, published by the CDC, which is not currently endorsed by the AAP, can be found at https://www.cdc.gov/vaccines/hcp/imz-schedules/downloads/child/0-18yrs-child-combined-schedule.pdf.

EXHIBIT C

← Post

Secretary Kennedy
@SecKennedy

This is a screenshot from American Academy of Pediatrics' webpage, thanking the organization's top corporate donors. These four companies make virtually every vaccine on the CDC recommended childhood vaccine schedule. AAP is angry that CDC has eliminated corporate influence in decisions over vaccine recommendations and returned CDC to gold-standard science and evidence-based medicine laser-focused on children's health.

AAP today released its own list of corporate-friendly vaccine recommendations. The Trump Administration believes in free speech and AAP has a right to make its case to the American people. But AAP should follow the lead of HHS and disclose conflicts of interest, including its corporate entanglements and those of its journal—Pediatrics—so that Americans may ask whether the AAP's recommendations reflect public health interest, or are, perhaps, just a pay-to-play scheme to promote commercial ambitions of AAP's Big Pharma benefactors.

AAP should also be candid with doctors and hospitals that recommendations that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act.

4:17 PM · Aug 19, 2025 · **1.1M** Views

1.7K 12K 33K 3K

Read 1.7K replies

New to X?
Sign up now to get your own personalized timeline!
Sign up with Google
Sign up with Apple
Create account
By signing up, you agree to the Terms of Service and Privacy Policy, including Cookie Use.

Something went wrong. Try reloading.
Retry

EXHIBIT 9

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-WGY District Judge: William G. Young Magistrate Judge: M. Page Kelley

DECLARATION OF MARK DEL MONTE

I, Mark Del Monte, declare, pursuant to 28 U.S.C. § 1746, that the following is true and correct and within my personal knowledge.

1. I am over 18 years old, reside in Illinois, and currently am the Chief Executive Officer/Executive Vice President of the American Academy of Pediatrics ("AAP"), a position that I have held since September 2019. I have been an employee of AAP since 2005.

2. I completed my law degree from the University of California, Berkeley – School of Law in 1997.

3. I saw the video that United States Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary"), posted on X on May 27, 2025 announcing that he had directed the Centers for Disease Control and Prevention ("CDC") to remove from its immunization schedules the recommendations that pregnant individuals and children receive the Covid-19 vaccine. Since 2005 when I started at AAP, I have never seen a Secretary of Health and Human Services make a unilateral decision to change the CDC's immunization schedules, let alone ignore

the Advisory Committee on Immunization Practices ("ACIP") process of first studying and analyzing the data and evidence about the vaccine, then debating whether to change the CDC schedule at ACIP meetings open to the public, and then voting on changes to CDC schedules in an open meeting of the ACIP. In the May 27 video, and in the "Secretarial Directive" dated May 19, 2025 (the "Directive") that purported to document the decision, the Secretary cited no evidence that warranted a change to the CDC schedules with regard to the Covid vaccine, and he has released no supporting evidence for the Directive since.

4. Since the release of the Directive, AAP has had to divert significant resources to navigate and guide its 67,000 members on the implications of the Directive. The additional activities that the Directive has required AAP to engage in have included, but are not limited to, the following:

- Updating Frequently Asked Questions (FAQs) and guidance documents for pediatric practices.
- Fielding additional calls and emails from AAP members seeking clarification about the implications of the Directive.
- Holding two impromptu webinars focused on navigating the Directive and its implications for pediatricians and infants, children, adolescents, and young adults, including children with complex health care needs.
- Publishing additional guidance in the AAP Section on Administration and Practice Management ("SOAPM") online platform.
- Holding cross-team meetings to align advocacy, clinical, and communications efforts.
- Holding an SOAPM webinar on Countering Vaccine Hesitancy and Misinformation.
- Convening a meeting to address Covid concerns that six staff and 17 volunteer members attended.
- Holding multiple meetings to discuss the implications of the AAP's own immunization (IZ) schedule diverging from that of the CDC, which at least eight staff attended.

- Convening a meeting to discuss the AAP's COVID vaccine recommendations that seven staff and 50 volunteer members attended.
- Editing and finalizing the recommendations for the IZ schedule, including the Covid recommendations, involving multiple staff members and many hours.
- Developing a new policy statement, "Recommendations for COVID-19 Vaccines in Infants, Children, and Adolescents," which was pre-published online on August 19, 2025. At least ten staff members spent a significant amount of time developing this new policy statement.
- Developing a new AAP IZ schedule that was published online on August 19, 2025. At least twelve staff members spent many hours developing the new schedule in light of the Directive.
- Conducting a webinar hosted by four staff and four volunteer members on September 11, 2025 to discuss the Covid recommendation confusion that the Directive has created. The hosts of the webinar spent approximately 36 hours preparing for the webinar.
- Holding a meeting of four staff and 22 volunteer members to discuss which Covid vaccines were approved and recommended for use for different population groups.

5. Multiple different teams within AAP have had to divert their attention from other urgent matters related to child health to contend with the impact of the Directive, including staff at all levels on the Senior Leadership Team, the Pediatric Practice and Health Care Delivery Team, the Quality Team, the Finance and Payment Strategy Team, the Public Affairs Team, the Communications Team, the Publishing Team, and the Information Technology Team.

6. The Directive has generated, nearly on a daily basis, outreach from members communicated through phone calls, text messages, and emails. One Senior Vice President at AAP estimates that the volume of text, instant, and email messages in her inbox, and the number of meetings, has doubled due to the Directive and other statements and actions of the Secretary.

7. The Directive has forced multiple staff members to advocate to payers to continue to cover the Covid-19 vaccine to maintain immunization access for infants, children, adolescents, and young adults, regardless of the type of recommendation listed on the CDC schedules.

8. AAP has received outreach from other professional medical and public health societies that also have concerns about the public health impact and the impact to their members of the Directive. This has led to multiple meetings with other professional societies to try to achieve alignment and consensus on how to address the fallout from the Directive.

9. In short, the Directive has significantly affected the operations of the AAP and forced all levels of the AAP to divert significant time away from other tasks and initiatives related to child health. In my opinion, this diversion of AAP resources has been totally unnecessary because the evidence and the science strongly indicate that any changes to the CDC's immunization schedules' recommendations with regard to the Covid-19 vaccine could have been conducted with credible scientific evidence and established process through the ACIP. The impact of the Secretary's unilateral action has predictably sown confusion and chaos in this country's health care system. The AAP has had to expend significant time and resources to attempt to clear up the confusion and diminish the chaos that the Directive has, unfortunately and unnecessarily, generated. I respectfully implore the Court to right this wrong and vacate the Directive.

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of [state in which sign], that the foregoing is true and correct.

Executed on September 23, 2025 in Itasca, Illinois.

Mark Del Monte

/s/ Mark Del Monte

EXHIBIT 10

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

DECLARATION OF JAMES LEWIS, MD, MPH

I, James Lewis, declare pursuant to 28 U.S.C. § 1746 that the following is true and correct and within my personal knowledge.

1. I am over 18 years old and reside in Everett Washington.

2. I earned a Master of Public Health degree from the University of North Carolina and a Doctor of Medicine degree from the University of Arkansas for Medical Sciences. I am board certified in Internal Medicine, Infectious Diseases, and Preventive Medicine. I am an adjunct Clinical Assistant Professor at the University of Washington in the Division of Allergy and Infectious Diseases.

3. I am the Health Officer for the Snohomish County Health Department.

4. I am a member of the American Public Health Association ("APHA").

5. I have viewed the video that the Secretary of Health and Human Services, Robert F. Kennedy, Jr. (the "Secretary") posted on X on May 27, 2025, and have read the related May 19 "Secretarial Directive" ("Directive") confirming what the Secretary said in the video. I disagree

with the decisions announced in the May 27 video and in the Directive to remove recommendations from the Centers for Disease Control and Prevention's ("CDC's") immunization schedules that pregnant women and children receive the COVID-19 vaccine. Those decisions have personally affected my job and caused me to focus a significant amount of my time and attention on attempting to mitigate the damage that the Directive had had on public health in my county. This, in turn, has diverted my ability to work on other tasks and initiatives that serve the residents of Snohomish County.

6. One initiative that I am working on because of the Directive and other actions by the Secretary that undermine trust in vaccines, such as firing all of the members of the Advisory Committee on Immunization Practices ("ACIP") on June 9 of this year, is an initiative to change local and state laws that have tied vaccine recommendations to the ACIP and CDC guidance. I and those with whom I am working on this initiative no longer trust the new ACIP, its recommendations, or CDC guidance and immunization schedules. Accordingly, we are working on changing state and local laws to no longer defer to CDC guidance or ACIP recommendations.

7. Another initiative that I am working on because of the Directive and the Secretary's other actions is to revise internal Snohomish County policies so that they no longer defer to ACIP recommendations and CDC guidance.

[SIGNATURE APPEARS ON NEXT PAGE]

I declare under penalty of perjury and laws of the United States, including 28 U.S.C. § 1746, and the laws of the State of Washington, that the foregoing is true and correct.

Executed on September 23, 2025 in Everett, Washington.

James Lewis, MD, MPH

/s/ _____

James Lewis, MD, MPH