UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., *et al.*, Defendants.	Case No. 1:25-cv-11916-BEM

Defendants' Second Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction

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INTRODUCTION

This opposition addresses the remaining four actions challenged in Plaintiffs' preliminary injunction motion: (1) the May 2025 Secretarial Directive regarding COVID-19 vaccines for children and pregnant women, (2) the Advisory Committee on Immunization Practices's ("ACIP") June 2025 vote recommending that children and adults be administered thimerosal-free influenza vaccines, (3) ACIP's September 2025 vote to recommend shared clinical decision-making for pediatric and adult COVID-19 vaccines, and (4) ACIP's December 2025 vote to recommend shared clinical decision-making for the hepatitis B vaccine for certain infants. Plaintiffs are not entitled to preliminary relief from any of these actions.

To start, there is no likelihood of success on the merits. Plaintiffs offer no evidence of a cognizable injury specifically traceable to any of the four challenged actions and thus lack standing. Even if Plaintiffs could establish standing, the Court lacks jurisdiction over their Administrative Procedure Act ("APA") claims because the Secretarial Directive and the Centers for Disease Control and Prevention's ("CDC") decisions to adopt the ACIP recommendations are committed to the agency's discretion and outside the APA's ambit. Regardless, on the merits, Plaintiffs have not shown these actions were arbitrary and capricious; Plaintiffs merely disagree with the current policies. That will not do under the APA.

Plaintiffs also have not established they will suffer irreparable harm absent extraordinary relief. Again, the analytical window is narrow: the few months before the Court rules on the merits. Plaintiffs do not clearly show irreparable harm in that short period for all the reasons in Defendants' first opposition plus several more that are specific to the four challenged actions addressed here. Plaintiffs' months-long delay in challenging the June 2025 ACIP vote about thimerosal precludes any claim of irreparable harm. And they seek to preliminarily enjoin a variety of actions by various individuals over the course of several months—the Secretarial

Directive and three ACIP recommendations, as adopted by CDC—without bothering to break down how any particular action causes immediate, irreparable harm. Instead, Plaintiffs improperly mix everything together under the generic labels of "Non-ACIP Actions" and "ACIP Actions" and thereby fail to demonstrate how any challenged action would cause any specific harm that cannot be redressed after summary judgment.

Lastly, the public interest strongly disfavors Plaintiffs' attempt to force HHS to espouse immunization recommendations that it no longer agrees with. Plaintiffs cannot substitute their preferred vaccination policies for those adopted by HHS leadership—appointed by the President and confirmed by the U.S. Senate—and in the exercise of discretionary, statutory authority. Nor is the public served by the whiplash a preliminary injunction would inflict by temporarily reinstating recommendations that HHS does not support. Plaintiffs' motion should be denied.

BACKGROUND

I. CDC's Immunization Recommendations

In the United States, vaccine regulation occurs at both the federal and state levels. Before vaccines are distributed and marketed, they must be approved by the Food and Drug Administration ("FDA"). 42 U.S.C. § 262(a). But the rules for prescribing and administering a particular vaccine are generally made at the state and local level through the exercise of police powers. *See Zucht v. King*, 260 U.S. 174, 176 (1922); *e.g.*, Mass. Gen. Laws Ann., ch. 111, §§ 6, 181, ch. 76, § 15 (2024); *Preston v. United States*, No. CV 19-11034-MPK, 2022 WL 3093235, at *19 (D. Mass. May 25, 2022).

Relatedly, Congress directed the Secretary of Health and Human Services to "assist States and their political subdivisions in the prevention and suppression of communicable diseases and with respect to other public health matters" and to "advise the several States on matters relating to the preservation and improvement of the public health." 42 U.S.C. § 243(a).

One way the Secretary (through CDC) has done so is by publishing non-binding schedules of vaccines recommended for children and adults. *See, e.g.*, ECF Nos. 185-13 and 185-14 (recommended schedules for adults and children as of October 2025). The schedules generally contain three types of recommendations: (1) immunizations recommended for everyone in an age group, (2) immunizations recommended for certain high-risk groups or populations, and (3) immunizations recommended based on shared clinical decision-making. *See* ECF Nos. 185-13 and 185-14. CDC also sometimes makes no recommendation. *See* ECF No. 185-14, at 4 ("No Guidance/Not Applicable" category).

"Shared clinical decision-making" means the decision whether to vaccinate is "individually based and informed by a decision process between the health care provider and the patient or parent/guardian." CDC, *ACIP Shared Clinical Decision-Making Recommendations* (Jan. 7, 2025), https://perma.cc/QE5B-D8WU. A health care provider is "anyone who provides or administers vaccines: primary care physicians, specialists, physician assistants, nurse practitioners, registered nurses, and pharmacists." *Id.* There "is not a prescribed set of considerations or decision points in the decision-making process," and the decision "may be informed by" factors including "the individual's characteristics" and "the health care provider's clinical discretion." *Id.* Cost, however, is not a factor. Vaccines administered through shared clinical decision-making, when that is recommended by CDC, "generally are required to be covered by group health plans and health insurance issuers offering group or individual health insurance coverage without imposing any cost-sharing requirements (such as a copayment, coinsurance, or deductible)." *Id.* (citing 42 U.S.C. § 300gg-13; 26 C.F.R. § 54.9815-

2713(a)(1)(ii); 29 C.F.R. § 2590.715-2713(a)(1)(ii); 45 C.F.R. § 147.130(a)(1)(ii)).[1]

II. The May 2025 Secretarial Directive

On May 27, 2025, Secretary Kennedy issued the Directive. ECF No. 185-1.[2] The Secretary noted that HHS "continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available [FDA] approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations." *Id.* After reviewing a new recommendation from FDA and National Institutes of Health (NIH) officials regarding COVID-19 vaccines for "healthy U.S. children ages six months to 17 years," the Secretary weighed the risks and benefits of COVID-19 vaccines for such children. *Id.* Based on this analysis, the Secretary rescinded two Secretarial Directives from June 2022 agreeing with CDC recommendations that all healthy U.S. children ages six months to 17 years receive the COVID-19 vaccine. *Id.*

The Secretary also reviewed an FDA official's recommendation regarding COVID-19 vaccines for pregnant women. *Id.* Based on that analysis, the Secretary "determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby." *Id.* The Secretary therefore rescinded CDC's "recommendation that pregnant

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[1] *See* CDC, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers* (Oct. 6, 2025), https://perma.cc/SD3P-G2V7 ("Like routine recommendations, individual-based-decision-making allows for immunization coverage through all payment mechanisms including entitlement programs such as the Medicare, Medicaid, Children's Health Insurance Program, and the Vaccines for Children Program, as well as insurance plans regulated by the Affordable Care Act."); Centers for Medicare & Medicaid Services, *Affordable Care Act Implementation FAQs - Set 12*, Question 8 (last modified Sept. 10, 2024), https://perma.cc/NL2N-3W9D.

[2] An initial version of the Directive was mistakenly dated May 19, 2025, despite being executed on May 27, 2025. However, the Secretary executed another copy correctly dated May 27, 2025.

women receive the COVID-19 vaccine." *Id.*

Over the summer, CDC implemented the Directive. ECF No. 103-2 (rev. Aug. 7, 2025); ECF No. 103-3 (same). The Recommended Child and Adolescent Immunization Schedule was revised to recommend "shared clinical decision-making" between "the health care provider and the patient or parent/guardian" about administration of the COVID-19 vaccine to healthy children. ECF No. 103-2 at 5. That meant where "the parent presents with a desire for their child to be vaccinated, children 6 months and older may receive COVID-19 vaccination, informed by the clinical judgment of a healthcare provider and personal preference and circumstances." *Id.* CDC also revised the entry for the COVID-19 vaccine for pregnant women in the pediatric and adult immunization schedules to indicate "No Guidance/Not Applicable." ECF No. 103-2 at 4; ECF No. 103-3 at 3.

III. The ACIP Recommendations of June, September, and December 2025

"[I]n connection with any of" the Secretary's "functions," such as advising states on the prevention and suppression of communicable diseases, he may "appoint such advisory councils or committees . . . as he deems desirable . . . for the purpose of advising him." 42 U.S.C. § 217a(a). Exercising that discretion, the Secretary established the ACIP to advise the CDC Director "regarding use of vaccines and related agents for effective control of vaccine-preventable diseases." ECF No. 185-21, at 2. ACIP recommendations are reviewed by the CDC Director, who has discretion whether to adopt them as official CDC/HHS recommendations. *Id.*

In June 2025, Secretary Kennedy removed the then-serving ACIP members. HHS, *HHS Takes Bold Step to Restore Public Trust in Vaccines by Reconstituting ACIP* (June 9, 2025),

https://perma.cc/C5YC-Q7ZA. He has since appointed 16 new ACIP members,[3] who are "highly credentialed scientists, leading public-health experts, and some of America's most accomplished physicians . . . committed to evidence-based medicine, gold-standard science, and common sense." Robert F. Kennedy, Jr. (@SecKennedy), X (June 11, 2025, 4:36 PM), https://perma.cc/49T9-C7NJ. All current ACIP members hold an M.D., Pharm.D., or Ph.D., have relevant expertise, and represent a wide range of clinical and research backgrounds. *See* CDC, *ACIP Membership Roster* (Jan. 14, 2026), https://perma.cc/74CV-D3NT. Four seats on ACIP remain vacant.

Three ACIP votes are at issue here. ***First***, in June 2025, ACIP recommended that adults and children "receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative." ACIP, June 25-26, 2025, ACIP Meeting Summary, at 72–74, https://perma.cc/WEP5-K2LD. HHS adopted the recommendation to remove thimerosal, a "mercury-based preservative," in July 2025.[4] HHS, *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines* (last revised July 28, 2025), https://perma.cc/4UFD-HXZ4.

"The effort to remove mercury from childhood vaccines," HHS explained, "began in 1999 when the U.S. Public Health Service, the American Academy of Pediatrics (AAP), and vaccine manufacturers jointly agreed that any potential risk from mercury warranted its removal as soon as possible." *Id.* "[B]y voting to remove mercury entirely from all influenza vaccines,"

[3] HHS announced the appointment of two new ACIP members on February 27, 2026. HHS, *Secretary Kennedy Appoints Two Physicians to CDC's Advisory Committee on Immunization Practices* (Feb. 27, 2026), https://perma.cc/AR66-A574. Additionally, one of the ACIP members the Secretary had appointed, Dr. Kulldorff, is no longer a member of the ACIP.

[4] At the time, the office of CDC Director was vacant, so the ACIP's recommendation was adopted by the Secretary.

ACIP had "broke[n] with long-standing inaction" and "align[ed] U.S. policy with that of Europe, which phased out mercury additives years ago." *Id.* Further, "[v]accine manufacturers have confirmed they have the capacity to replace multi-dose vials containing mercury, ensuring the Vaccines for Children (VFC) program and adult vaccine supplies will remain uninterrupted." *Id.* Thus, HHS believed this recommendation would "restore trust with Americans" and "enhanc[e] public confidence in vaccines" by "removing risk while sustaining access to vaccines." *Id.*

Second, in September 2025, the ACIP voted to recommend the COVID-19 vaccine for children and adults based on shared clinical decision-making (also referred to as individual-based decision-making). ACIP, September 18-19, 2025, ACIP Meeting Summary, at 88–89, https://perma.cc/Q5AE-PN4R. For "[i]ndividuals 6 months to 64 years," the ACIP emphasized "that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors." *Id.* at 87–88; *see* HHS, *ACIP Recommends COVID-19 Immunization Based on Individual Decision-Making* (last revised Sept. 19, 2025), https://perma.cc/BP2T-97ZS.

In October 2025, CDC adopted these recommendations and updated its child and adult immunization schedules accordingly. *See* ECF Nos. 185-13 and 185-14. The agency explained that the prior recommendation of COVID-19 vaccines for all children and adults had "deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent." CDC, *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers* (Oct. 6, 2025), https://perma.cc/SD3P-G2V7. It noted that "just 23% of adults followed the CDC's most recent seasonal [COVID-19] booster recommendation" and that "[t]he booster shots prompted

widespread risk-benefit concerns about their safety and efficacy as the COVID-19 virus became endemic following population-wide immunity acquired during the pandemic" and Operation Warp Speed. *Id.*

Third, in December 2025, the ACIP voted to recommend shared clinical decision-making "for parents deciding whether to give the hepatitis B vaccine, including the birth dose, to infants born to women who test negative for the virus." CDC, *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test Negative for the Virus* (Dec. 5, 2025), https://perma.cc/QQ8P-DVNQ. The ACIP recommended that "parents and health care providers should consider whether there are infection risks such as a household member who has hepatitis B or frequent contact with persons who have emigrated from areas where hepatitis B is common." *Id.* The ACIP further recommended that "[f]or those infants not receiving the birth dose, . . . the initial dose be administered no earlier than two months of age." *Id.* CDC adopted these recommendations, explaining that they "reflect[] ACIP's rigorous review of the available evidence" and "restor[e] the balance of informed consent to parents whose newborns face little risk of contracting hepatitis B." CDC, *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus* (Dec. 16, 2025), https://perma.cc/6R3R-E2HJ.

IV. Procedural History

Plaintiffs moved for a preliminary injunction on January 26, 2026. ECF No. 183. On January 30, 2026, the Court bifurcated proceedings on Plaintiffs' motion. ECF No. 190. The first phase addressed two of the challenged actions: CDC's January 2026 changes to certain childhood and adolescent immunization recommendations, and the ACIP meeting scheduled for February 25–27, 2026 (which has been rescheduled to March 18–19, 2026). *Id.* Defendants filed an opposition regarding those actions on February 9, 2026, ECF No. 232, and the Court heard

argument on February 13, 2026, ECF No. 241.

Now, in the second phase, Defendants address the remaining four actions challenged in Plaintiffs' preliminary injunction motion: (1) the May 2025 Secretarial Directive regarding COVID-19 vaccines for children and pregnant women, (2) the ACIP's June 2025 vote recommending that children and adults be administered thimerosal-free influenza vaccines, (3) the ACIP's September 2025 vote to recommend shared clinical decision-making for pediatric and adult COVID-19 vaccines, and (4) the ACIP's December 2025 vote to recommend shared clinical decision-making for the hepatitis B vaccine for certain infants.

LEGAL STANDARD

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24 (2008). Rather, a "plaintiff requesting a preliminary injunction 'must establish' that: (1) it is 'likely to succeed on the merits'; (2) it is 'likely to suffer irreparable harm in the absence of preliminary relief'; (3) 'the balance of equities tips in its favor'; and (4) 'an injunction is in the public interest.'" *Planned Parenthood Fed'n of Am., Inc. v. Kennedy*, 162 F.4th 155, 166 (1st Cir. 2025) (quoting *Winter*, 555 U.S. at 20). The injunction "should not be granted unless the movant, *by a clear showing*, carries the burden of persuasion" on each factor. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (quoting 11A Wright *et al.*, Fed. Prac. & Proc. § 2948, 129–130 (2d ed. 1995)); *see Becky's Broncos, LLC v. Town of Nantucket*, 138 F.4th 73, 77 (1st Cir. 2025) ("The party seeking the preliminary injunction bears the burden of establishing that these four factors weigh in its favor." (quoting *Esso Standard Oil Co. (P.R.) v. Monroig-Zayas*, 445 F.3d 13, 18 (1st Cir. 2006))).

ARGUMENT

I. Plaintiffs Are Not Likely to Succeed on the Merits

Like their claims addressed in Defendants' first opposition, Plaintiffs' challenges to the

Secretarial Directive and the June, September, and December ACIP recommendations ask the Court to intrude into complex questions of science and health policy on which reasonable minds might disagree. These are questions for scientists and policymakers—not judges—and Plaintiffs cannot use the APA to impose their policy preferences on the country. Plaintiffs lack standing, and their claims are not cognizable under the APA because vaccine advice from the Secretary, the ACIP, or CDC to states and localities is committed to agency discretion. If the Court reached the merits of Plaintiffs' claims, those claims still fail because the challenged actions are not arbitrary and capricious. Even on the limited record available in reviewing Plaintiffs' preliminary injunction motion, it is plain that HHS "reasonably considered the relevant issues and reasonably explained [its] decision[s]." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021).

A. Plaintiffs Lack Standing

Defendants incorporate their standing arguments from their first opposition, ECF No. 232 at 30–36, which apply equally to the four challenged actions covered by this brief. Additionally, Plaintiffs' attempt to show standing for these four actions has several further, fatal deficiencies.

1. ACIP's June 2025 Thimerosal Recommendation

Plaintiffs have not offered evidence of their alleged injury from the ACIP's June 2025 thimerosal recommendation, as adopted by HHS. *See Murthy v. Missouri*, 603 U.S. 43, 58 (2024) (requiring plaintiffs to "make a 'clear showing'" that they are "'likely' to establish each element of standing" at the "preliminary injunction stage" (quoting *Winter*, 555 U.S. at 22)). Generalized allegations of harm from the allegedly "final agency actions challenged herein," ECF No. 245, ¶ 105, or the "ACIP Actions," PI Mem., ECF No. 237, at 22, are insufficient because Plaintiffs must show a cognizable injury traceable to each "challenged action," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). After all, a litigant who may have "standing to challenge one government action" cannot "challenge other governmental actions that did not injure" them.

DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 353 n.5 (2006). Thus, under the requisite "claim-by-claim" analysis, *Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 733 (1st Cir. 2016), Plaintiffs have failed to show standing to challenge the thimerosal recommendation.

That failure is hardly surprising because *AAP has supported removing thimerosal* from vaccines because of its mercury content. In 1999, "the U.S. Public Health Service, [AAP], and vaccine manufacturers jointly agreed that any potential risk from mercury warranted its removal [from vaccines] as soon as possible." *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines*, *supra*. Today, only about 4–5% of influenza vaccine doses are in thimerosal-containing multi-dose vials. ACIP, June 25-26, 2025, ACIP Meeting Summary, at 69, https://perma.cc/WEP5-K2LD. "Vaccine manufacturers have confirmed they have the capacity to replace multi-dose vials containing mercury, ensuring the Vaccines for Children (VFC) program and adult vaccine supplies will remain uninterrupted." *Id.* Thus, Plaintiff have not—and cannot—show any injury from the challenged thimerosal recommendation.

2. The May 2025 Secretarial Directive, ACIP's September 2025 COVID-19 vaccine recommendation (as adopted by CDC), and ACIP's December 2025 Hepatitis B vaccine recommendation (as adopted by CDC)

To have standing to "seek[] prospective relief such as an injunction, the plaintiff must establish a sufficient likelihood of *future* injury." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 381 (2024) (emphasis added). And the future is assessed as of February 17, 2026, the date the Fourth Amended Complaint was filed. *See Rockwell Int'l Corp. v. United States*, 549 U.S. 457, 473–74 (2007); ECF No. 245.

Plaintiffs lack standing to challenge the Secretarial Directive, ACIP's September 2025 COVID-19 vaccine recommendation, and ACIP's December 2025 hepatitis B vaccine recommendation because those actions have no future effect and so cannot cause Plaintiffs any future injury. CDC adopted a new immunization schedule in January 2026, including

recommendations for the COVID-19 and hepatitis B vaccines. ECF No. 185-18. Although the January 2026 decision memorandum mentioned the ACIP recommendations for those vaccines, it was not contingent on those recommendations, as adopted by CDC, but simply considered them along with other relevant information, such as peer countries' practices regarding the COVID-19 and hepatitis B vaccines. *Id.* at 6, 8. In other words, CDC's operative recommendations for the COVID-19 and hepatitis B vaccines date from the January 2026 decision, not the September and December 2025 ACIP votes. Thus, Plaintiffs cannot show any "future injury" caused by the challenged Secretarial Directive and September and December 2025 ACIP votes. *All. for Hippocratic Med.*, 602 U.S. at 381; *see Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016).

For the same reasons, Plaintiffs cannot show their alleged injuries are "likely to be redressed" by an order vacating the Secretarial Directive, ACIP's September 2025 COVID-19 vaccine recommendation, and ACIP's December 2025 hepatitis B vaccine recommendation. *Spokeo*, 578 U.S. at 338. Such an order would not affect the operative January 2026 immunization schedule because the January 2026 action was not contingent on the Secretarial Directive or the September and December 2025 ACIP recommendations, as adopted by CDC. Thus, if the Court vacated the actions challenged here, the shared clinical decision-making recommendations for the COVID-19 and hepatitis B vaccines on the January 2026 schedule would remain in place.

The same analysis shows why Plaintiffs' challenges to the Secretarial Directive and the ACIP's September and December 2025 recommendations are moot. The January 2026 immunization schedule has "overtaken" these actions, *Bos. Bit Labs, Inc. v. Baker*, 11 F.4th 3, 6 (1st Cir. 2021), and Plaintiffs "lack a legally cognizable interest in the outcome" of their

challenges to those actions because an order vacating them would not change the operative January 2026 schedule, *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013) (quotation omitted).

B. The Challenged Actions Are Unreviewable Because CDC's Immunization Recommendations Are Committed to Agency Discretion by Law

Each of Plaintiffs' claims arises under the APA, but that statute does not apply where "agency action is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). That exception applies, as here, "when the relevant statute is drawn so that a court would have no meaningful standard against which to judge the agency's exercise of discretion." *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 17 (1st Cir. 2020) (quotations omitted).[5]

The four challenged actions occurred under the Secretary's authority to "assist States and their political subdivisions in the prevention and suppression of communicable diseases" and "advise the several States on matters relating to the preservation and improvement of the public health." 42 U.S.C. § 243(a). Beyond a general authorization to "assist" and "advise," section 243(a) provides no standard "for judging how and when" the Secretary, the ACIP, or CDC "should exercise its discretion." *Heckler v. Chaney*, 470 U.S. 821, 830 (1985). The statute does not mention immunization recommendations—much less require them—and contains no "requirements to guide [the court] in assessing the propriety of [the] agency's procedures" in exercising its authority under section 243(a). *Marasco & Nesselbush, LLP v. Collins*, 6 F.4th 159, 171 n.26 (1st Cir. 2021) (quoting *Union of Concerned Scientists*, 954 F.3d at 21). It certainly does not "constrain[]" CDC's discretion about whether to make immunization recommendations

[5] Although this issue was not raised in Defendants' motion to dismiss the Third Amended Complaint, Plaintiffs' Fourth Amended Complaint and preliminary injunction motion assert new claims. Regardless, this issue implicates sovereign immunity, *Cowels v. FBI*, 936 F.3d 62, 66 (1st Cir. 2019) (citing 5 U.S.C. § 702), which "is jurisdictional in nature," *FDIC v. Meyer*, 510 U.S. 471, 475 (1994), and "cannot be waived in litigation," *In re Rivera Torres*, 432 F.3d 20, 23 n.3 (1st Cir. 2005); *see* Fed. R. Civ. P. 12(h).

and, if the agency so chooses, their "form and content." *Dep't of Com. v. New York*, 588 U.S. 752, 772 (2019).

A search "for a 'set of statutory or regulatory requirements to guide [the court] in assessing the propriety of'" the Secretarial Directive and CDC's adoption of the challenged June, September, and December 2025 ACIP votes yields nothing. *Marasco & Nesselbush*, 6 F.4th at 171 n.26 (quoting *Union of Concerned Scientists*, 954 F.3d at 21). Plaintiffs cannot simply point to the arbitrary and capricious standard in 5 U.S.C. § 706(2)(A). *See* PI Mem. 25–34. That, of course, would reduce the exception to a nullity. Instead, the necessary statutory or regulatory standards must exist "*apart from* 'the reasoned decision-making standards of the APA alone.'" *Marasco & Nesselbush*, 6 F.4th at 171 n.26 (emphasis added) (quoting *Union of Concerned Scientists*, 954 F.3d at 21). Here, they do not.

Although certain statutes and regulations reference the ACIP's immunization recommendations and CDC's potential adoption of those recommendations, *e.g.*, 42 U.S.C. § 300gg-13(a)(2); 26 C.F.R. § 54.9815-2713(a)(1)(ii), they do not prescribe how the ACIP should formulate a recommendation or CDC should determine whether to adopt it. *See Marasco & Nesselbush*, 6 F.4th at 171 n.26 (the court needs a "set of statutory or regulatory *requirements* to guide [it] in assessing the propriety of" the challenged actions (emphasis added) (quoting *Union of Concerned Scientists*, 954 F.3d at 21)). Moreover, as relevant to the Secretarial Directive, although these statutes and regulations acknowledge the existence of a process whereby ACIP makes immunization recommendations that CDC may adopt, they say nothing about whether CDC may also follow other processes to make immunization recommendations, such as making recommendations that are not based on ACIP's. Thus, these statutes and regulations do not constrain the Secretary's broad and unreviewable discretion under 42 U.S.C. § 243(a) to "assist"

and "advise" States about preventing communicable diseases and preserving public health, including through the ACIP and CDC.

The absence of meaningful standards for the Secretarial Directive and issuance of immunization recommendations by the ACIP and CDC stands in contrast to FACA's fair balance and inappropriate influence provisions, 5 U.S.C. § 1004(b)(2)–(3), (c), which, the First Circuit held, provide "sufficient standards . . . for meaningful review," *Union of Concerned Scientists*, 954 F.3d at 20. The concepts of fair balance and avoiding inappropriate influence "tell [courts] what Congress intended the [agency] to consider" in constituting advisory committees. *Union of Concerned Scientists*, 954 F.3d at 19–20. But beyond a general permission to "assist" and "advise" States about preventing communicable diseases and preserving public health, 42 U.S.C. § 243(a) does not "tell [courts] what Congress intended" the Secretary, the ACIP, or CDC "to consider" about when and how to exercise that authority to give non-binding recommendations and advice. *Union of Concerned Scientists*, 954 F.3d at 19–20. Because section 243(a) "is drawn so that a court would have no meaningful standard against which to judge the . . . exercise of discretion" in making immunization recommendations, *id.* at 17 (quotations omitted), such actions are "committed to agency discretion by law," 5 U.S.C. § 701(a)(2). Thus, all the actions challenged here are unreviewable under the APA.

C. The Challenged Actions Are Not Final Agency Action

For the reasons set out in Defendants' first opposition, ECF No. 232, at 13–15, the four additional actions challenged here are not final agency actions subject to APA review—but instead recommendations without concrete legal effects on Plaintiffs. Plaintiffs have not met

their burden to show otherwise.[6] Indeed, their brief (PI Mem. 23–24) does not even analyze whether each specific action they challenge satisfies the Supreme Court's test for final agency action, in light of the "unique constellation of statutes and regulations that govern the action at issue." *Sierra Club v. EPA*, 955 F.3d 56, 61 (D.C. Cir. 2020) (quotation omitted).

Plaintiffs' continued attempt to challenge these four actions—on top of the two addressed in the last round of briefing—illustrates that, at its core, this litigation is not about the sort of "discrete" final agency action reviewable under the APA at all. Instead, it amounts to a programmatic challenge to HHS's vaccine policy writ large that is not cognizable under the APA. As the Supreme Court has explained, an APA challenge may "proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004). "These limitations rule out several kinds of challenges," including "the kind of broad programmatic attack" raised here. *Id*. Plaintiffs may firmly disagree with HHS's views on vaccination policy, but they "cannot seek wholesale improvement of this program by court decree, rather than in the offices of the Department or the halls of Congress, where programmatic improvements are normally made." *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 875 (1990). The Court should thus decline Plaintiffs' invitation to effectively serve as a special monitor indefinitely overseeing the federal government's vaccination recommendations.

D. The Challenged Actions Were Reasonable and Reasonably Explained

Under the APA's standard of review, 5 U.S.C. § 706(2)(A), the court has "only a narrow

[6] Plaintiffs also cannot compensate for this failure by falsely asserting Defendants "waived any contention that the Challenged Actions are not final agency actions." PI Mem. 23. As we stated previously, "Plaintiffs' quotations of Defendants' counsel's comments do not concede anything on finality." ECF No. 232, at 14. And arguments about a lack of final agency action—a species of failure to state a claim—may be raised at any time through trial. *See* Fed. R. Civ. P. 12(h)(2).

role to play," *Dist. 4 Lodge of the Int'l Ass'n of Mechanists & Aerospace Workers Loc. Lodge 207 v. Raimondo*, 18 F.4th 38, 44 (1st Cir. 2021). The court "simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 592 U.S. at 423. If the agency action is "supported by any rational view of the record," it must be upheld. *Littlefield v. DOI*, 85 F.4th 635, 643 (1st Cir. 2023), *cert. denied*, 144 S. Ct. 1117 (2024) (mem.) (quoting *Marasco & Nesselbush*, 6 F.4th at 172). A difference of opinion about how to evaluate the evidence has no place in arbitrary and capricious review. *See Dist. 4 Lodge*, 18 F.4th at 45–47. The court cannot "substitute its judgment for that of the agency" and must "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted).

Plaintiffs assert that the May 2025 Secretarial Directive and the ACIP recommendations from June, September, and December 2025, as adopted by CDC, were arbitrary and capricious. For each of these actions, however, the agency "reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 592 U.S. at 423. The agency's full reasoning will be set out in the administrative records for these decisions, which have not yet been produced, but even considering just the publicly available documents, the challenged decisions plainly were well "within a zone of reasonableness." *Id.*

1. The May 2025 Secretarial Directive Was Reasonable

The Secretarial Directive and the scientific assessments on which it is based provide ample support for the Secretary's decision to rescind the recommendation that all children and pregnant women receive the COVID-19 vaccine. Regarding the recommendation for children, the Secretary's decision was supported by a scientific assessment from the Principal Deputy Director of NIH, Matthew Memoli, M.D., M.S., and the Principal Deputy Commissioner of

FDA, Sara Brenner, M.D., M.P.H. Ex. A[7] at 1. This assessment explained that in June 2022, then-Secretary of Health and Human Services Xavier Becerra issued Secretarial Directives "recommending that children between the ages of 6 months and 17 years receive the COVID-19 vaccine." *Id.* But "after a review of relevant existing data," including 39 scientific references and "new studies unavailable to Secretary Becerra when he issued his Directives" in June 2022, Drs. Memoli and Brenner found "no clear evidence that the benefits of vaccination for COVID-19 outweigh the risk of harm in children under 18 years of age." *Id.*

The Memoli-Brenner assessment began by considering the risks to children from COVID-19. It found that "[t]he risks associated with SARS-COV-2 infection, and subsequent clinical disease known as COVID-19, in children under 18 has been extremely low since the novel virus emerged in 2019." *Id.* at 2. For example, "the mortality from SARSCoV-2 infection among children without underlying health conditions is much less than one per million, which is significantly less than from RSV or influenza," and "there is no clear evidence that vaccination plays a role in preventing these exceedingly rare deaths." *Id.* "Hospitalization rates of children from COVID-19 are also extremely low and have decreased since 2019," and in fact are "substantially lower than for influenza and RSV in the United States." *Id.* Additionally, "Multi-Inflammatory Syndrome in Children (MIS-C)" and "[l]ong COVID" in children are "exceedingly rare," and no reliable evidence shows "a reduction in risk of th[ese] condition[s] due to vaccination." *Id.* at 3.

The Memoli-Brenner assessment next considered the risks of COVID-19 vaccination. It found that "[p]ost-vaccination myo- and pericarditis are well-established side effects of COVID-

[7] References to "Ex. A" and "Ex. B" refer to exhibits to the Declaration of Isaac C. Belfer, filed with this brief.

19 vaccination identified in adolescent boys and girls" and that "[p]ost-vaccination myocarditis can be severe and may have lasting consequences in children and young adults" and may even result in death. *Id.* at 3–4. Although "myocarditis can be a consequence of SARS-CoV-2 infection in children and young people, the risk from vaccination appears to be significantly higher," and "no robust evidence has shown vaccination to reduce post-COVID-19 myocarditis risks." *Id.* at 4. "Additional risks that have been associated with mRNA vaccination"—and COVID-19 mRNA vaccines—include "seizures, Bell's palsy, transverse myelitis, clotting disorders, strokes, heart attacks, and acute kidney injury," as well as "non-COVID-19 lower respiratory tract infection." *Id.*

The Memoli-Brenner assessment then noted "the past and current true efficacy of the COVID-19 vaccines remains unclear." *Id.* at 5. "The initial clinical trials in children and adolescents included less than 2,500 children and were unable to determine efficacy against severe COVID-19," and there have not been "[m]ore recent randomized placebo-controlled trials of original and/or updated vaccine formulations . . . to evaluate the safety or efficacy of any COVID-19 vaccines." *Id.* Beyond these deficiencies in the existing safety and efficacy data, "the ever-changing nature of the SARS-COV-2 viral antigens makes it unlikely that the current vaccination strategy will provide durable immunity against COVID-19." *Id.* Ultimately, Drs. Memoli and Brenner concluded that "currently available data and published studies do not provide sufficient clinical and scientific evidence to broadly recommend COVID-19 vaccination for those under 18 years of age." *Id.* Rather, "[g]iven the low risk of infection to those under the age of 18, the known risks of vaccination outweigh any small potential benefit." *Id.*

Turning to COVID-19 vaccination for pregnant women, the Secretary's decision was based on a scientific assessment from Tracy Beth Høeg, MD, PhD, an advisor to the FDA

Commissioner, which cited 11 scientific references. Ex. B. The Høeg assessment explained there was "[a] lack of high-quality data on the safety of mRNA Vaccines during pregnancy." *Id.* at 1. Vaccine manufacturer "Novavax has thus far not sought authorization of their vaccine in pregnancy as they lacked safety data," and "Pfizer and Moderna also lack high quality, randomized trial safety data—specifically, there was one insufficiently powered (very small) randomized study of the Pfizer COVID-19 vaccine and no randomized trial pregnant women has been done of the Moderna COVID-19 vaccine." *Id.*

Thus, the Høeg assessment explained, "our knowledge about the safety of COVID vaccination during pregnancy relies on lower quality data including findings from pharmacovigilance systems and on retrospective observational studies." *Id.* at 1–2. "There are numerous issues with relying on these datasets and analyses," including that "pharmacovigilance data tends to be vastly underreported" and "observational studies are prone to multiple potential biases." *Id.* at 2. Dr. Høeg also observed that "the COVID-19 mRNA vaccines have been shown . . . to cross the placenta," that "mRNA vaccination has also been linked to multiple types of blood clots," and that "[p]lacental blood clots can decrease oxygen to the fetus, cause birth defects, growth restriction, miscarriage and other pregnancy complications." *Id.* at 3.

In addition to these safety questions, the Høeg assessment found that "the current benefit of mRNA COVID-19 vaccination against severe disease is uncertain" given "widespread immunity from prior infection and a lack of randomized placebo control trials looking at clinical outcomes in this setting." *Id.* Furthermore, "vaccine efficacy in our current circumstances has been deduced from observational data and immunobridging data," and "the applicability of the initial randomized controlled trials to today's epidemiological circumstances" and a population that has been exposed to the SARS-CoV-2 virus is not "well defined." *Id.* Thus, Dr. Høeg

concluded that "[d]ue to a lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy and some basis for concern, it would be wise to err on the side of caution and recommend against . . . vaccination in pregnancy until there is certainty the benefits of vaccination are likely to outweigh potential risks to the mother and developing baby." *Id.* Although the Secretary declined to recommend against vaccination in pregnancy, he did rescind the routine recommendation that all pregnant women receive the COVID-19 vaccine because "the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby." ECF No. 185-1.

As the above summary illustrates, the Secretary "reasonably considered the relevant issues and reasonably explained the decision." *Prometheus Radio Project*, 592 U.S. at 423. Contrary to Plaintiffs' assertion that the Secretarial Directive was not based on safety and efficacy data, PI Mem. 32, the scientific assessments from FDA and NIH conducted an evidence-based balancing of the risks (i.e., safety) and benefits (i.e., efficacy) of COVID-19 vaccination.[8] And Secretary Kennedy "ha[d] discretion to rely on the reasonable opinions of [his] own qualified experts." *Marsh v. Or. Nat. Res. Council*, 490 U.S. 360, 378 (1989). Even if the Court disagrees with how the agency weighed the evidence, it cannot "substitute its judgment for that of the agency." *State Farm*, 463 U.S. at 43 (citation omitted); *see Dist. 4 Lodge*, 18 F.4th at 45–47. Indeed, the Court should "be at its most deferential" because vaccine evaluations are

[8] Plaintiffs claim the Secretarial Directive did not consider "new data or evidence-based analysis" regarding the vaccine's safety or efficacy. PI Mem. 33. As an initial matter, the agency was not required to consider "new" information—just to "reasonably consider[] the relevant issues and reasonably explain[] the decision." *Prometheus Radio Project*, 592 U.S. at 423. Regardless, the scientific assessments cited multiple "new" references from 2024 and 2025. Ex. A at 7–10; Ex. B at 5.

"scientific determination[s]" within the agency's "area of special expertise." *Balt. Gas & Elec. Co. v. Nat. Res. Def. Council, Inc.*, 462 U.S. 87, 103 (1983); *see, e.g.*, *Novartis Pharms. Corp. v. Kennedy*, 156 F.4th 626, 629-30 (D.C. Cir. 2025) (deferring to FDA where its analysis turned "squarely on the FDA's expertise in evaluating the clinical significance of drug studies, which we will not lightly second-guess"); *Rempfer v. Sharfstein*, 583 F.3d 860, 867 (D.C. Cir. 2009) (affording a "high level of deference" to FDA's "scientific judgment within its area of expertise") (quotations omitted)).

Plaintiffs argue that the change to COVID-19 vaccine recommendations for pregnant women is inconsistent with data presented by government officials regarding the risks of COVID-19 to pregnant women. PI Mem. 10–11, 29 (citing ECF No. 180-1, ¶ 98). There is no inconsistency: Neither Dr. Høeg's assessment nor the Secretarial Directive suggested there was no risk to pregnant women from COVID-19. The Secretary merely rescinded his predecessor's blanket recommendation that all pregnant women get vaccinated, based on "the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination." ECF No. 185-1. Plaintiffs also cite data regarding child deaths and hospitalizations from COVID-19, PI Mem. 11, but the Memoli-Brenner assessment explained why the data likely overestimate the true incidence of such events, Ex. A at 2–3. Likewise, the Memoli-Brenner assessment did not solely consider the risks to children from COVID-19, but the broader evidence regarding the COVID-19 vaccine's safety and efficacy.[9]

Plaintiffs' remaining arguments are equally meritless. Plaintiffs criticize the Secretarial

[9] Having reasonably considered the state of the evidence on the vaccine's safety and efficacy, the agency was not required to consider as well the various factors Plaintiffs identify, such as "changes to practice guidelines published by Plaintiffs or other professional organizations." PI Mem. 32; *see also* 42 U.S.C. § 243(a) (leaving it to the agency's discretion to determine which factors to consider in advising states and localities on public health).

Directive for making changes to the immunization schedules that were not based on an ACIP vote. PI Mem. 28. But HHS has wide, unreviewable discretion to make vaccine recommendations and is not required to base them on an ACIP vote or on any particular methodology. *See supra* pp. 13–15; ECF No. 232 at 15–17. Indeed, HHS has previously deviated from the ACIP's recommendations. *See* Feb. 13, 2026, Hearing Tr. 46:10–47:17.

Finally, Plaintiffs had no "reliance interests" in the CDC's COVID-19 vaccine recommendations for children and pregnant women that were in place before the Secretarial Directive. *Contra* PI Mem. 33–34. Vaccine recommendations are never permanent. *See* PI Mem. 26 n.68 (noting how "[e]ven after the first universal recommendation, ACIP continued to assess and revise HepB vaccination recommendations"). Indeed, the potential for revision or withdrawal of an immunization recommendation is baked into the ACIP Charter. *See* ECF No. 185-21, at 3. Thus, Plaintiffs have no "*reasonable* reliance interests" in any particular iteration of a vaccine recommendation. *FDA v. Wages & White Lion Invs., LLC*, 604 U.S. 542, 569 (2025) (emphasis added); *see Bell Atl. Tel. Cos. v. FCC*, 79 F.3d 1195, 1205 (D.C. Cir. 1996) (agency's adjustments to price cap index did "not upset petitioners' reliance interests" because agency had announced it would review the price cap system and thus "Petitioners could not have reasonably assumed that the price cap index would not be altered").

2. The June 2025 Thimerosal Recommendation Was Reasonable

The ACIP's June 2025 recommendation to administer thimerosal-free influenza vaccines, as adopted by the CDC, was also "within a zone of reasonableness." *Prometheus Radio Project*, 592 U.S. at 423. At its June 2025 meeting, the ACIP received a presentation titled *Thimerosal as a Vaccine Preservative* from Lyn Redwood RN, MSN. https://perma.cc/J8EA-MCK5; *see* CDC, *ACIP Meeting Materials: June 25-26, 2025, Meeting* (June 24, 2025), https://perma.cc/DP2D-BH7C. The presentation noted several safety concerns with thimerosal, which is about "49.6%

mercury by weight." Lyn Redwood, *Thimerosal as a Vaccine Preservative*, at 10–20 (June 2025), https://perma.cc/J8EA-MCK5. It further observed that, in 1999, the U.S. Public Health Service and AAP had jointly recommended that "thimerosal-containing vaccines should be removed as soon as possible." *Id.* at 3 (quotations omitted). The Institute of Medicine had concurred. *Id.* at 4, 20. Consistent with these recommendations and the cited evidence, the presentation recommended removing thimerosal from influenza vaccines and noted that "[w]e currently have enough thimerosal free flu vaccines" for "all pregnant women, infants and children." *Id.* at 20.

This issue was thoroughly discussed at the June 2025 ACIP meeting. ACIP, June 25-26, 2025, ACIP Meeting Summary, *supra*, at 64-74. For example, Drs. Kulldorff and Malone expressed concerns with cumulative mercury exposure from multiple sources, including annual influenza vaccination. *Id.* at 67. Dr. Kulldorff noted that "removing mercury-containing preservatives from vaccines could also help build public confidence" in vaccines, given "the consumer rejection of mercury in other products, such as food." *Id.* Dr. Levi discussed ways to ensure vaccine integrity without using thimerosal. *Id.* And Dr. Hoeg, representing FDA, reported that only about 4–5% of influenza vaccine doses in the 2024–2025 season "were thimerosal-containing multi-dose vials" and that "there does not appear to be a limitation in supply if a shift were made to using only single-dose formulations." *Id.* at 69. Based on this analysis, the ACIP recommended that adults and children "receive seasonal influenza vaccines only in single dose formulations that are free of thimerosal as a preservative." *Id.* at 72–74.

The Secretary adopted this recommendation in July 2025, explaining that it would "restore trust with Americans" and "enhanc[e] public confidence in vaccines" by "removing risk while sustaining access to vaccines." *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines*, *supra*. He explained there had been "more than two decades of

delay" since the 1999 recommendation to remove thimerosal from vaccines and that his adoption of the ACIP's recommendation "fulfills a long-overdue promise to protect our most vulnerable populations from unnecessary mercury exposure." *Id.* "Injecting any amount of mercury into children when safe, mercury-free alternatives exist defies common sense and public health responsibility." *Id.* This action "mark[ed] the final step to remove mercury from all vaccines given to Americans" and "align[ed] U.S. policy with that of Europe, which phased out mercury additives years ago." *Id.* Moreover, "[v]accine manufacturers have confirmed they have the capacity to replace multi-dose vials containing mercury, ensuring the Vaccines for Children (VFC) program and adult vaccine supplies will remain uninterrupted." *Id.*

Plaintiffs argue HHS should have "explained why [the ACIP] did not apply the GRADE approach, utilize the EtR framework, or consult with ACIP Work Groups to examine relevant data before adopting" the thimerosal recommendation. PI Mem. 28. But regardless of any past application of the GRADE approach or the EtR framework, the ACIP was not required—whether by statute, regulation or other source of law—to follow these internal operating procedures for thimerosal. *See Air Transp. Ass'n of Am., Inc. v. Nat'l Mediation Bd.*, 719 F. Supp. 2d 26, 43 (D.D.C. 2010) ("Because the Board's precedent did not require an evidentiary hearing in connection with a proposed rulemaking, the Board's decision not to conduct one was not arbitrary and capricious."), *aff'd*, 663 F.3d 476 (D.C. Cir. 2011). And because the internal procedures Plaintiffs demand were "not required," the agency was not required to explain why it did not follow those procedures in making the thimerosal recommendation. *Am. Wild Horse Campaign v. Stone-Manning*, No. 23-CV-117-KHR, 2024 WL 3872558, at *12 (D. Wyo. Aug. 14, 2024), *rev'd and remanded on other grounds sub nom. Am. Wild Horse Campaign v. Raby*, 144 F.4th 1178 (10th Cir. 2025).

Even if the ACIP were required to explain why it did not use the GRADE, EtR, and workgroup processes, any error was harmless. *See* 5 U.S.C. § 706. Plaintiffs do not challenge the ACIP recommendation itself, just HHS's adoption of it. *See* ECF No. 245, ¶ 170. And the Secretary properly exercised his unreviewable, unconstrained discretion to adopt the ACIP's recommendation regardless of which internal procedures ACIP followed. *See supra* pp. 13–15.

Plaintiffs' remaining arguments are unavailing. The agency was not required to consider "new data," PI Mem. 17, 33, but simply to "reasonably consider[] the relevant issues and reasonably explain[] the decision," which it did, *Prometheus Radio Project*, 592 U.S. at 423; *see supra* n.8. HHS also was not required to cite data (PI Mem. 31) in support of its explanation that removing thimerosal from season influenza vaccines would "restore trust with Americans" and "enhanc[e] public confidence in vaccines" by "removing risk while sustaining access to vaccines." *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines*, *supra*. As Dr. Kulldorff observed, it is common sense that "removing mercury-containing preservatives from vaccines could . . . help build public confidence" in vaccines, given "the consumer rejection of mercury in other products, such as food." June 25-26, 2025, ACIP Meeting Summary, *supra*, at 67.

Finally, Plaintiffs had no "reliance interests" in CDC's past position on the use of thimerosal in seasonal influenza vaccines. *See supra* p. 23; *contra* PI Mem. 33–34. That is confirmed by Plaintiffs' six-month delay in challenging the recommendation (*i.e.*, from HHS's adoption of ACIP's recommendation in July 2025 to filing the Fourth Amended Complaint in January 2026). If the recommendation had harmed Plaintiffs by disrupting their reliance interests, surely Plaintiffs would have exercised greater diligence in challenging it.

3. The September 2025 Shared Clinical Decision-Making Recommendation for the COVID-19 Vaccine

The ACIP's September 2025 recommendation regarding the COVID-19 vaccine, as adopted by the CDC, was also "within a zone of reasonableness." *Prometheus Radio Project*, 592 U.S. at 423. At the September meeting, the ACIP received numerous scientific presentations about the COVID-19 vaccine from experts in the field, including CDC subject matter experts and members of the ACIP's COVID-19 Immunization Work Group:

- An introductory presentation from the ACIP COVID-19 Immunization Work Group Chair Retsef Levi, Ph.D., Professor of Operations Management at MIT Sloan School of Management;
- "Updates to COVID-19 epidemiology" by Arjun Srinivasan, MD, from CDC's National Center for Immunization and Respiratory Diseases;
- "COVID-19 Vaccination Implementation" by Dr. Srinivasan;
- "Updates to COVID-19 Vaccine Effectiveness" by Dr. Srinivasan;
- "Vaccine safety signal detection and evaluation" by John Su from the CDC Immunization Safety Office;
- "Workgroup Safety Uncertainties of mRNA COVID Vaccines" by ACIP COVID-19 Immunization Work Group members Wafik El-Deiry, MD, PhD, FACP, Director of the Legorreta Cancer Center and Associate Dean of Oncologic Sciences at the Warren Alpert Medical School of Brown University; and Charlotte Kuperwasser, PhD, Director of the Tufts Convergence Laboratory of Biomedical, Physical, and Engineering Sciences and Professor of Developmental, Molecular & Chemical Biology at Tufts University School of Medicine;
- "Genomics of Vaccine-Induced Myocarditis" by ACIP COVID-19 Immunization Work

Group member Bruce Carleton, Pharm.D., Professor of Pediatrics, Medical Genetics, Pharmaceutical Sciences, and Population and Public Health at the University of British Columbia;

- "Economic Analysis of COVID-19 Vaccination" by Dr. Srinivasan on behalf of the University of Michigan;
- Updates from COVID-19 vaccine manufacturers;
- "COVID-19 Vaccine Discussion Framing, 2025-2026" by Dr. Levi;
- "Additional Workgroup Considerations in COVID-19 Vaccination Policy and Practice" by ACIP COVID-19 Immunization Work Group members Henry Bernstein, DO MHCM, Professor of Pediatrics at Zucker School of Medicine at Hofstra/Northwell; Mitchell Miglis, MD, Clinical Associate Professor of Adult Neurology and Psychiatry and Behavioral Sciences at Stanford University School of Medicine; and Stanley Perlman, MD, PhD, Professor of Microbiology and Immunology and Professor of Pediatrics at the Carver College of Medicine at the University of Iowa.

CDC, *ACIP Presentation Slides: September 18-19, 2025, Meeting* (Sept. 18, 2025), https://perma.cc/F4MW-2YE4.

During the meeting, the ACIP members and other participants thoroughly discussed the safety and efficacy of COVID-19 vaccines, as well as other considerations such as public trust and confidence in the vaccines. *See* ACIP, September 18-19, 2025, ACIP Meeting Summary, *supra*, at 52–94. They also discussed the proposal to recommend shared clinical decision-making. The COVID-19 Immunization Work Group Chair, Dr. Levi, explained that work group "[m]embers debated whether vaccination guidance should be based on population-level recommendations or individual clinical decisions." *Id.* at 85. He reported that "[t]he majority

supported an individual-based approach, concluding that COVID-19 vaccines should be prescribed by a clinician rather than administered under standing orders." *Id.* Dr. Levi explained that "[t]his approach would allow for personalized discussions between patients and healthcare providers about prior infections, immune response, comorbidities, and the balance of risks and benefits." *Id.* He "noted that this level of individual consideration is more appropriate now that the situation is no longer an emergency." *Id.* After Dr. Levi's presentation, Dr. Bernstein shared the view of a "minority of [work group] members" that shared clinical decision-making "create[s] unnecessary barriers to vaccination" and "can lead to confusion." *Id.* at 85–86.

ACIP member Dr. Hibbeln said "the committee's discussions clearly demonstrate that members are not opposed to vaccines" and that "the robust scientific debate, mutual respect among members, and inclusion of external experts reflect a thoughtful, open-minded approach rather than any predetermined stance." *Id.* at 88. He affirmed that "understanding the risks and benefits of vaccines is essential to the committee's work, acknowledging the difficulty of quantifying these factors." *Id.*

The ACIP also considered whether a shared clinical decision-making recommendation would have implications for insurance coverage. Dr. Kulldorff explained "the recommendation ensures coverage with zero cost-sharing under [the Children's Health Insurance Program ("CHIP")], [Affordable Care Act ("ACA")] plans, and Medicare Part B for all individuals aged six months and older, including children up to age 18." *Id.* at 88. Thus, he explained, "there would be no insurance restrictions on receiving the vaccine." *Id.*

Following this discussion, the ACIP voted to recommend the COVID-19 vaccine for children and adults based on shared clinical decision-making. *Id.* at 88–89. The ACIP further recommended that, for "[i]ndividuals 6 months to 64 years," shared clinical decision-making

"emphasi[ze] that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors." *Id.* The ACIP also rejected a proposal to recommend that COVID-19 vaccines be available only by prescription. *Id.* at 93.

When CDC adopted the shared clinical decision-making recommendation in October 2025, it explained that the prior recommendation of COVID-19 vaccines for all children and adults had "deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent." *CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19 and Standalone Vaccination for Chickenpox in Toddlers*, *supra*. It further observed that "just 23% of adults followed the CDC's most recent seasonal [COVID-19] booster recommendation" and that "[t]he booster shots prompted widespread risk-benefit concerns about their safety and efficacy as the COVID-19 virus became endemic." *Id.*

The ACIP's deliberations, together with CDC's reasoning in adopting the ACIP's recommendation, show that the agency "reasonably considered the relevant issues," including the COVID-19 vaccine's safety and efficacy, impacts on insurance coverage, and concerns about vaccine trust and confidence, and "reasonably explained the decision" to recommend the vaccine based on shared clinical decision-making. *Prometheus Radio Project*, 592 U.S. at 423; *contra* PI Mem. 32. These deliberations were based on scientific evidence and input from the ACIP COVID-19 Immunization Work Group, other ACIP members, and CDC experts. *See* ACIP, September 18-19, 2025, ACIP Meeting Summary, *supra*, at 52–94; *contra* PI Mem. 17 (incorrectly claiming ACIP "did not consult with the Covid Work Group prior to the vote"). And in adopting the ACIP's recommendation, CDC permissibly relied on "the reasonable opinions of [ACIP's] qualified experts." *Marsh*, 490 U.S. at 378.

Plaintiffs merely rehash their debunked arguments in opposition. The ACIP was not required to consider "new data." PI Mem. 33; *see supra* n.8. In any event, the committee *did consider* recent data from 2024 and 2025. *See* ACIP, September 18-19, 2025, ACIP Meeting Summary, *supra*, at 52–94. There were no "reliance interests" the agency needed to consider. *See supra* p. 23; *contra* PI Mem. 33–34. And the ACIP was not required to explain why it did not follow the GRADE and EtR frameworks—or if it was, this procedural foot fault was harmless. *See supra* pp. 25–26; *contra* PI Mem. 28.

4. The December 2025 Shared Clinical Decision-Making Recommendation for the Hepatitis B Vaccine

Finally, the ACIP's December 2025 recommendation regarding the hepatitis B vaccine, as adopted by the CDC, was also well "within a zone of reasonableness." *Prometheus Radio Project*, 592 U.S. at 423. Although the minutes from the December 2025 meeting have not yet been posted, the publicly available presentations from the meeting and CDC's adoption of the ACIP's recommendation suffice to show that the agency "reasonably considered the relevant issues and reasonably explained the decision." *Id.*

At the December meeting, the ACIP received multiple scientific presentations about the hepatitis B vaccine from CDC, the Centers for Medicare & Medicaid Services ("CMS"), and the Childhood/Adolescent Schedule Workgroup:

- "Hepatitis B Virus Vaccine Birth Dose" by ACIP member and Childhood/Adolescent Schedule Workgroup Chair Vicky Pebsworth, PhD, RN;
- "Burden of disease" by Dr. Nevison from CDC;
- "Safety Review of Hepatitis B Birth Dose Vaccination" by Mark F. Blaxill, MBA, from the Office of the CDC Director;
- A presentation from hepatitis B vaccine manufacturers by Drs. Robinson, Goveia, and

Chit;

- A presentation on the Childhood/Adolescent Schedule Workgroup's process and findings by Dr. Pebsworth;
- "VFC Resolution Update: Hepatitis B Vaccine" by Dr. Santoli of the CDC National Center for Immunization & Respiratory Diseases;
- "Overview of Vaccine Coverage" by Mr. A. Johnson from CMS.

CDC, *ACIP Presentation Slides: December 04-05, 2025, Meeting* (Dec. 5, 2025), https://perma.cc/N7NQ-46GT.

Dr. Pebsworth's second presentation noted that the Childhood/Adolescent Schedule Workgroup met seven times between October 17 and November 24, 2025, and received "12 presentations by CDC staff, workgroup members, and invited ad hoc experts that covered clinical ethics, non-specific vaccination effects, aluminum adjuvant exposures, clinical practice challenges and solutions, and the Alaska Hepatitis B vaccine trials." Vicky Pebsworth, *Summary of Information*, at 5 (Dec. 4, 2025), https://perma.cc/GS4X-5X79. Dr. Pebsworth reported "Full/Nearly Full Agreement" among the workgroup for the following findings:

- Although hepatitis B "is a serious disease[] and can be prevented by vaccination with the HBV vaccine," there is uncertainty about incidence rates and "whether all three recommended doses are needed to acquire protection."
- "There are gaps in evidence and limitations related to evidence of safety (per GRADE quality of safety evidence is poor)."
- Pregnant mothers should be screened for hepatitis B, and "[i]nfants born to mothers who test positive for [hepatitis B] should continue to be vaccinated with [the hepatitis B] vaccine and receive hepatitis B immunoglobulin soon after birth."

- "Infants born to mothers who test negative for [hepatitis B] have extremely low risk of horizontal infection during childhood and particularly in first months of life and therefore, do not need to be routinely vaccinated with the [hepatitis B] vaccine at birth."

Id. at 6–7.

Dr. Pebsworth reported that the workgroup favored shared clinical decision-making (also known as individual-based decision-making) for the hepatitis B vaccine for infants born to mothers who test negative. *Id.* at 9. The presentation discussed the advantages of a shared clinical decision-making approach and potential concerns with that approach. *Id.* at 10–13. Ultimately, the workgroup decided to recommend shared clinical decision-making because, among other reasons, it "[p]rovides for a return of decision-making to parents in collaboration with the health care provider" and allows providers "to recommend a flexible schedule and . . . tailor care to individual needs, risks and preferences." *Id*. at 12. The presentation also considered vaccine safety concerns and the risk of hepatitis B infection. *Id.* at 10. Its discussion of vaccine safety was consistent with the Blaxill presentation. Mark F. Blaxill, *Safety Review of Hepatitis B Birth Dose Vaccination* (Dec. 4, 2025), https://perma.cc/GE6J-ZVF5. Finally, Dr. Pebsworth provided the workgroup's rationale for recommending that infants who do not receive the birth dose receive the initial dose no earlier than two months of age. *Summary of Information*, *supra*, at 12.

Having considered these presentations, along with other information discussed at the meeting, the ACIP voted to recommend shared clinical decision-making "for parents deciding whether to give the hepatitis B vaccine, including the birth dose, to infants born to women who test negative for the virus," and it identified infection risks to consider. CDC, *ACIP Recommends Individual-Based Decision-Making for Hepatitis B Vaccine for Infants Born to Women Who Test*

Negative for the Virus (Dec. 5, 2025), https://perma.cc/QQ8P-DVNQ. The ACIP further recommended that "[f]or those infants not receiving the birth dose, . . . the initial dose be administered no earlier than two months of age." *Id.*

CDC adopted these recommendations, explaining that they "reflect[] ACIP's rigorous review of the available evidence" and "restor[e] the balance of informed consent to parents whose newborns face little risk of contracting hepatitis B." *CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for Hepatitis B Virus*, *supra*. In addition to the "[v]ery low incidence of perinatal hepatitis B transmission in the U.S. due to existing prevention systems," CDC noted the "[h]igh reliability of prenatal hepatitis B screening, which identifies nearly all hepatitis B infections during pregnancy." CDC, *Fact Sheet Hepatitis B Immunization* (Dec. 16, 2025), https://perma.cc/T927-DBYV. When "maternal hepatitis B status is confirmed negative," CDC determined that "[f]amilies and providers should be afforded flexibility." *Id.* Finally, CDC explained that it would "[d]evelop materials to support clinicians in discussing vaccination timing with families." *Id.*

Plaintiffs' arguments against this decision are meritless. Again, the ACIP was not required to consider "new data." PI Mem. 33; *see supra* n.8. In any event, the committee *did consider* recent data from 2024 and 2025. *See, e.g.*, *Safety Review of Hepatitis B Birth Dose Vaccination*, *supra*; *Summary of Information*, *supra*, at 5 (noting that the Childhood/Adolescent Schedule Workgroup received 12 expert presentations on medical and scientific issues at its meetings in October and November 2025). There were no "reliance interests" the agency needed to consider. *See supra* p. 23; *contra* PI Mem. 33–34. And the ACIP was not required to explain why it did not follow the GRADE and EtR frameworks, *see supra* pp. 25–26; *contra* PI Mem. 27–28, though Dr. Pebsworth's second presentation at least partially applied the GRADE framework, *see*

Summary of Information, *supra*, at 6.

In sum, the ACIP and CDC "reasonably considered the relevant issues," including the hepatitis B vaccine's safety and efficacy, impacts on insurance coverage, and the advantages and potential disadvantages of a shared clinical decision-making recommendation, and "reasonably explained" their recommendations. *Prometheus Radio Project*, 592 U.S. at 423; *contra* PI Mem. 18, 32. These deliberations were based on scientific evidence and input from the ACIP Childhood/Adolescent Schedule Workgroup and CDC experts. *See ACIP Presentation Slides: December 04-05, 2025, Meeting*, *supra*; *contra* PI Mem. 18 (incorrectly claiming "[n]o Work Group presented at this ACIP meeting on HepB"). And in adopting the ACIP's recommendations, CDC permissibly relied on "the reasonable opinions of [ACIP's] qualified experts." *Marsh*, 490 U.S. at 378.

II. Plaintiffs Will Not Suffer Irreparable Harm Before The Court Rules On The Merits

Plaintiffs have not clearly shown they will suffer immediate, irreparable harm unless the Court grants extraordinary relief. *See Winter*, 555 U.S. at 20; *Mazurek*, 520 U.S. at 972. We maintain (and reassert) all arguments against irreparable harm from our initial opposition brief, *see* ECF No. 232, at 37-43, and discuss herein only our additional arguments specific to the May 2025 directive and the ACIP votes from June, September, and December.

Off the bat, Plaintiffs' substantial delay in challenging the June 2025 ACIP vote about thimerosal precludes any claim of irreparable harm. *See Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 163 (1st Cir. 2004) ("[D]elay between the institution of an action and the filing of a motion for preliminary injunction, not attributable to intervening events, detracts from the movant's claim of irreparable harm."). "If [Plaintiffs] were genuinely at risk of irreparable harm" from the June recommendation (as adopted by HHS in July), they "presumably" would not have waited six months before moving to add this vote to the case. *Doe v. Trs. of Dartmouth*

Coll., 597 F. Supp. 3d 511, 514 (D.N.H. 2022). This months-long delay strongly "militates against a finding of irreparable harm." *Wreal, LLC v. Amazon.com, Inc.*, 840 F.3d 1244, 1248 (11th Cir. 2016); *see Doe*, 597 F. Supp. 3d at 514-15 (finding no irreparable harm based on a delay of several months). And of course, Plaintiffs "cannot delay the initiation of litigation and then use an 'emergency' created by [their] own decisions concerning timing to support a motion for preliminary injunction." *Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften E.V. v. Whitehead Inst. for Biomedical Rsch.*, 650 F. Supp. 2d 114, 123 (D. Mass. 2009).

Furthermore, despite seeking to preliminarily enjoin four distinct actions—the Secretarial Directive and three ACIP votes—Plaintiffs do not explain how *each* "challenged conduct causes some harm that cannot be adequately redressed" after summary judgment. *Nagle v. Gerry*, No. 08-CV-432-SM, 2009 WL 702798, at *5 (D.N.H. Mar. 13, 2009). Rather, they lump everything together under general labels like "the ACIP Actions." PI Mem. 43. That does not suffice where, as here, each challenged action has a distinct subject and effect. *City of Lowell v. Enel N. Am., Inc.*, 705 F. Supp. 2d 116, 120 (D. Mass. 2010) (finding no irreparable harm when city addressed only "the *overall* risk of massive flooding, not to the increased flood risk based upon the [challenged] use of five-foot flashboards").

For example, to enjoin the June ACIP "vote to remove thimerosal from all influenza vaccines distributed in the United States," ECF No. 183-1, at 2, Plaintiffs must establish why this vote, in particular, will likely cause them irreparable harm. That requires addressing factors like AAP's past support for "remov[ing] mercury from childhood vaccines" and vaccine manufacturers' confirmation that "they have the capacity to replace multi-dose vials containing mercury, ensuring the [VFC] program and adult vaccine supplies will remain uninterrupted." *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines*,

supra. The evidence on these points will necessarily differ from that which would purportedly show irreparable harm from the Secretary's May instruction "to remove the recommendations from CDC immunization schedules that pregnant women and children [routinely] receive the Covid vaccine." ECF No. 183-1, at 2. Yet Plaintiffs ignore all these distinctions, offering only generalized statements of harm in the aggregate. Thus, Plaintiffs fail to carry their burden of showing how they will likely suffer irreparable harm from each action they seek to enjoin. *See, e.g.*, *City of Lowell*, 705 F. Supp. 2d at 120.

III. The Public Interest Strongly Disfavors Plaintiffs' Attempt to Suppress Differing Viewpoints About Vaccine Policy

Plaintiffs' motion should also be denied because the public interest disfavors Plaintiffs' extraordinary proposal to enjoin HHS from giving non-binding recommendations to states and localities. "In exercising [its] sound discretion," the Court must "pay particular regard for the public consequences in employing the extraordinary remedy of injunction." *Winter*, 555 U.S. at 24 (quoting *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982)). Here, both "the balance of equities and consideration of the overall public interest in this case tip strongly in favor of" CDC and HHS. *Id.* at 26.

Plaintiffs are trying to substitute their preferred policies for those adopted by senior, democratically accountable federal officials. However, Congress directed "[t]he Secretary" of Health and Human Services—not Plaintiffs—to "assist States . . . in the prevention and suppression of communicable diseases and with respect to other public health matters" and to "advise the several States on matters relating to the preservation and improvement of the public health." 42 U.S.C. § 243(a). And Congress authorized the Secretary to establish the ACIP, *see id.* § 217a(a), to advise the CDC Director "regarding use of vaccines and related agents for effective control of vaccine-preventable diseases," ECF No. 185-21, at 2. The ACIP, the CDC Director,

and the Secretary then must remain free to "select the views that [they] want[] to express" about vaccine recommendations and protection of the public health. *Nat'l Rifle Ass'n of Am. v. Vullo*, 602 U.S. 175, 187 (2024) (quoting *Pleasant Grove City v. Summum*, 555 U.S. 460, 467-68 (2009)). And these officials may share their views "in the hopes of persuading others to follow [their] lead." *Id.* at 188.

Furthermore, Plaintiffs' desired preliminary injunction would create the very "state of confusion" they decry. PI Mem. 54. Over the past months, the current Administration has developed and released its immunization recommendations. To suddenly revert to the previous advice through a preliminary injunction would subject the public and healthcare practitioners to whiplash and create confusion about the actual position of CDC and HHS. And if Defendants prevail on the merits and the preliminary injunction is dissolved, more whiplash will occur as the current recommendations are restored. The public interest is significantly disserved by such ambiguity about the current, actual recommendations of those democratically accountable officials charged with advising and assisting States to protect the public health.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' preliminary injunction motion.

February 27, 2026

Respectfully submitted,

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/s/ Isaac C. Belfer
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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

February 27, 2026

/s/ Isaac C. Belfer
Isaac C. Belfer

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, Plaintiffs, v. ROBERT F. KENNEDY, JR., *et al.*, Defendants.	Case No. 1:25-cv-11916-BEM

Declaration of Isaac C. Belfer

Pursuant to 28 U.S.C. § 1746, I, Isaac C. Belfer, declare as follows in support of Defendants' Second Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction:

1. I am a trial attorney in the Federal Programs Branch, Civil Division, U.S. Department of Justice, and am representing Defendants in this matter. The purpose of this declaration is to authenticate and enclose the exhibits cited in Defendants' Second Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction.

2. Attached hereto as **Exhibit A** is a true and correct copy of the May 12, 2025, Memorandum to Secretary of Health and Human Services Robert F. Kennedy, Jr. from Matthew Memoli, M.D., M.S., Principal Deputy Director of NIH, and Sara Brenner, M.D., M.P.H., Principal Deputy Commissioner of FDA, titled, "Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age."

3. Attached hereto as **Exhibit B** is a true and correct copy of the May 12, 2025, Memorandum to Secretary of Health and Human Services Robert F. Kennedy, Jr. from Tracy Beth Høeg, M.D., Ph.D. (FDA), titled, "COVID-19 vaccine safety in pregnant women."

I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge. Executed on February 27, 2026.

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CERTIFICATE OF SERVICE

I hereby certify that this document, filed through the CM/ECF system, will be sent via electronic mail to the registered participants as identified on the Notice of Electronic Filing.

February 27, 2026

/s/ Isaac C. Belfer
Isaac C. Belfer

Exhibit A

MEMORANDUM TO THE SECRETARY

THROUGH: HEATHER MELANSON, CHIEF OF STAFF
CORTNEY MCCORMICK, EXECUTIVE SECRETARY

FROM: MATTHEW MEMOLI, M.D., M.S., PRINCIPAL DEPUTY DIRECTOR, NIH

SARA BRENNER, M.D., M.P.H., PRINCIPAL DEPUTY COMMISSIONER, FDA

SUBJECT: Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age

DATE: May 12, 2025

On June 18 and June 24, 2022, Secretary of Health and Human Services Becerra issued "Secretarial Directives" recommending that children between the ages of 6 months and 17 years receive the COVID-19 vaccine. At this time, after a review of relevant existing data, including new studies unavailable to Secretary Becerra when he issued his Directives on June 18, 2022, and June 24, 2022, there is no clear evidence that the benefits of vaccination for COVID-19 outweigh the risk of harm in children under 18 years of age.

Vaccines are products designed to be given to individuals to stimulate immunity against a certain pathogen thereby preventing disease and its sequelae. A departmental recommendation of any vaccination should be based on a careful evaluation of probable benefits weighed against risks and potential harms. The benefits and risks of vaccination should be clearly established using randomized controlled trials prior to a recommendation. Vaccination of any population should only be recommended when it is clear, based on the best available evidence from these trials, that the benefits are likely to outweigh the known and potential risks of the vaccines. Once a recommendation is made, reevaluation of the recommendation is regularly required, as new data will continue to emerge as a vaccine is used in a population and as a pathogen evolves.

Risks of COVID-19 to Children

Mortality

The risks associated with SARS-COV-2 infection, and subsequent clinical disease known as COVID-19, in children under 18 has been extremely low since the novel virus emerged in 2019. A review using death certificates in countries with widespread COVID-19 testing found that deaths were over-attributed to COVID-19 by as much as 40-50% early in the pandemic and possibly as high as 60-70% after the emergence of Omicron (Friis, 2023). This type of over-attribution led to widespread misunderstanding among the U.S. population about the mortality attributable to COVID-19 in children due to CDC's public dashboard on COVID-19 deaths, COVID Data Tracker, which consistently overstated the number of deaths attributed to COVID-19 in children by 20% or more compared with the CDC's standard and more carefully adjudicated National Center for Healthcare Statistics database (Krohnert, 2023). A clearer picture of the low risk in children emerged in multiple studies, including a landmark study from 2020-2021 of over 750,000 healthy children ages 5-17 infected with SARS-CoV-2. This study identified no deaths due to the virus in their cohort (Sorg, 2022). This study was performed early in the pandemic when death rates were highest from COVID-19 and prior to the current widespread immunity and evolution of milder SARS-COV-2 variants. A subsequent study found the omicron subvariants later in the pandemic posed even lower risk to children with an over 3-fold reduction in infection mortality rate in children and young people compared to early in the pandemic (Hani, 2023), while some of the few overall deaths observed occurred in vaccinated children. By the end of 2023, CDC reported a death rate in children under 18 of 0.5 per million cases (https://data.cdc.gov/Public-Health-Surveillance/Rates-of-COVID-19-Cases-or-Deaths-by-Age-Group-and/54ys-qyzm) with that number likely an over-estimate given unreliable denominators (total number of actual infections was higher than captured in the data) and has been decreasing even further since. These data together suggest that the mortality from SARS-CoV-2 infection among children without underlying health conditions is much less than one per million, which is significantly less than from RSV or influenza. Furthermore, there is no clear evidence that vaccination plays a role in preventing these exceedingly rare deaths.

Hospitalization

Hospitalization rates of children from COVID-19 are also extremely low and have decreased since 2019; they are now substantially lower than for influenza and RSV in the United States. Similar to COVID-19 deaths, starting early in the pandemic, hospitalization rates of children due to SARS-CoV-2 in the U.S. were likely overestimated by at least 40% (Beck, 2021). This suggests that nearly half or more of the children who had been reported to be hospitalized from COVID-19 were hospitalized either due to other illness or injury, or unnecessarily hospitalized due to fear of COVID-19. This again gave the public an inaccurate sense that hospitalization due to

severe COVID-19 was common in children. This also likely led to an inflated perceived effect of vaccination on hospitalization, as the vaccine availability calmed some of these fears.

Multi-Inflammatory Syndrome in Children (MIS-C)

An additional condition of potential risk related to COVID-19 in children is a post-infection inflammatory condition, named Multi-Inflammatory Syndrome in Children (MIS-C). This condition was rare, but is now exceedingly rare with less than 80 total cases nationwide in 2024. To date, no randomized controlled trials have demonstrated a reduction in risk of this condition due to vaccination. Observational data assessing effectiveness of COVID-19 vaccines against MIS-C are likely unreliable due to underlying biases (Høeg, 2024).

Long COVID

Long COVID is a diagnosis which suffers from broad and imprecise case definitions (Høeg, 2024). However, the most well-conducted studies indicate that infection-related lasting symptoms in children are exceedingly rare (Selvakumar, 2023; Høeg, 2023). Randomized studies have also not assessed the efficacy of vaccination against Long COVID (Munro, et al.). One study among Norwegian children found vaccination to be an independent risk factor for more severe fatigue following SARS-CoV-2 infection (Selvakumar, 2025) suggesting a possible worsening of Long COVID associated symptoms, but observational studies have been mixed and prone to multiple biases when evaluating the relationship between vaccination and Long COVID. (Høeg, 2023; Høeg, 2024).

Vaccination Risks

Post-Vaccination Myocarditis and Pericarditis, Including Sudden Cardiac Death and Sequelae

Post-vaccination myo- and pericarditis are well-established side effects of COVID-19 vaccination identified in adolescent boys and girls (Krug, 2022; Kracalik, 2023). About 1 in 2,700 boys vaccinated with a second dose of Pfizer were hospitalized with myo- and/or pericarditis according to a prospective study from Hong Kong (Chua, 2022). Post-vaccination myocarditis can be severe and may have lasting consequences in children and young adults (Kracalik, 2023). In that study, about 1 in 5 children were admitted to intensive care for the condition. At 90 days follow up, over 30% had still not been cleared for physical activity and about 25% were still being prescribed medications. Rates of subclinical myo- and pericarditis, and associated long term health outcomes, have yet to be fully characterized.

Deaths post-vaccination due to myocarditis appear to be rare but have been reported in young people (Mevorach, 2021). A nationwide Korean study (Cho, 2023) attributed 21 total deaths to vaccination-induced myocarditis, corresponding to a death rate of 1-2 per million primary series mRNA vaccinations given in the 12–44-year-old age group, consistent with a nationwide study from Qatar (Butt, 2023). In these two studies together, there was one death and three

fulminant cases in those under 21, highlighting a serious risk of vaccination that should be weighed with a lack of certainty of vaccination benefit and an exceedingly low rate of death among children—well below 1 per million infections in healthy children.

While myocarditis can be a consequence of SARS-CoV-2 infection in children and young people, the risk from vaccination appears to be significantly higher. A study performed in 2021 (Karlstad, 2022) that included 23 million residents of Norway, Sweden, Denmark, and Finland ages 12 and older found no cases of post-COVID myocarditis in children between 12-15 years of age, but did find cases in 16–24-year-olds. However post-vaccination myocarditis was at least six times more common than myocarditis post-COVID infection among both males and females (details in supplement). Furthermore, no robust evidence has shown vaccination to reduce post-COVID-19 myocarditis risks.

Additional Safety Signals and Potential Risks of Vaccination in Children

Additional risks that have been associated with mRNA vaccination include but are not limited to seizures, Bell's palsy, transverse myelitis, clotting disorders, strokes, heart attacks, and acute kidney injury (Faskova, 2024; Dag Berild, 2022; Lim 2025; Hu, 2024; Hwang, 2025). Analysis of the randomized trials in children suggests there may be an increased risk of non-COVID-19 lower respiratory tract infection (Hoffman, 2023). The potential benefit in healthy children of vaccination is very small given the low risk of severe disease and, based on existing data, may not outweigh the risks of vaccination. This is most likely the reason why, as mentioned during the 2025 ACIP meeting on April 15, 2025, the U.S. is currently a global outlier in recommending yearly routine vaccination of children under 18 for COVID-19. The WHO European Nations, Australia, Canada, and the UK do not currently recommend routine vaccination of non-high-risk children. Denmark notably does not offer the COVID-19 vaccine to anyone under the age of 65 unless they have certain underlying medical conditions and children <18 may not receive a COVID-19 vaccine unless they have a chronic illness and have been assessed by a pediatrician who recommends vaccination for them. Notably, the Director General of the Danish Health Authority, Søren Brostrøm, stated in the summer of 2022 that "it was a mistake" (det var in fejl) to vaccinate children for COVID-19. Furthermore, updated versions of COVID-19 vaccines, which claim to provide protection against severe illness due to infection with new subvariants, may have additional, new, and/or unknown risks. The clinical efficacy of updated vaccines has also not been established on the basis of randomized controlled trials and health outcomes data; and similarly, comprehensive adverse event data has yet to be captured and fully analyzed for these new products, leading to an incomplete benefit/risk analysis. An example of this in another setting was the 2009 inactivated influenza vaccine, Pandemrix, manufactured by Glaxo Smith Klein which caused narcolepsy in children (Buonocore, 2022). Well over 1,000 children were affected by the time this link was made with the vaccine the following year (Doshi, 2018) as well as additional serious safety concerns. This is a good example of why continued consideration and evaluation of vaccine recommendations must be done regularly.

Lack of Clear Evidence of Vaccination Benefit

As described above, there is insufficient evidence based on clinical outcomes data to render a positive benefit risk assessment for vaccinating children at this time. The initial clinical trials in children and adolescents included less than 2,500 children and were unable to determine efficacy against severe COVID-19 (Frenck, 2021; Ali, 2021; Walter, 2022; Creech, 2022; Anderson, 2022; Muñoz, 2023). Any purported protection against symptomatic disease identified in epidemiological data appears modest and wanes rapidly (Munro, 2024; Chemaitelly, 2022). More recent randomized placebo-controlled trials of original and/or updated vaccine formulations have *not* been conducted to evaluate the safety or efficacy of any COVID-19 vaccines. This is especially relevant and necessary in the setting of current widespread population immunity (as understood from seroprevalence studies) or against the new subvariants in children or adults. What makes this even more concerning is that by the time a new formulation is manufactured and released based on currently circulating variants, the virus has evolved away from the variant the vaccine was designed against, likely reducing efficacy and again altering the benefit/risk calculation

To estimate efficacy, randomized placebo-controlled trials of boosters and updated vaccination formulas have thus far measured neutralizing antibody response to re-vaccination. However, the clinical correlate of protection to this response among children and adults who have previously had SARS-CoV-2 infection one or multiple times has not been established (Zhang, 2025). Further the ever-changing nature of the SARS-COV-2 viral antigens makes it unlikely that the current vaccination strategy will provide durable immunity against COVID-19. Observational data are largely unreliable to assess vaccine efficacy due to multiple biases; one of the most significant being the “Health Vaccinee Bias” that reflects better underlaying health among vaccinated populations (Høeg, 2023, Fürst, 2024, Chemeitelly, 2024). For this reason, the past and current true efficacy of the COVID-19 vaccines remains unclear.

Conclusions

In conclusion, currently available data and published studies do not provide sufficient clinical and scientific evidence to broadly recommend COVID-19 vaccination for those under 18 years of age. No clear benefit of vaccination in children under 18 has been established with current formulations of COVID-19 vaccines against current circulating variants, especially given the widespread immunity from prior infection(s) that currently exists in the population. Given the low risk of infection to those under the age of 18, the known risks of vaccination outweigh any small potential benefit. It is HHS’s priority to ensure the health and safety of this vulnerable population—whether risk comes from a disease or a treatment/vaccine. We have a duty to set a gold standard for scientific review of products that are recommended to Americans and that those products, including vaccines, must have clearly defined benefits that outweigh the risks. Ultimately, decisions regarding risk and benefit must be tailored to the individual and made through shared decision making between patients and their physicians.

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Exhibit B

Memorandum

Date: May 12th, 2025

To: Secretary Robert F. Kennedy, Jr.

From: Tracy Beth Høeg, MD, PhD (FDA)

Subject: COVID-19 vaccine safety in pregnant women

A lack of high-quality data on the safety of mRNA Vaccines during pregnancy

The initial randomized clinical trials of Pfizer, Modern and Novavax excluded pregnant women; for this reason, safety could not be determined from these initial trials. In March of 2021, Pfizer stated that " Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy." Pfizer announced in February of 2021 that they would enroll 4,000 women in a randomized controlled trial to evaluate safety, tolerability and immunogenicity in healthy pregnant women. However, Pfizer ended up substantially reducing the size of the study to only include only 173 women vaccinated late in pregnancy (between 24 and 34 weeks). Not only was this study underpowered to detect safety issues during pregnancy, it could not provide *any data at all* on the safety of vaccination early in pregnancy up until week 24. Importantly, the risk of toxicity leading to miscarriage or developmental defect is the highest in the early phase of pregnancy, during the first and early second trimester.

Notably, Novavax has thus far not sought authorization of their vaccine in pregnancy as they lacked safety data. However, Pfizer and Moderna also lack high quality, randomized trial safety data – specifically, there was one insufficiently powered (very small) randomized study of the Pfizer COVID-19 vaccine and no randomized trial pregnant women has been done of the Moderna COVID-19 vaccine.

Limitations of observational data to evaluate safety of vaccines in pregnancy

Because of the above issues, our knowledge about the safety of COVID vaccination during pregnancy relies on lower quality data including findings from pharmacovigilance systems and

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on retrospective observational studies. There are numerous issues with relying on these datasets and analyses.

First, pharmacovigilance data tends to be vastly underreported. (Shumabukuro, 2015) Pregnant women or their obstetricians may not consider the vaccine as a cause of common or non-rate pregnancy outcomes such as miscarriage or fetal abnormality. Also, even if reported to a phamacovigilance database, small percentage increases (such as a couple of percentage points) in conditions such as fetal loss may not be found to be statistically significant from baseline rate but may still impact many women.

Second, observational studies are prone to multiple potential biases, of which *healthy vaccinee bias* (where people who get vaccinated tend to be healthier at baseline than those who do not get vaccinated) is potentially the most important. This bias has been thoroughly documented for the COVID-19 and the influenza vaccine in numerous countries across the world(Høeg, 2023; Fürst, 2024; Chemeitelly, 2024; Reidmann, 2025 Remschmidt, 2015). Women who have better underlying health are also less likely to have pregnancy complications. This may cause us to miss real safety issues if the unvaccinated are more prone to pregnancy complications.

Furthermore, another important bias, selection bias, stems of the fact only a few observational studies have looked at COVID vaccination during early stages of pregnancy, when the risk of toxicity leading to miscarriage or developmental defect is the highest. Most observational studies have not found a significant association between vaccination and adverse outcomes in pregnancy.

Potential safety concerns

However, a large study from Ontario did find a higher rate of fetal loss among women vaccinated prior to week 20. (Velez, 2023) This associations disappeared when excluding induced abortions. However, it is unclear if these were truly elective or recommended due to impending fetal loss. Furthermore, this study adjusted for time of year, which was likely to be inappropriate given the rapid timing of the vaccination rollout in Ontario in this age group.

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Another study from Israel (Dick, 2022), where the population was almost exclusively vaccinated with the Pfizer mRNA vaccine found that women vaccinated in the second trimester had a 1.9% higher rate of preterm birth and this was highly significant. This signal persisted after adjusting for multiple potential confounders.

Additionally, another small study of women who underwent *in vitro* fertilization found a 50% higher clinical pregnancy loss rate among COVID-19 vaccinated women compared with unvaccinated (Aharon, et al. 2022), however this was not found to be statistically significant and again, observational studies are subject to multiple biases.

Importantly, the COVID-19 mRNA vaccines have been shown in a study in the American Journal of Obstetrics and Gynecology to cross the placenta (Lin, 2024). mRNA vaccination has also been linked to multiple types of blood clots (Faskova, 2024). Placental blood clots can decrease oxygen to the fetus, cause birth defects, growth restriction, miscarriage and other pregnancy complications.

Uncertainty about vaccine efficacy

In the setting of widespread immunity from prior infection and a lack of randomized placebo control trials looking at clinical outcomes in this setting, the current benefit of mRNA COVID-19 vaccination against severe disease is uncertain. This is because vaccine efficacy in our current circumstances has been deduced from observational data and immunobridging data and the applicability of the initial randomized controlled trials to today's epidemiological circumstances and in a non-immune naïve population is not well defined.

Conclusion

Due to a lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy and some basis for concern, it would be wise to err on the side of caution and recommend against during vaccination in pregnancy until there is certainty the benefits of vaccination are likely to outweigh potential risks to the mother and developing baby.

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Memorandum

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