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' Opposition to Plaintiffs' Motion for Leave to File their Fourth Amended Complaint

BRETT A. SHUMATE
Assistant Attorney General
Civil Division

ERIC J. HAMILTON
Deputy Assistant Attorney General

JAMES W. HARLOW
Acting Assistant Director

ISAAC C. BELFER (D.C. Bar No. 1014909)
Trial Attorney
Federal Programs Branch
Civil Division
U.S. Department of Justice
1100 L Street, NW
Washington, DC 20005
(202) 305-7134
(202) 514-8742 (fax)
Isaac.C.Belfer@usdoj.gov

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Rules

Other Authorities

INTRODUCTION

Plaintiffs filed this case on July 7, 2025. Since then, they have amended the complaint three times, most recently in November 2025. Now Plaintiffs want to file a *Fourth* Amended Complaint, which would make *five* complaints total for a case filed only seven months ago. Whereas the prior complaints focused on recommendations for the COVID-19 vaccine, the proposed Fourth Amended Complaint would expand this case to encompass several recommendations about vaccines for diseases other than COVID-19. Although Defendants did not oppose the three prior amendments, a fourth amendment (the fifth total complaint) is a bridge too far. Defendants object to Plaintiffs' unrelenting and abusive practice of both expanding the litigation playing field mid-suit and moving back the goalposts for a final resolution of this case.

Plaintiffs' new proposed claims are unrelated to their existing claims and would significantly expand the scope of this case. The challenged June and December 2025 recommendations did not involve COVID-19 vaccines—the focus of this suit to date. And the Centers for Disease Control and Prevention's ("CDC") modifications of certain immunization recommendations in January 2026 did not change the shared clinical decision-making recommendations for the COVID-19 vaccine, which had been addressed in 2025.

Defendants are prejudiced by the continued expansion of this case. Each new action Plaintiffs challenge means an additional administrative record for Defendants to compile and produce. That may, in turn, multiply the number of merits briefs. Indeed, the bifurcated briefing for Plaintiffs' current motion for a preliminary injunction demonstrates the point. The end result of Plaintiffs' metastasizing complaint is more delay in the entry of a final judgment on the merits. Such delay harms the interests of judicial economy and efficiency. And Plaintiffs have no intention of stopping these serial amendments. As they told the Court, they will keep amending the complaint any time there are "new actions" they want to challenge—seemingly *any*

development in federal vaccine policy. Jan. 12, 2026, Status Conference Tr. 31:4–7.

The proposed amendment also is futile. Plaintiffs have not shown standing to challenge any of the new actions. This failure is especially stark for the June 2025 recommendation, which Plaintiffs do not even attempt to allege harmed them. The newly challenged actions are also unreviewable under the Administrative Procedure Act ("APA") because they are committed to agency discretion by law and are not final agency action.

Finally, at a minimum, Plaintiffs unduly delayed adding a challenge to the ACIP's June 26, 2025, recommendation regarding the use of thimerosal as a preservative in influenza vaccines. Plaintiffs could have included that in the original complaint (July 2025), the First Amended Complaint (later in July 2025), the Second Amended Complaint (September 2025), or the Third Amended Complaint (November 2025). Yet Plaintiffs did not; nor do they offer any explanation for this substantial delay.

At bottom, the proposed Fourth Amended Complaint is unduly delayed, futile, unduly prejudicial to Defendants, and a disservice to judicial economy. The Court should deny Plaintiffs' motion and keep this case on schedule for a final resolution. If Plaintiffs want to challenge governmental actions beyond those referenced in the Third Amended Complaint, they need only file a new lawsuit.

BACKGROUND

Plaintiffs' original complaint, filed on July 7, 2025, challenged one action: the May 2025 Secretarial Directive on Pediatric COVID-19 Vaccines for Children less than 18 Years of Age and Pregnant Women. ECF No. 1, ¶¶ 111–28. Within the next two months, Plaintiffs filed the First Amended Complaint (July 23, 2025), and the Second Amended Complaint (September 3, 2025), which both still challenged only the Secretarial Directive. ECF No. 63, ¶¶ 111–30; ECF No. 99, ¶¶ 118–37.

On November 5, 2025, Plaintiffs filed the operative Third Amended Complaint. ECF No. 139. The Third Amended Complaint challenges four actions: (1) the Secretarial Directive; (2) CDC's October 2025 shared clinical decision-making recommendation for the COVID-19 vaccine for children; (3) CDC's October 2025 shared clinical decision-making recommendation for the COVID-19 vaccine for adults; and (4) Secretary Kennedy's appointment of new Advisory Committee on Immunization Practices ("ACIP") members since June 2025. *See* ECF No. 139, ¶¶ 5–9, 108–26. Those claims are past the pleading stage, with the Court denying Defendants' motion to dismiss and setting a production schedule for the administrative records. *See* ECF Nos. 168, 182.

On January 19, 2026, Plaintiffs moved for leave to file a Fourth Amended Complaint. ECF No. 180. The proposed Fourth Amended Complaint still challenges (1) the Secretarial Directive, (2) the ACIP's September 2025 recommendations of shared clinical decision-making for pediatric and adult COVID-19 vaccines, which were adopted by CDC in October 2025, and (3) the Secretary's ACIP appointments. It then adds claims challenging unrelated recommendations, namely (4) the ACIP's June 2025 recommendation that manufacturers discontinue the use of thimerosal as a preservative in influenza vaccines, (5) the ACIP's December 2025 recommendation of shared clinical decision-making for the hepatitis B vaccine for certain infants, as well as (6) CDC's January 2026 changes to certain childhood and adolescent immunization recommendations, which did not change the shared clinical decision-making recommendation for COVID-19 vaccines. ECF No. 180-1, ¶¶ 146–83.

LEGAL STANDARD

After a plaintiff has amended its complaint once as a matter of right, it may file a further amended complaint "only with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). The Court "should freely give leave when justice so requires," *id.*, but that "does

not mean that leave will be granted in all cases," *Acosta-Mestre v. Hilton Int'l of Puerto Rico, Inc.*, 156 F.3d 49, 51 (1st Cir. 1998) (quoting 6 Wright *et al.*, Fed. Prac. & Proc. § 1487, at 611 (2d ed.1990)). Courts should consider "the totality of the circumstances" and may deny leave to amend when, for example, "the request is characterized by 'undue delay, bad faith, futility, [or] the absence of due diligence on the movant's part.'" *Nikitine v. Wilmington Tr. Co.*, 715 F.3d 388, 390 (1st Cir. 2013) (alteration in original) (quoting *Palmer v. Champion Mortg.*, 465 F.3d 24, 30 (1st Cir. 2006)). Courts may also deny leave to amend when allowing the amendment would cause "undue prejudice to the opposing party," *Acosta-Mestre*, 156 F.3d at 51, or run counter to "efficiency and case management" concerns, *Ryan v. Newark Grp., Inc.*, No. 4:22-CV-40089-MRG, 2024 WL 4815478, at *11 (D. Mass. Nov. 18, 2024) (quotations omitted), *reconsideration denied,* 349 F.R.D. 254 (D. Mass. 2025).

ARGUMENT

After an original complaint and three prior amendments, the interest of justice does not require—much less support—a *fifth* complaint in this case. Instead, the Court should deny leave to amend for three reasons.[1] *First*, by significantly expanding the scope of this case, the proposed amendment would correspondingly increase Defendants' administrative record obligations and delay adjudication of the merits—all to the prejudice of Defendants and sound judicial

[1] Although Plaintiffs' motion for leave does not invoke Rule 15(d)'s provision for supplemental pleadings, that arguably is the proper vehicle to add allegations about events post-dating the Third Amended Complaint. *See Connectu LLC v. Zuckerberg*, 522 F.3d 82, 90 (1st Cir. 2008) (distinguishing scenarios for amended and supplemental complaints). However, the considerations for a supplemental complaint under Rule 15(d) are analogous to those for an amended complaint under Rule 15(a): "prejudice to the opposing party," "futility of supplementation," and "unreasonable delay in attempting to supplement." *United States ex rel. Gadbois v. PharMerica Corp.*, 809 F.3d 1, 7 (1st Cir. 2015). Accordingly, a mislabeled motion "will ordinarily be recharacterized and addressed under the correct rubric." *Id.* at 7 n.3. Both rubrics lead to the same conclusion here: the proposed Fourth Amended Complaint is unduly delayed, futile, unduly prejudicial to Defendants, and a disservice to judicial economy.

administration. *Second*, the proposed amendment is futile because Plaintiffs lack standing to assert their new claims, and the newly challenged actions are not reviewable under the APA. *Finally*, Plaintiffs unduly delayed challenging the June 2025 ACIP vote, which they could have addressed in any prior iteration of the complaint.

I. The Proposed Amendment Would Unduly Prejudice Defendants and Delay the Final Resolution of this Case

The Court should deny leave to amend because the proposed amendment would cause "undue prejudice" to Defendants, *Acosta-Mestre*, 156 F.3d at 51, and disserve "efficiency and case management" concerns, *Ryan*, 2024 WL 4815478, at *11 (quotations omitted); *contra* ECF No. 180 at 8. The proposed Fourth Amended Complaint adds novel claims against three separate actions: the June 2025 ACIP recommendation about the use of thimerosal as a preservative in influenza vaccines, the December 2025 ACIP recommendation on the Hepatitis B vaccine, and the January 5, 2026, changes to the vaccine recommendation for rotavirus, influenza, meningococcal disease, hepatitis A, and hepatitis B, though not to the shared clinical decision-making recommendation for COVID-19 vaccines. *See* HHS, Fact Sheet: CDC Childhood Immunization Recommendations, https://perma.cc/B9TR-FFKQ (last reviewed Jan. 5, 2026). These new claims do not actually "arise[] out of the same factual allegations already pleaded in the Third Amended Complaint," ECF No. 180 at 8, which focused on the Secretarial Directive regarding the COVID-19 vaccine, CDC's COVID-19 vaccine recommendations, and the reconstitution of the ACIP. Each new claim in the proposed Fourth Amended Complaint has a distinct administrative record, the assembly and production of which significantly adds to Defendants' burden in this case and delays the date of a final, appealable judgment.

Because the proposed Fourth Amended Complaint "seeks to expand the scope and nature of the original litigation by bringing in . . . claims unrelated to earlier pleadings," it would

"unduly prejudic[e]" Defendants by requiring them to compile several additional administrative records and delay the Court's ability to adjudicate the merits. *Ryan*, 2024 WL 4815478, at *11; *see Gadbois*, 809 F.3d at 4 (leave to supplement complaint may be denied when it would "cause undue delay" or "prejudice the rights of any of the other parties" (quoting 6A Wright *et al.*, Fed. Prac. & Proc. § 1504, at 258–59 (3d ed.))).

And given the minimal overlap between the new and existing claims—challenging different actions with different records relating to different vaccines and involving different actors—it is patently inefficient to add these new claims to this litigation. "[W]hen the matters alleged in a supplemental pleading have no relation to the claim originally set forth and joinder will not promote judicial economy or the speedy disposition of the dispute between the parties, refusal to allow the [amended] pleading is entirely justified." *Thomas v. Spaulding*, No. 1:19-CV-11982-NMG, 2021 WL 3516474, at *5 (D. Mass. Aug. 10, 2021) (citing *Stow v. McGrath*, No. 17-088-LM, 2018 WL 1545701, at *3 (D.N.H. Mar. 2, 2018), *report and recommendation approved,* No. 17-CV-88-LM, 2018 WL 1542324 (D.N.H. Mar. 28, 2018); 6A Wright *et al.*, Fed. Prac. & Proc. § 1506 (3d ed. 2017)). These inefficiencies are already being felt. Because of all the new issues jammed into Plaintiffs' motion for a preliminary injunction, the Court had to bifurcate consideration of the motion into two separate rounds of briefing, hearings, and rulings. Merits briefing for the proposed Fourth Amended Complaint likely would require separate tracks as well. *See EMW Women's Surgical Ctr., P.S.C. v. Sec'y of Kentucky's Cabinet for Health & Fam. Servs.*, No. 3:19-CV-178-DJH-RSE, 2022 WL 2824661, at *2 (W.D. Ky. Apr. 22, 2022) (denying motion to supplement where supplementation would "split this case into three tracks").

In weighing whether to permit this amendment, the Court should not ignore Plaintiffs' admission that they will not stop at a Fourth Amended Complaint. "[F]rom the beginning,"

Plaintiffs have intended to keep amending because "the facts were going to develop every day and there might be new actions that need to be challenged." Jan. 12, 2026, Status Conference Tr. 31:4–7. In other words, this case will continue to metastasize as Plaintiffs try to thwart any change in federal vaccine policy. But Plaintiffs cannot keep "subject[ing] defendants to a moving target of litigation" and "bombard[ing] the [c]ourt" with amendment after amendment. *Thomas*, 2021 WL 3516474, at *5 (citations modified) (quoting *Negron v. Turco*, 253 F. Supp. 3d 361, 363 (D. Mass. 2017)). Both Defendants and the Court must have certainty about the scope of the case and the endpoint for resolution.

The procedural solution is simple: Plaintiffs should bring any new claims in a "separate action." *Thomas*, 2021 WL 3516474, at *6 (quoting *Gadbois*, 809 F.3d at 4). Indeed, Plaintiffs concede that they "could in the alternative file a new complaint." ECF No. 180 at 8.[2] As "First Circuit case law" recognizes, "the possibility that plaintiffs may file a 'new, virtually-identical' suit" asserting their new claims "is not a sufficient reason" to grant leave to amend. *Nat'l Fed'n of the Blind v. Container Store*, No. CV 15-12984-NMG, 2020 WL 533022, at *5 (D. Mass. Feb. 3, 2020) (citing cases). That makes sense. Challenges to separate actions with separate records are best resolved in separate lawsuits, each yielding a final, appealable judgment. That is "[t]he proper way to bring new claims" about "the way the [Government] conducts its business," especially when there is "an ever-evolving situation." *Solomon v. Blinken*, No. 2:23-cv-00219-NT, 2024 WL 127019, at *5 (D. Me. Jan. 11, 2024).

Defendants demonstrated good faith by not opposing Plaintiffs' three prior amendments

[2] Plaintiffs are wrong to presume a new case would be properly designated as "related." Under Local Rule 40.1(g)(3), "[c]ivil cases, even when they involve some or all of the same parties, shall not be deemed related to each other solely on the ground that they: (A) involve the same or substantially similar challenges to a law, regulation, or government policy or practice; or (B) otherwise involve a common question of law."

to the complaint. *See Nikitine*, 715 F.3d at 390 (considering whether the plaintiff "had a prior opportunity to amend"). However, Defendants cannot allow the continued abuse of their good faith. The Court should close the pleadings and adjudicate this case as pleaded.

II. The Proposed Amendment Is Futile

"[A] district court may properly deny a motion for leave to amend where the moving party's amendments would be futile, i.e. the amended complaint would not withstand a [Rule 12(b)(1) or] Rule 12(b)(6) motion." *Ryan*, 2024 WL 4815478, at *12 (citing *Efron v. UBS Fin. Servs. Inc. of P.R.*, 96 F.4th 430, 437 (1st Cir. 2024)). The new claims asserted in the proposed Fourth Amended Complaint are futile. Plaintiffs lack standing to assert the new claims. And the newly challenged actions are unreviewable under the APA because they are committed to agency discretion by law and are not final agency action.

A. Plaintiffs Lack Standing to Assert Their New Claims

Article III standing is a core jurisdictional requirement that "prevents the federal courts from becoming a vehicle for the vindication of the value interests of concerned bystanders." *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024) (quotation omitted). Plaintiffs must show they have "(1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016), *as revised* (May 24, 2016).

Plaintiffs do not even attempt to allege that the June 2025 ACIP recommendation injured them. At most, the proposed Fourth Amended Complaint alleges generally that Plaintiffs were injured by the asserted "final agency actions challenged herein," then focuses "particularly [on] the December 5 ACIP vote on the hepatitis B vaccine and the January 5 changes to the Childhood Schedule." ECF No. 180-1, ¶ 105. That is insufficient. Plaintiffs must show a cognizable injury traceable to each "challenged action." *Lujan v. Defs. of Wildlife*, 504 U.S. 555,

560–61 (1992). 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). Because a generic allegation of harm from allegedly "final agency actions challenged herein," ECF No. 180-1, ¶ 105, does not show that the June 2025 ACIP recommendation, in particular, injured Plaintiffs, they lack standing to press that claim, *see Hochendoner v. Genzyme Corp.*, 823 F.3d 724, 733 (1st Cir. 2016) (assessing standing "claim-by-claim").

As for the December 2025 ACIP recommendation and January 2026 action, Plaintiffs reprise the standing theories in the Third Amended Complaint. For example, Plaintiffs allege they have diverted resources away from their normal operations to respond to the December and January actions. *E.g.*, ECF No. 180-1, ¶ 105. As Defendants explained in their motion to dismiss the Third Amended Complaint, these theories fail to show standing. ECF No. 145, at 9–18; ECF No. 154, at 3–9. Although the Court denied the motion to dismiss, Defendants respectfully maintain that under binding precedent Plaintiffs lack standing. Defendants' argument is fully set forth in our contemporaneously filed opposition to Plaintiffs' preliminary injunction motion.

B. The Newly Challenged Immunization Recommendations Are Unreviewable Under the APA Because They Were Committed to Agency Discretion by Law and Were Not Final Agency Action

Defendants' opposition to Plaintiffs' preliminary injunction motion explains that the January 2026 action is unreviewable under the APA because it was (1) committed to agency discretion by law, and (2) not final agency action. The other actions challenged for the first time in the proposed Fourth Amended Complaint—Defendants' recommendations regarding the use of thimerosal as a preservative in influenza vaccines and regarding the Hepatitis B vaccine—are unreviewable for the same reasons.

Like the January 2026 action, the other newly challenged recommendations are

"committed to agency discretion by law," 5 U.S.C. § 701(a)(2), because "a court would have no meaningful standard against which to judge the agency's exercise of discretion" in issuing immunization recommendations. *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 17 (1st Cir. 2020) (quotations omitted). The other newly challenged recommendations are also not "final agency action," 5 U.S.C. § 704, because, like the January 6 action, they are not actions "by which 'rights or obligations have been determined,' or from which 'legal consequences will flow,'" *Bennett v. Spear*, 520 U.S. 154, 178 (1997).

III. Plaintiffs Unduly Delayed Challenging the June 2025 ACIP Recommendation

"[U]ndue delay, on its own, may be enough to justify denying a motion for leave to amend." *Nat'l Fed'n of the Blind*, 2020 WL 533022, at *3 (alteration in original) (quoting *Hagerty ex rel. United States v. Cyberonics, Inc.*, 844 F.3d 26, 34 (1st Cir. 2016)); *see Nikitine*, 715 F.3d at 390. "As a case progresses, and the issues are joined, the burden on a [moving party] seeking to amend a complaint becomes more exacting." *Ryan*, 2024 WL 4815478, at *11 (alteration in original) (quoting *Steir v. Girl Scouts of the USA*, 383 F.3d 7, 12 (1st Cir. 2004)). And "the longer a plaintiff delays, the more likely the motion to amend will be denied, as protracted delay, with its attendant burdens on the opponent and the court, is itself a sufficient reason for the court to withhold permission to amend." *Steir*, 383 F.3d at 12 (citing *Acosta–Mestre,* 156 F.3d at 52–53).

Considering what Plaintiffs "knew or should have known and what [they] did or should have done," Plaintiffs unduly delayed challenging the June 2025 ACIP recommendation on thimerosal. *Ryan*, 2024 WL 4815478, at *11 (quoting *Leonard v. Parry*, 219 F.3d 25, 30 (1st Cir. 2000)). They did not challenge this action "promptly after" it occurred or "at their earliest opportunity." ECF No. 180 at 7. The June 2025 ACIP vote occurred before Plaintiffs filed their original complaint on July 7, 2025, and HHS adopted the ACIP's recommendation on thimerosal

on July 23, 2025,[3] ECF No. 180-1, ¶ 170, before Plaintiffs filed their Second Amended Complaint on September 3, 2025. Thus, "[t]his is not an instance in which newly discovered evidence, not previously available, suddenly came to light; the plaintiff[s] [were] aware of the factual predicate" for their challenge to the June 2025 vote "before [they] brought suit," or at the latest before they filed their Second Amended Complaint. *Palmer*, 465 F.3d at 31 (affirming denial of leave to amend). Plaintiffs simply "have not demonstrated due diligence" by explaining why they did not previously challenge the June 2025 vote. *Ryan*, 2024 WL 4815478, at *14 (quotations omitted) (denying plaintiffs' motion for leave to file amended complaint).

Instead, Plaintiffs waited until January 19, 2026—over six months after filing their original complaint and over four months after filing their Second Amended Complaint—to seek to challenge the June 2025 vote. Plaintiffs' delay exceeds the delays of "four months, and even less than three months," that the First Circuit has found to be undue delay warranting denial of a motion for leave to amend. *Ryan*, 2024 WL 4815478, at *11 (citing *Villanueva v. United States*, 662 F.3d 124, 127 (1st Cir. 2011); *Kay v. N.H. Democratic Party*, 821 F.2d 31, 34 (1st Cir. 1987) (per curiam)); *see Nikitine*, 715 F.3d at 390. When such "a considerable period of time has passed between the filing of the complaint and the motion to amend, courts have placed the burden upon the movant to show some valid reason for his neglect and delay." *Nikitine*, 715 F.3d at 390–91 (quotations omitted) (affirming denial of leave to amend). Yet Plaintiffs do not even attempt to meet this burden, which suffices to deny leave to amend. *See Nat'l Fed'n of the Blind*, 2020 WL 533022, at *3 (citing *Hagerty*, 844 F.3d at 34).

Denying leave to amend because of undue delay is "especially" appropriate here because

[3] The HHS website announced this action the same day. *See* HHS, *HHS Adopts ACIP Recommendation to Remove Thimerosal from All U.S. Influenza Vaccines*, https://perma.cc/YXA6-78CH (July 23, 2025).

"allowing the amendment will cause further delay in the proceedings." *Acosta-Mestre*, 156 F.3d at 52. Adding a challenge to the ACIP's recommendation on thimerosal would require Defendants to compile a separate administrative record on top of the multiple other administrative records Defendants already must produce in this case. That will undoubtedly delay the Court's adjudication of the merits and issuance of an appealable final judgment. Thus, Plaintiffs should not be permitted to inject the June 2025 ACIP recommendation into this case.

CONCLUSION

For these reasons, the Court should deny Plaintiffs' motion for leave to file the proposed Fourth Amended Complaint.

February 9, 2026

Respectfully submitted,

/s/ Isaac C. Belfer
ISAAC C. BELFER (D.C. Bar No. 1014909)
Trial Attorney
Federal Programs Branch
Civil Division
U.S. Department of Justice
1100 L Street, NW
Washington, DC 20005
(202) 305-7134
(202) 514-8742 (fax)
Isaac.C.Belfer@usdoj.gov

Counsel for Defendants

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 9, 2026

/s/ Isaac C. Belfer
Isaac C. Belfer