

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF PEDIATRICS,
AMERICAN COLLEGE OF PHYSICIANS,
INC., AMERICAN PUBLIC HEALTH
ASSOCIATION, INFECTIOUS DISEASES
SOCIETY OF AMERICA, MASSACHUSETTS
PUBLIC HEALTH ASSOCIATION D/B/A
MASSACHUSETTS PUBLIC HEALTH
ALLIANCE, SOCIETY FOR MATERNAL-
FETAL MEDICINE, THE MASSACHUSETTS
CHAPTER OF THE AMERICAN ACADEMY
OF PEDIATRICS, JANE DOE 1, JANE DOE 2,
and JANE DOE 3,

Plaintiffs,

vs.

ROBERT F. KENNEDY, JR., in his official
capacity as Secretary of the Department of Health
and Human Services; UNITED STATES
DEPARTMENT OF HEALTH AND HUMAN
SERVICES; JIM O'NEILL, in his official capacity
as Acting Director of Centers for Disease Control
and Prevention; CENTERS FOR DISEASE
CONTROL AND PREVENTION; and DOES 1–
50, inclusive,

Defendants.

Case No. 1:25-cv-11916-BEM

PLAINTIFFS' MOTION FOR LEAVE TO FILE A FOURTH AMENDED COMPLAINT

Plaintiffs move for leave to file a Fourth Amended Complaint pursuant to Fed. R. Civ. P. 15(a)(2) to address new final agency actions and related conduct taken by Defendants since Plaintiffs' filing of the Third Amended Complaint. On January 5, 2026, two weeks to the day of this request, Defendants arbitrarily—and illegally—revised the existing childhood and adolescent immunization schedule through a “Decision Memorandum” to downgrade six different vaccines

without following the evidentiary-driven, and legally required processes for issuing recommended vaccine schedules in the United States. This drastic overhaul of the childhood vaccine schedule is but one in a series of arbitrary and harmful actions taken by the Defendants since Plaintiffs filed the Third Amended Complaint alleging Defendants violated the Administrative Procedures Act through a series of unlawful agency actions. Recent developments necessitate further amendment to allegations in the Third Amended Complaint.

The Court should exercise its discretion to permit Plaintiffs to file the Fourth Amended Complaint attached as Exhibit 1.

Background

On July 7, 2025, Plaintiffs filed the instant action challenging Defendants' unlawful administrative actions (ECF No. 1). As described below, Defendants' harmful and unlawful conduct upending both the process and recommended childhood and adolescent vaccine schedules in the United States has continued uninterrupted by Plaintiffs' filing this action on July 7, 2025. As they have in this motion, Plaintiffs have thrice amended their claims to incorporate new allegations capturing Defendants' latest violative actions, which have consistently and directly harmed Plaintiffs and the public health and welfare at large.

On May 27, 2025, the Secretary posted a video on the social media platform X in which he ordered the CDC to remove the recommendation of the Covid-19 vaccine for pregnant women and "healthy" children from CDC schedules. That same day, the Secretary released a one-page "SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN," backdated May 19, 2025 (the "Directive") repeating the instruction to the CDC that he gave in the video. On June 9, 2025, the Secretary fired all seventeen members of the ACIP for pretextual reasons. Two days after the terminations, on June 11, 2025, the Secretary announced the appointment of eight new members

to the ACIP. The first ACIP meeting with the new members was held on June 25–26, 2025. On July 7, 2025, Plaintiffs filed this lawsuit challenging the Directive and reconstitution of the ACIP (ECF No. 1) and later amended this Complaint as a matter of course under FED. R. CIV. P. 15(a)(1), on July 23, 2025 (ECF No. 63).

On July 31, 2025, an email from acip.cdc.gov was sent to members of ACIP Liaison organizations, which included members of Plaintiffs AAP and ACP, informing them that Liaison organizations were terminated from participating in ACIP workgroups, including the Covid-19 Work Group. On August 20, 2025, Plaintiffs filed a Motion for Leave to File a Second Amended Complaint to reflect the July changes to the ACIP workgroup membership (ECF No. 94). This Motion was allowed on September 3, 2025 (ECF No. 96), and Plaintiffs' Second Amended Complaint was filed that same day (ECF No. 99). Also on September 3, 2025, Defendants filed their Motion to Dismiss for Lack of Jurisdiction (ECF No. 103).

On September 11, 2025, the Secretary announced four more appointments to the ACIP, citing pretextual reasons for the appointments. On September 18–19, 2025, an ACIP meeting was held, and the improperly reconstituted ACIP voted to change the Covid-19 vaccine recommendation for adults from routine to SCDM without applying GRADE criteria or following the EtR framework. This vote codified the May 19 Secretarial Directive without following the standard ACIP policy. Plaintiffs filed their Opposition to Defendants' Motion to Dismiss on September 24, 2025 (ECF No. 118) and the hearing on the Motion to Dismiss was scheduled for October 8, 2025 (ECF No. 113).

On September 30, 2025, the eve of the government shut down, the Court cancelled the hearing on the Motion to Dismiss and the Bench Trial scheduled for October 14, 2025, with the intention of rescheduling them at a later date (ECF No. 119). Defendants filed a Motion for a Stay

on October 1, 2025 (ECF No. 121). Considering the government shut down, Plaintiffs agreed not to oppose the stay. On October 20, 2025, twenty days after Plaintiffs agreed to stay this Matter, the government was still shut down with no indication of when services would resume. With the flu season beginning and Covid-19 cases rising, Plaintiffs filed a Motion to Continue this Case (ECF No. 127). On October 22, this Case was assigned to Your Honor (ECF No. 129). Defendants filed their opposition to Plaintiffs' Motion to Continue on October 29, 2025 (ECF No. 133), and a hearing was held on October 30, 2025 (ECF No. 134).

At the October 30 hearing, the Court ordered the stay lifted in this case and for litigation to continue (ECF No. 134). The Court granted Plaintiffs leave to amend the Second Amended Complaint to include all harms occurring since that Complaint was filed August 2025. Plaintiffs and Defendants agreed on a schedule going forward, requiring the Motion to Dismiss and associated hearing to occur in short order (ECF No. 134).

On November 5, 2025, Plaintiffs filed the Third Amended Complaint with this Court, addressing the harms arising out of the September ACIP appointments and the Covid-19 recommendation change adopted at the September ACIP meeting. On November 19, 2025, Defendants filed their Motion to Dismiss the Third Amended Complaint for Lack of Jurisdiction and Failure to State a Claim (ECF No. 144). Plaintiffs filed their opposition to this motion on December 3, 2025 (ECF No. 146).

On December 4–5, 2025, an ACIP meeting was held, at which the committee voted to change the schedule of the Hepatitis B vaccine and presented the idea of aligning the U.S. Child and Adolescent Immunization Schedule (the “Childhood Schedule”) with Denmark’s childhood vaccine schedule. The hearing on the Motion to Dismiss was held on December 17, 2025 (ECF No. 164). The Court took the matter under advisement (ECF No. 164). The following day, on

December 18, 2025, CDC experts presented a slide deck on how the Childhood Schedule compares to other developed countries and indicated that an announcement on children's vaccine health would come after January 1, 2026.

On January 5, 2026, the Department of Health and Human Services issued a press release titled "CDC Acts on Presidential Memorandum to Update Childhood Immunization Schedule," which announced that the Childhood Schedule was changing to align with Denmark's childhood vaccine schedule, effective immediately. One day later, on January 6, 2026, Your Honor denied Defendants' Motion to Dismiss (ECF No. 168). On January 13, 2026, HHS and CDC announced the appointment of two more members to the ACIP.

The actions of the Defendants taken throughout this litigation have caused an abundance of harm and created a moving target. The enumerated actions above are escalations of the allegations already pleaded by Plaintiffs in the operative complaints not yet known or come to fruition at the time of Plaintiffs' earlier amendments.

Plaintiffs have been transparent with Defendants and the Court of their intentions to challenge Defendants' recent conduct. Just two days after the CDC issued the January 5 Decision Memo, Plaintiffs' counsel informed counsel for Defendants that Plaintiffs intended to seek leave to file a Fourth Amended Complaint (and injunctive relief) to address the January 5 Decision Memo and preceding actions of Defendants, including the dissemination of inaccurate information at the December 4–5, 2025 ACIP meeting. Through the parties' Joint Status Report (ECF No. 175) and at the status conference held on January 12, 2026, Plaintiffs previewed for the Court their plan to move for leave to amend and presented an agreed-upon briefing schedule to specifically accommodate Plaintiffs' motion for leave and motions for injunctive relief. The Court entered an Order adopting the parties' proposed schedule and set a deadline of January 19, 2026, for this

motion for leave (ECF No. 176).¹ On January 18, 2026, counsel for Plaintiffs sent a draft of the Fourth Amended Complaint to counsel for Defendants for their review. Defendants oppose the filing of a Fourth Amended Complaint.

Argument

Leave to amend is appropriate in this instance. Rule 15(a) embraces a “liberal amendment policy” under which “[t]he court should freely give leave when justice so requires.” FED. R. CIV. P. 15(a)(2). District Courts have “significant latitude in deciding whether to grant leave to amend.” *U.S. ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 48 (1st Cir. 2009). Indeed, “[l]eave should be freely given absent an apparent or declared reason, such as undue delay, bad faith or dilatory motive on the part of the movant”. *Lukas v. United States*, 133 F.Supp.3d 284, 286 (D. Mass. 2015) (citation modified). The analysis whether to grant leave to amend, even for complaints that have already been amended, is case specific. *See Gusakovs v. Johnson & Johnson*, No. 17-cv-11502-DJC, 2023 WL 4053059, at *5 (D. Mass. June 16, 2023) (“There is no delay that is *per se* undue and a district court mulling a motion to amend in a particular case must consider any alleged delay with that case’s specific history in mind.” (citation modified)).

Far from futile, Plaintiffs move to amend and incorporate recent agency actions, such as the January 5 Decision Memo, which drastically expand the scope of injuries and harm to Plaintiffs of downgrading the childhood and adolescent recommendations for one vaccine (Covid-19) to the consequences of downgrading *six different* vaccines.² Plaintiffs’ amendments also include other recent public actions and statements by the Defendants taken in conjunction with this upending of

¹ On January 12, 2026, the Court ordered Plaintiffs file a motion for leave to file the Fourth Amended Complaint by January 19, 2026; Plaintiffs’ motion(s) for preliminary junctive relief by January 26, 2026; and, Defendants’ response to that motion and any subsequently filed motions, due by February 9, 2026.

² This Court held that Plaintiffs have standing to pursue to the claims set forth in the Third Amended Complaint, which allege Defendants violated the APA. ECF No. 168.

the vaccine schedule and spreading misinformation about vaccine efficacy and safety, including through the December 4–5, 2025 ACIP meeting and other forums. Plaintiffs respectfully submit that justice requires that they can challenge this conduct and litigate these evolving issues in good faith.

Plaintiffs’ request is timely. Plaintiffs bring this motion at their earliest opportunity, providing notice to the Defendants of the intention to seek leave just two days after the most recent—and egregious—of the challenged action. Defendants issued the January 5 Decision Memo just two weeks ago. *See Amyndas Pharms, S.A. v. Zealand Pharma A/S*, 48 F.4th 18, 37 (1st Cir. 2022) (explaining that “[a]scertaining whether a delay is ‘undue’ is not simply a matter of counting days but, rather, depends on the totality of the circumstances in the particular case” (citation modified)). Unlike Defendants, Plaintiffs were unaware of these actions prior to the public announcement. Plaintiffs learned of the statements made in support of the now-implemented, sweeping changes proposed to the Childhood Schedule along with the general public, in December 2025. Those misstatements and sham meetings have now culminated in the January 5 December Memo. The fact that Plaintiffs have thrice amended their complaint only illustrates that the Defendants harm-inducing actions have continued unabated. Plaintiffs have met their burden of showing a valid reason to amend at this juncture in spades. *See Hagerty ex rel United States v. Cyberonics*, 844 F.3d 26, 34 (1st Cir. 2016) (explaining that “[i]n assessing whether a movant has carried this burden, courts must take into account what the plaintiff knew or should have known and what he did or should have done.” (citation modified)).

Importantly, granting leave will not unduly prejudice Defendants. Plaintiffs bring this motion promptly after the final agency actions they seek to incorporate and challenge. Amending the complaint allows Plaintiffs to respond to Defendants’ latest in its longstanding pattern of

unlawful agency actions and provides a basis to seek immediate injunctive relief. Defendants have long been on notice of Plaintiffs' allegations challenging the Defendants' failure to comply with the APA, including well-before Defendants ratified the January 5 Decision Memo, once again side-stepping the required administrative procedures for issuing vaccine recommendations. Presumably, then, Defendants were aware of the basis for this amendment well before Plaintiffs learned of events. *See Meador v. United States*, No. 22-cv-40024-DJC, 2024 WL 583687 (D. Mass. Feb. 13, 2024) (finding no undue prejudice where defendants had notice of claims at or before the time plaintiffs became aware of them).

Finally, the impact of the January 5 Decision Memo to Plaintiffs and the public at large cannot be overstated. Where this action arises out of the same factual allegations already pleaded in the Third Amended Complaint, Plaintiffs seek leave to amend the operative complaint to move efficiently and expeditiously to adjudicate their claims. While Plaintiffs could in the alternative file a new complaint as a related case, this Circuit favors granting leave to amend to promote judicial economy. *See United States v. Medtronic, Inc.*, 189 F.Supp.3d 259, 266–67 (D. Mass. 2016) (noting judicial economy is an important factor in the balance of pertinent considerations when deciding whether to allow an amended complaint).

Dated: January 19, 2026

Respectfully submitted,

By: /s/ James Oh

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Attorneys for Plaintiffs

**LOCAL RULE 7.1 CERTIFICATE REGARDING PLAINTIFFS' MOTION FOR LEAVE
TO FILE THEIR FOURTH AMENDED COMPLAINT**

Per Local Rule 7.1, counsel for Plaintiffs state that they conferred with counsel for Defendants via e-mail on January 19, 2026. In that conversation, counsel for Defendants stated that Defendants oppose Plaintiffs' Motion for Leave to File a Fourth Amended Complaint.

/s/ James J. Oh

James J. Oh

CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 19th day of January 2026:

Robert F. Kennedy, Jr., in his official capacity as Secretary of Health and Human Services	Jim O’Neill, in his official capacity as Acting Director of the Centers for Disease Control and Prevention
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/s/ James J. Oh

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