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 **JOINT STATUS REPORT REGARDING THE ADMINISTRATIVE RECORD**

Defendants' Position

The currently operative complaint—Plaintiffs' Third Amended Complaint—challenges four distinct actions: the May 2025 Secretarial Directive on Pediatric COVID-19 Vaccines for

Children less than 18 Years of Age and Pregnant Women (the "Secretarial Directive")[1]; the Centers for Disease Control and Prevention's ("CDC") October 2025 shared clinical decision-making recommendation for the COVID-19 vaccine for children; CDC's October 2025 shared clinical decision-making recommendation for the COVID-19 vaccine for adults; and the reconstitution of the Advisory Committee on Immunization Practices ("ACIP"). *See* ECF No. 139, ¶¶ 5–9, 108–26. Each of these actions has its own administrative record ("AR"). Defendants can produce each AR on the following schedule:

1. May 2025 Secretarial Directive on March 12, 2026 (i.e., within 50 days);
2. CDC's October 2025 shared clinical decision-making recommendations for the COVID-19 vaccine for children and adults, adopting ACIP's September 19, 2025, recommendations on the COVID-19 vaccine, on March 23, 2026 (i.e., within 61 days, given that the 60-day mark falls on a Sunday);
3. Secretary Kennedy's reconstitution of ACIP[2] on April 21, 2026 (i.e., within 90 days).

The proposed staggered schedule reflects differences in the complexity of compiling the ARs, and the demands of compiling multiple records upon limited agency resources. In particular, compilation of the AR for the reconstitution of ACIP is a significant undertaking. Agency counsel are collecting records from multiple offices within CDC and other components of the Department of Health and Human Services ("HHS"). *See* ECF No. 140 at 2. Employees of those offices will

[1] Defendants explained why any challenge to the Secretarial Directive is moot. ECF No. 145 at 8–9. However, the Court found that Defendants did not show mootness for purposes of their Rule 12(b)(1) motion, ECF No. 168 at 18–19, so Defendants will produce the administrative record for the Secretarial Directive.

[2] Specifically, Secretary Kennedy's removal of the then-serving ACIP members in June 2025 and appointment of new ACIP members between June 2025 and January 2026.

need to take time away from their existing full-time responsibilities to assist with compiling the record. In addition to identifying and interviewing custodians and collecting documents, agency counsel will conduct searches of electronic files to ensure that the compiled record is complete. And once materials have been collected, agency counsel will need to conduct a privilege review, given the involvement of HHS's Office of the General Counsel in the reconstitution of the ACIP.

Plaintiffs' proposed Fourth Amended Complaint challenges three additional and unrelated actions—seven actions challenged in total: ACIP's June 26, 2025, recommendation on thimerosal, ECF No. 180-1, ¶¶ 169–76; ACIP's December 5, 2025, recommendation on the Hepatitis B vaccine, *see id.*; and CDC's adoption of a revised childhood and adolescent immunization schedule on January 5, 2026, *see id.*, ¶¶ 146–55. In their forthcoming opposition to Plaintiffs' motion for leave to file a Fourth Amended Complaint, Defendants may explain why ACIP's June 26, 2025, and December 5, 2025, recommendations are not final agency actions and do not have an administrative record under the Administrative Procedure Act. Moreover, each newly challenged action has a distinct record for which Defendants are still in the early stages of identifying the scope.

Nonetheless, if the Court grants Plaintiffs leave to file the Fourth Amended Complaint, Defendants estimate they can produce the AR for the January 5 action by June 5, 2026 (i.e., within 135 days). As with the AR for the reconstitution of the ACIP, Defendants expect that compilation of the AR for the January 5 action will be a significant undertaking. Agency counsel may need to collect records from multiple components within HHS, such as CDC, the Food and Drug Administration, the Centers for Medicare and Medicaid Services, and the National Institutes of Health. Additionally, employees will need to take time away from their existing full-time

responsibilities to assist with compiling the record, and agency counsel will need to conduct a privilege review.

Defendants did not learn that Plaintiffs also want to challenge ACIP's June 26, 2025, recommendation on thimerosal and December 5, 2025, recommendation on the Hepatitis B vaccine until receiving a draft of the proposed Fourth Amended Complaint on January 19, 2026, when government offices were closed for Martin Luther King Jr. Day. Defendants could only start inquiring into the scope of the records for these actions (to the extent they have records, as discussed above) on January 20. Thus, Defendants are unable to provide a production estimate (and, again, Defendants would produce records for these actions only if the Court grants leave to add these new claims to the case, which Defendants oppose).

Plaintiffs' Position

At the January 12, 2026, status hearing, the Court stated: "I would think 60 days would be more than enough to produce the administrative record." (Tr. 28:18-19). Plaintiffs appreciate that Defendants now agree to the concept of a staggered production of the Administrative Record ("AR") as Plaintiffs had suggested at the January 12 hearing (Tr. 24:6-7) and in their Reply to Defendants' November 12 Status Report (ECF # 142, p. 15).

With regard to Defendants' statements on when they would produce the AR on the final agency actions challenged in the Third Amended Complaint and in the Fourth Amended Complaint (if Plaintiffs are granted leave to file it), Plaintiffs state as follows:

Defendants' Position	**Plaintiffs' Position**
May 2025 Secretarial Directive on March 12, 2026 (i.e., within 50 days)	No objection
CDC's October 2025 shared clinical decision-making recommendations for the COVID-19 vaccine for children and adults, adopting ACIP's September 19,	No objection

2025, recommendations on the COVID-19 vaccine, on March 23, 2026 (i.e., within 61 days, given that the 60-day mark falls on a Sunday)	
Secretary Kennedy's reconstitution of ACIP on April 21, 2026 (i.e., within 90 days), specifically, Secretary Kennedy's removal of the then-serving ACIP members in June 2025 and appointment of new ACIP members between June 2025 and January 2026.	Objection. Plaintiffs believe that the AR on this final agency action should also be produced on **March 23, 2026**. Plaintiffs filed the Third Amended Complaint on November 5, 2025, 77 days ago. March 23 is another 61 days from today and is 137 days after Defendants received notice of this claim. Further, as noted in Plaintiffs' Reply to Defendants' November 12 Status Report on the AR, the ACIP's Executive Secretary or Designated Federal Official is responsible for administration of the ACIP and is required by the ACIP Charter to "ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives." (ECF # 142, p.13). Further, the CDC Executive Secretariat is responsible for "[m]aintaining official agency records of the CDC Director's decisions and correspondence." Plaintiffs believe that collecting and producing the AR on this claim is not as cumbersome as Defendants represent because there are two central locations for where the records on appointments to the ACIP have traditionally been housed.
The January 5, 2026 action changing the CDC's Childhood Schedule: Defendants estimate they can produce the AR for the January 5 action by June 5, 2026 (i.e., within 135 days).	Objection. As stated at the January 12, 2026, status hearing, the AR on this claim could cover a relatively discrete window of time, *i.e.*, from the December 5, 2025, Presidential Memoranda to the January 5, 2026 announcement. (Tr. 13:13-24). Further, the document constituting this final agency action, Defendant O'Neill's January 5, 2026, Decision Memo, identifies only two documents upon which he based his decision to change the CDC's Childhood Schedule. Accordingly, this AR could be thin and, therefore, should be easy to collect and produce. Defendants should be ordered to produce the AR on this action by **March 23, 2026**.
The ACIP's December 5, 2025, vote to remove the recommendation that babies receive the hepatitis B vaccine at birth: Defendants state that they cannot provide an estimate at this time	Plaintiffs' position is that Defendants should produce the AR on this action within **60 days** of the Court's ruling on the motion for leave to file the Fourth Amended Complaint, should it be granted.

of when they could produce the AR on this final agency action.	
The ACIP's vote on thimerosal on June 26, 2025: Defendants state that they cannot provide an estimate at this time of when they could produce the AR on this final agency action.	Plaintiffs' position is that Defendants should produce the AR on this action within **60 days** of the Court's ruling on the motion for leave to file the Fourth Amended Complaint, should it be granted.

Respectfully submitted,

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Dated: January 21, 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.

January 21, 2026

/s/ Isaac C. Belfer
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