

**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' Status Report Regarding the Administrative Record

As the Court ordered during the October 30, 2025, Motion Hearing, ECF No. 134, Defendants respectfully submit this status report regarding compilation of the administrative record.

The Third Amended Complaint, filed on November 5, 2025, challenges three actions that Plaintiffs did not previously challenge. ECF No. 139. Whereas the Second Amended Complaint challenged only the May 27, 2025, Secretarial Directive on Pediatric COVID-19 Vaccines for Children less than 18 Years of Age and Pregnant Women, ECF No. 99, ¶¶ 118–37, the Third Amended Complaint challenges (1) the current recommendation in the Centers for Disease Control and Prevention's ("CDC") immunization schedules that children receive the COVID-19 vaccines through shared clinical decision-making, (2) the current recommendation in CDC's immunization schedules that adults receive the COVID-19 vaccines through shared clinical decision-making, and (3) Secretary Kennedy's removal of the then-serving members of the Advisory Committee on Immunization Practices ("ACIP") in June 2025 and appointment of new ACIP members, ECF No. 139, ¶¶ 5–9, 108–26.

Defendants have not begun compiling the administrative record for these three newly challenged actions. Given the continuing lapse in appropriations, they are not permitted to do so. Moreover, the lapse in appropriations and associated furloughs have prevented Defendants from having the internal discussions that would be necessary to understand the full scope of the administrative record and generate a timeline for compiling the record. Nonetheless, based on what Defendants know now, it is clear that compiling the record will require significant work.

The three newly challenged actions involved multiple HHS agencies and offices. Although the process of identifying potential custodians is ongoing, agency counsel has already determined that they will need to consult with the following sub-agencies and offices to compile the entire record:

- CDC, Immediate Office of the Director;
- CDC, National Center for Immunization and Respiratory Diseases;
- CDC, Office of Strategic Business Initiatives;
- HHS Immediate Office of the Secretary;
- HHS Office of the General Counsel, including the Immediate Office, the CDC branch, and the Ethics Division; and
- The Food and Drug Administration.

Record materials may need to be collected by conducting searches of email and other electronic information repositories. And if the lapse in appropriations continues, contacting potential record custodians will be difficult, as many individuals in these sub-agencies and offices are on furlough status. Some individuals may be recalled to assist with compiling the record, but that process takes time and requires approval.

Once the record items are identified and collected, agency counsel will need to conduct a privilege review. Especially given the involvement of the Office of the General Counsel in the challenged actions, the initial collection will likely capture information that is protected by the attorney-client privilege and/or the deliberative process privilege.

It would be inappropriate to require Defendants to expend the significant time and effort necessary to compile the administrative record before the Court resolves Defendants' forthcoming motion to dismiss. The administrative record will not be necessary to resolve Defendants' motion, and if the Court grants the motion in full, that will obviate the need for an administrative record altogether. Moreover, if the Court agrees with Defendants that Plaintiffs lack standing to assert any of their claims, then the Court would lack jurisdiction to take action beyond dismissing the complaint, including ordering the production of an administrative record. *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998). If the Court grants Defendants' motion in part, that may narrow the scope of the record by determining which of Plaintiffs' claims are properly before the Court. Thus, Defendants should not be required to compile the administrative record before the Court resolves their forthcoming motion to dismiss.

Plaintiffs have suggested that Defendants could produce the portion of the administrative record relating to the Secretarial Directive now. The Third Amended Complaint is ambiguous about whether it challenges the Secretarial Directive. But even if it does, that claim should be dismissed as moot. As Defendants will explain in their forthcoming motion to dismiss, the Secretarial Directive no longer has any effect on the CDC immunization schedules and cannot cause any future harm to Plaintiffs because it has effectively been overtaken by subsequent ACIP recommendations that were adopted by CDC. *See Already, LLC v. Nike, Inc.*, 568 U.S. 85, 91 (2013); *see also FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 381 (2024). Accordingly, unless and until the Court confirms its own jurisdiction and identifies which claims are properly before the Court, it should not require Defendants to compile and produce even those parts of the record related to the Secretarial Directive.

November 12, 2025

Respectfully submitted,

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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.

November 12, 2025

/s/ Isaac C. Belfer
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