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

PLAINTIFFS' REPLY TO DEFENDANTS' NOVEMBER 12 STATUS REPORT

District Judge: Hon. Brian E. Murphy
Magistrate Judge: Hon. M. Page Kelley

I. INTRODUCTION

Plaintiffs submit this reply to the Defendants' Status Report Regarding the Administrative Record (ECF 140) for four reasons. First, Defendants did not do what the Court ordered them to do at the in-court hearing on October 30, 2025. At that hearing, the Court ordered the Defendants to provide an estimate of the amount of time it would take to compile the Administrative Record

("AR"), and "if the administrative record is relatively easily prepared, meaning a couple of hours of work, then I just want it produced by December 1st." (*See* Exhibit 1 to Declaration of James J. Oh, Transcript of October 30 Hearing at 28:4-10). Defendants did not provide an estimate of the amount of time it would take to compile the AR on any of the actions that Plaintiffs challenge in their Third Amended Complaint. Even more troubling, Defendants admit that "they have not begun compiling the administrative record." (ECF 140, p.2).

Second, Defendants mischaracterize Plaintiffs' Third Amended Complaint (ECF 139) with their statement that Plaintiffs "challenge[] three actions that Plaintiffs *did not previously challenge*." (ECF 140, p.1) (italics added). In the Second Amended Complaint, however, Plaintiffs alleged that "[a]lthough the Directive ordered the CDC 'to remove Covid-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age,' the CDC … strangely did not entirely remove the recommendation that children be routinely vaccinated against Covid. Instead, on May 29, 2025, the CDC downgraded the recommendation to a 'shared clinical decision-making ("SCDM") recommendation from routine." (ECF 99, ¶ 92). In the Third Amended Complaint, Plaintiffs challenge the "[d]esignation of the Covid-19 vaccine for children as Shared Clinical Decision Making." (ECF 139, ¶ 5). Thus, Plaintiffs have previously challenged the change of the Covid-19 immunization on the CDC's childhood immunization schedule to SCDM. Defendants' mischaracterization of the Third Amended Complaint should not provide an excuse for further delay of production of the AR *on that challenged action*.

Third, Defendants argue that the challenge of the Secretarial Directive dated May 19 is moot and, therefore, the AR with respect to that action need not be compiled or produced. While this is not the time or place for a fulsome legal discussion of mootness, Plaintiffs explain below

why, factually, the challenge to the Directive is not moot and, therefore, cannot excuse the Defendants from compiling what is likely to be a very thin AR.

Fourth, in a November 7, 2025 letter to counsel for Defendants, Plaintiffs proposed a staggered production of the AR and asked to schedule a meet and confer. Agency counsel, however, refused to meet and confer. Accordingly, Plaintiffs request that the Court schedule an in-court status conference as soon as possible to discuss further a schedule for production of the AR and other case management issues.

II. BACKGROUND

A chronology of key events regarding the actions challenged in the Third Amended Complaint is provided below to provide factual context for the decisions the Court may need to make regarding the AR and possible extra-record discovery in this case.

DATE	EVENT
February 4, 2025	Robert F. Kennedy, Jr. ("RFK" or the "Secretary") promises Congress that, if confirmed, he would "maintain the Centers for Disease Control and Preventions Advisory Committee on Immunization Practices without changes." (KFF Health News, *Sen. Cassidy Says RFK Jr. Promised Key Vaccine Safety Commitments*, at 2:02. YouTube (Feb. 4, 2025), https://www.youtube.com/watch?v=QrJcBtkfwvo)
February 13, 2025	RFK confirmed as Secretary of the United States Department of Health and Human Services ("HHS")
February 20, 2025	HHS announces postponement of the meeting of the Advisory Committee on Immunization Practices ("ACIP") scheduled for February 26-28. The stated reason for the postponement was "'to accommodate public comment in advance of the meeting.'" (CIDRAP, "Scheduled Meeting of CDV vaccine advisers postponed" (February 20, 2025) https://www.cidrap.umn.edu/adult-non-flu-vaccines/scheduled-meeting-cdc-vaccine-advisers-postponed
April 15-16, 2025	ACIP meets at the Centers for Disease Control and Prevention ("CDC") in Atlanta, Georgia. On April 15, Robert Schechter, MD, MSc, COVID-19 ACIP Work Group Chair, recommends that the ACIP discuss and vote on recommended use of the 2025-2026 vaccine at the June 25-26, 2025 meeting of the ACIP. (Exhibit A to Declaration of Dr. Jason Goldman, ECF 75-18, p. 24). At the April 15 meeting, Dr. Lakshmi Panagiotakopoulos, MD, MPH, an epidemiologist at the CDC, presents on "Use of 2025-2026 COVID-19 Vaccines: Work Group Considerations." (Exhibit B to Declaration of Dr.

	Jason Goldman, ECF 75-18, p. 29). In her presentation, she notes that those who were pregnant or recently pregnant posed a "Higher Risk of Severe Illness of COVID-19 (conclusive)." (Id., p. 40). At that same meeting, Fiona Havers, MD, MHS, FIDSA, also an epidemiologist at the CDC, presents data on "COVID-19-Associated Hospitalizations" that "[a]mong children and adolescents eligible for COVID-19 vaccines, cumulative rates of COVID-19 hospitalizations remain the highest among children ages 6 months-4 years." (*See* ECF 75-2, p.54, citation to https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/03-Havers-COVID-508.pdf).
May 19, 2025	Date of one-page document signed by the Secretary titled "SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN." (The "May 19 Directive"). (ECF 103-1).
May 22, 2025	RFK testifies before Congress that "what I would say is my opinions about vaccines are irrelevant," and "I don't think people should be taking medical advice from me." (ECF 139, ¶ 70).
May 27, 2025	The Secretary posts a video on his official X account, in which he states that he "couldn't be more pleased to announce that, as of today, the COVID vaccine for health children and healthy pregnant women has been removed from the CDC recommended immunization schedule." https://x.com/SecKennedy/status/1927368440811008138
May 27, 2025	HHS releases the written May 19 Directive, the last sentence of which states: "the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above." (ECF 103-1)
May 29, 2025	The CDC's childhood and adolescent immunization schedule recommendation for the Covid-19 vaccine is changed to Shared Clinical Decision Making. (ECF 103-2) The adult immunization schedule is changed to "No Guidance/Not Applicable" with regard to pregnancy. (ECF 103-3).
June 9, 2025	At 4 p.m. ET, an Opinion Commentary written by the Secretary appears in the online version of the Wall Street Journal announcing that he was "totally reconstituting the Advisory Committee for Immunization Practices (ACIP)" and "retiring the 17 current members of the committee." Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, Wall Street Journal (June 9, 2025, 4:00 PM), https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112 The stated reasons for their terminations are "persistent conflicts of interest" and being a "rubber stamp for any vaccine."
June 9, 2025	The 17 members of the ACIP receive an email that evening providing "formal notice of your immediate termination as a member of the Advisory Committee on Immunization Practices (ACIP)." (ECF 139, ¶ 48).

June 11, 2025	The Secretary announces the appointment of eight new members to the ACIP. (ECF 139, ¶ 53).
June 12, 2025	New ACIP member Robert W. Malone posts on X that "i have already completed three months of vetting and COI training by the appropriate HHS officials." (ECF 139, ¶ 50).
June 20, 2025	A spokesperson for HHS is quoted as saying that "the new [ACIP] members ethics agreements 'will be made public' before they start work with the committee." (*Id.*). https://www.theguardian.com/us-news/2025/jun/20/cdc-vaccine-panel-rfk-jr
June 25-26, 2025	The newly-constituted ACIP meet at the CDC in Atlanta, Georgia. No vote on Covid-19 immunization recommendations for 2025-26 is taken. No ethics agreements are released. *See* Federal Register Vol 90, No. 109, p. 24278 (June 9, 2025)
July 31, 2025	Email sent to members of ACIP Liaison organizations terminating their participation in ACIP Work Groups because "[l]iaison organizations are special interest groups and are therefore expected to have a 'bias' based on their constituency and/or population they represent." https://www.ama-assn.org/press-center/ama-press-releases/statement-acip-medical-association-liaisons-ouster-vaccine-review
August 27, 2025	Susan Monarez, Ph.D., fired from her position of Director of the CDC. (ECF 139, ¶ 72) Three top-ranking officials at the CDC resign that same day. That evening, one of the resignees, Dr. Demetre Daskalakis, posts his resignation letter on X that states, in pertinent part: "[t]he recent change in the adult and children's immunization schedule threaten the lives of the youngest Americans and pregnant people. The data analyses that supported this decision have never been shared with CDC despite my respectful requests to HHS and other leadership." (*Id.*).
September 15, 2025	The Secretary announces the appointment of five new ACIP members. (ECF 139, ¶ 53). https://www.hhs.gov/press-room/hhs-cdc-announce-new-acip-members-sept-2025.html
September 17, 2025	Susan Monarez testifies before the Senate Finance Committee that: "[o]n the morning of August 25th, Secretary Kennedy demanded two things of me that were inconsistent with my oath of office and the ethics required of a public official. He directed me to commit in advance to approving every ACIP recommendation, regardless of the scientific evidence. He also directed me to dismiss career officials responsible for vaccine policy without cause. He said if I was unwilling to do both, I should resign. I responded that I could not pre-approve recommendations without reviewing the evidence, and I had no basis to fire scientific experts. He told me he had already spoken with the White House several times about having me removed." https://www.rev.com/transcripts/cdc-congressional-hearing

September 18-19, 2025	ACIP meeting held in Atlanta. On September 19, the ACIP votes in favor of Shared Clinical Decision Making for everyone under 65. https://www.cdc.gov/acip/meetings/upcoming.html
October 6, 2025	CDC releases statement "CDC Immunization Schedule Adopts Individual-Based Decision-Making for COVID-19." The statement quotes Defendant Acting CDC Director Jim O'Neill: "'Informed consent is back,' … 'CDC's 2022 blanket recommendation for perpetual COVID-19 boosters deterred health care providers from talking about the risks and benefits of vaccination for the individual patient or parent. That changes today.'" https://www.cdc.gov/media/releases/2025/cdc-immunization-schedule-adopts-individual-based-decision.html

III. DISCUSSION

A. Compliance With the Court's October 30 Order

Defendants have repeatedly argued in this case that they do not either have to compile or produce the AR until after the Court rules on a motion to dismiss for lack of subject-matter jurisdiction. In litigation, parties routinely have to do work on issues even when a dispositive motion is pending that might render the work done irrelevant. While the ruling on Defendants' impending motion to dismiss may render work compiling the AR irrelevant, there is a chance that it may not. Defendants apparently feel supremely confident in their impending motion to dismiss, since they admit that "they have not begun compiling the administrative record." (ECF 140, p.2).

Perhaps Defendants should account for some risk that their motion to dismiss may be denied, and, therefore, *at least start* to compile the AR on the Directive so as not to unreasonably delay this case of national importance from proceeding to the merits.[1] After all, in this case, Plaintiffs have thus far submitted 33 declarations from members of the Plaintiff Associations and the three Jane Does that, Plaintiffs believe, establish a genuine chance of Plaintiffs surviving the

[1] The one decision cited by the Defendants does not mandate that when one party alleges that there may be a jurisdictional question that all other aspects of the case must cease. ECF 140 at 3.

motion to dismiss. Physicians from around the country have attested to the financial harm that the Directive has caused their practices. *See, e.g., Declaration of Dr. Suzanne Berman* (ECF 118-4, ¶ 18: "The Directive's flipping of the recommendation to SCDM has and will result in continuing financial loss to my clinic. Shared decision making requires more time spent on counseling between physician and parent on the individual circumstances of the patient's health, medical history, family situation, and environmental/epidemiological milieu. … an increasing number of these discussions have resulted in refusal of the vaccine. In such cases, we are not reimbursed for the time spent counseling the parents or for the vaccine product that we had purchased."); *Declaration of Dr. Thomas Boyce* (ECF 118-7, ¶ 9: "This extra work caused by the Directive is work for which I am not paid. Health care providers like myself bill payers for their professional services using Current Procedural Terminology (CPT) codes. Each code is tied to a patient care service visit that is used to document and receive reimbursement for medical encounters. I am unaware of any CPT code that I or other pediatricians … can use to bill the extra time that we must now spend engaging in SCDM with parents of children."); *Declaration of Dr. Molly O'Shea* (ECF 118-8, ¶ 11: "The change in vaccine uptake and more time with each family is already resulting in financial harm to my practice that can be directly tied to the Directive because I typically am not able to bill for and therefore am not paid for the extra counseling time that the Directive has forced me to engage in."). The Plaintiff organizations have submitted declarations that attest to the resources that they have had to divert to offset the confusion and chaos that the Directive has injected into the American healthcare system. *See Plaintiffs' Opposition to Defendants' Motion to Dismiss for Lack of Subject-Matter Jurisdiction*, ECF 118, pp. 11-12; *Declaration of Mark Del Monte* (ECF # 118-9, ¶ 5: "Multiple teams within AAP [the American Academy of Pediatrics] have had to divert their attention from other urgent matters related to child health to contend with

the impact of the Directive"); *Declaration of Dr. James Lewis* (ECF 118-10, ¶ 6: "One initiative I am working on because of the Directive and other actions by the Secretary that undermine trust in vaccines … is an initiative to change local and state laws that have tied vaccine recommendations to the ACIP and CDC guidance. I and those with whom I work no longer trust the new ACIP … or CDC guidance"). These declarations and the 30 others in this record indicate Plaintiffs have established concrete injury sufficient to survive a motion to dismiss.

Moreover, at the October 30 hearing, this Court ordered as follows:

> if the administrative record is easily prepared, if it consists of, you know, 50 pages or something, then I would like that to be put together and provided to plaintiffs' counsel before -- before the December 12th date or before the December 17th date so that the -- the problem with December 17th, even if I -- my two weeks is a little tighter since I have one of those weeks off. And so you probably won't get a decision from me until the first week of -- first or second week of January. If you're then looking at the administrative record for the first time, we've now added probably two months to the whole undertaking. So if it's possible for you to assemble the administrative record and provide it to plaintiffs' counsel by December 1st, we might save ourselves a little bit of time there.
>
> However, I don't know how much work that is for you, so this is what I would like to you to do. **I'm going to order that you provide a status report to the Court by a week from today saying how much work that is**. Right? If you find that this is a trivial amount of work, then please do it and make the status report and say I'll do it by December 1st.
>
> If you tell me that the administrative record is going to be 200 hours of labor and 10,000 pages, I will probably say, you know, maybe we should wait until the motion to dismiss is decided. Does that make sense?
>
> MR. BELFER: Yes, it does. (Transcript of October 30 hearing at 23:13-24:13). …
>
> Just to be clear, what I'm looking for in the status report is **I want the administrative record produced in the meantime unless you tell me this is really a lot of work**, in which case I won't require you to do it. But if—if the administrative record is relatively easily prepared, meaning a couple of hours work, then I just want it produced by December 1st. (Transcript of October 30 hearing at 28:11-12).

Thus, when the parties appeared in this Court, there was a clear instruction to the Defendants to explain how much time and how much work it would take to compile the AR. If the burden was relatively small, then the Court ordered the Defendants to produce the AR by December 1, 2025. Agency counsel at the hearing plainly understood these instructions. The Defendants contend, however, that they were unable to compile the Administrative Record due to the government shutdown that started October 1, 2025 and ended November 12, 2025. (ECF 140 at 2). This argument assumes, incorrectly, that no employee of any agency within the Department of Health and Human Services was able to perform any work during the shutdown; this assumption is unfounded and is not entitled to any weight at all. The Defendants were on notice of their obligation to compile the record well in advance of the shutdown and should have been working on it before September 30. Equally important, the Defendants' position ignores the fact that within each component of the Department of Health and Human Services, certain employees were designated as essential employees and were obligated to work, albeit without pay. Complying with an obligation to this Court certainly falls within the scope of functions that could have been performed by those essential employees, many of whom occupy senior positions within HHS and exercise considerable authority, and Defendants have offered no explanation to the contrary. This case is one of national importance and moving it forward should take precedence over bureaucratic discomfort. *See, e.g., Banner Health v. Sebelius,* 797 F.Supp. 2d 97, 113-14 (D.D.C. 2011)(Secretary directed to produce the full administrative record before reaching the merits of the Secretary's motion to dismiss an action challenging Medicare reimbursement to hospitals).

Further, Defendants failed to provide the Court with an estimate of the amount of time it would take to compile the AR on the May 19 Directive, which was, as of the October hearing, the only final agency action being challenged in this case. The Court's instruction could not have been

clearer. *See* Transcript of October 30 hearing at 28:11-12. Defendants have simply ignored the Court's instructions, and instead state generically that "significant work" is needed to compile the Administrative Record. (ECF 140 at 2). What that work entails remains a mystery and, in all likelihood, is a misleading claim, for the reasons stated in the next section. Defendants' unsupported, unquantified "significant work" claim leaves this Court without any context to assess the veracity of the Defendants' representations.

B. The Directive and the SCDM Designation for Children Are Inextricably Intertwined

Defendants' failure even to begin compiling the AR on the May 19 Directive, their refusal to meet and confer, and their failure to comply with the Court's October 30 order are troubling. Defendants' conduct in this litigation thus far indicates that Defendants are doing everything they can to avoid producing the AR on the May 19 Directive. Defendants' claim that Plaintiffs' challenge to the May 19 Directive is moot is not well-taken. The relevant chronology is as follows:

May 27, 2025	The Secretary posts a video on his official X account, in which he states that he "couldn't be more pleased to announce that, as of today, the COVID vaccine for health children and healthy pregnant women has been removed from the CDC recommended immunization schedule."
May 27, 2025	HHS releases the written May 19 Directive, the last sentence of which states: "the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above."
May 29, 2025	The CDC's childhood and adolescent immunization schedule recommendation for the Covid-19 vaccine is changed to Shared Clinical Decision Making. The adult immunization schedule is changed to "No Guidance/Not Applicable" with regard to pregnancy.

These three actions are inextricably intertwined into one final agency action—the SCDM designation of the Covid-19 vaccine on the childhood immunization schedule. One of the unanswered questions in this case is why the May 19 Directive's instruction to remove the Covid-

19 vaccine from the childhood immunization schedule, which was announced in the May 27 video posted on X, was not implemented, but instead, the childhood immunization schedule was changed to SCDM for the Covid-19 vaccine. Neither the Secretary nor the CDC have offered any explanation for the change from the Directive's order to "remove" the Covid-19 vaccine to the "SCDM" designation that appeared two days later on the CDC's childhood immunization schedule. The May 19 Directive, the May 27 video, and the SCDM designation on the childhood immunization schedule on May 29 are one, inextricably-intertwined decision.[2] Therefore, the challenge to the May 19 Directive is far from moot.

Moreover, the AR on the May 19 Directive may contain evidence relevant to the standing argument that Defendants are likely to make in their Motion to Dismiss. The AR may contain evidence that Defendants considered the impact to physicians' practices around the country of removing the Covid-19 vaccine entirely from the childhood immunization schedule, which would be relevant to standing. The AR may also contain evidence that the Defendants considered the impact of the SCDM designation of the Covid-19 vaccine for children on physicians' practices around the country, which likewise would be relevant to standing. Accordingly, the AR on the May 19 Directive should be produced before Plaintiffs' December 3 deadline to file their opposition to Defendants' Motion to Dismiss.

The AR on the May 19 Directive is *not* likely to be voluminous. In the May 27 video, which Plaintiffs urge the Court to view,[3] the claim is made that removing the Covid-19 vaccine

---

[2] The phrase "the May 19 Directive" is thus meant to refer herein and in this litigation to (i) the document dated May 19 titled the "SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN," (ii) the May 27 video, and, (iii) the SCDM designation on the childhood immunization schedule made on May 29, 2025.

[3] https://x.com/SecKennedy/status/1927368440811008138

from the CDC's immunization schedules was "good science," but neither the Secretary, the CDC, nor anyone else at HHS have identified what the "good science" is supporting the Directive, such as citations to peer-reviewed published research or practice guidelines published by professional organizations. In addition, the former Director of the CDC's National Center for Immunization and Respiratory Diseases, Dr. Demetre Daskalakis, stated in his resignation letter dated August 27, 2025[4] that he asked HHS leadership for the "data analyses" that supported the "recent change in the adult and children's immunization schedule," but no data analyses were ever shared with him, which may mean that there is nothing to share. Dr. Daskalakis stated further in his resignation letter that "[w]e are seven months into the new administration, and no CDC subject matter expert from my Center has ever briefed the Secretary. I am not sure who the Secretary is listening to, but it is quite certainly not us. Unvetted and conflicted outside organizations seem to be the sources HHS use over the gold standard science of CDC and other reputable sources."[5]

Thus, it is troubling that the Defendants claim on page two of their report that they must consult with the "CDC, National Center for Immunization and Respiratory Diseases" in order to compile the AR when the Secretary never consulted with the Dr. Daskalakis or his staff at the Center for Immunization and Respiratory Diseases about the May 19 Directive, or anything else. The claim in the status report that Defendants need to consult with seven to eight sub-agencies on *all three actions* challenged in this case clearly is misleading. Accordingly, Plaintiffs request that the Court order Defendants to file a status report within seven days of today that itemizes and

---

[4] *See* Exhibit 2 to Declaration of James J. Oh: Demetre Daskalakis, *My Resignation letter from CDC*, posted on X on August 27, 2025 @ 6:14 p.m.

[5] Defendants have objected to Plaintiffs speaking to or deposing either Dr. Daskalakis, Dr. Susan Monarez, the CDC Director fired on August 27, or Dr. Melinda Wharton, the former Executive Secretary of the ACIP. *See* Exhibit 4 to Declaration of James J. Oh.

delineates which of the agencies listed in Defendants' status report must be consulted on each of the three challenged actions and how much time it will take to compile the AR on each of the three challenged actions from each sub-agency.

Curiously missing from the list of sub-agencies that agency counsel claim they need to consult with is any mention of the office of the ACIP's Executive Secretary or Designated Federal Official responsible for administration of the ACIP,[6] or the office of the CDC's Executive Secretariat. The ACIP Charter requires the CDC to "select a full-time or permanent part-time Federal employee to serve as the Designated Federal Office (DFO) to attend each committee meeting and ensure that all procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives."[7] Among the responsibilities of the CDC Executive Secretariat is *"[m]aintaining official agency records of the CDC Director's decisions and correspondence*."[8] In addition, the CDC Executive Secretariat is responsible for managing the conflicts of interest vetting of potential ACIP members. The "Apply for ACIP Membership" page on the CDC's website states that:

> Any actual or perceived conflict of interests will be explored fully by the Secretariat, CDC's Federal Advisory Committee Management Branch, and CDC legal counsel if necessary.
>
> Members with declared interests will be asked to recuse themselves from participating in the discussion and decision-making of the issues relating to that interest. *A member who has any doubt as to whether they have an*

[6] Dr. Melinda Wharton was removed from this role on June 9, 2025, the same day that the 17 ACIP members were fired. https://www.linkedin.com/in/melinda-wharton-002bab10/

[7] https://www.cdc.gov/acip/about/acip-charter.html

[8] https://www.cdc.gov/executive-secretariat/about/ (Emphasis added).

> *interest that should be declared, or whether they should take part in the proceedings, should ask the Secretariat for guidance*.[9]

Current ACIP member Robert Malone posted on X on June 12, 2025 that "i have already completed three months of vetting and COI training by the appropriate HHS officials." (ECF 139, ¶ 50). Presumably, records of Dr. Malone's conflicts vetting dating back to March or April of this year are in the possession of the CDC's Executive Secretariat, as are the records of the conflicts of interest vetting of the other current ACIP members.

The "Apply for ACIP Membership" page also has a Conflicts of Interest tab, which states:

> ACIP members are required to declare any potential conflicts of interest that arise in the course of ACIP tenure and any relevant business interests, positions of authority or other connections with organizations relevant to the work of the ACIP. Upon appointment, each voting member is required to file an Office of Government Ethics 450 form (OGE450), a Confidential Financial Disclosure Report, which is reviewed by the ACIP Secretariat, the Federal Advisory Committee Management Branch and the Office of General Counsel at CDC.[10]

The AR that is produced on the third action challenged here – the Secretary's reconstitution of the ACIP – must contain the Office of Government Ethics 450 and Confidential Financial Disclosure Reports filed by each of the current ACIP members as well as the 17 ACIP members terminated earlier this year. After all, the Secretary's stated reason for terminating the 17 ACIP members on June 9 of this year was "persistent conflicts of interest." He promised to release to the public the ethics and conflicts of interest forms on the current ACIP members, but has not fulfilled that promise. In this litigation, however, Defendants must produce those forms.

---

[9] https://www.cdc.gov/acip/apply-for-membership/ (Emphasis added).

[10] https://www.cdc.gov/acip/apply-for-membership/

Recognizing that the AR on Plaintiffs' challenge to the reconstitution of the ACIP is potentially more voluminous than the AR on the two other challenged actions, Plaintiffs proposed a staggered production of the AR on the three challenged actions, which is discussed next.

C. A Staggered AR Production Proposal

1. The May 19 Directive

The Third Amended Complaint, filed six days after the October 30 hearing on November 5, 2025, asserted two new challenges to final agency actions, which is why Plaintiffs asked agency counsel to meet and confer on a staggered production of the AR in November 7, 2025 correspondence. *See* Exhibit 3 to Declaration of James J. Oh. Agency counsel refused to meet and confer. See Exhibit 4 to Declaration of James J. Oh. The AR on the first challenged action, the May 19 Directive, as defined above, in all probability can be produced from one source—the Secretary. The facts of this matter indicate that the *only* decision-maker on the May 19 Directive was the Secretary. He is the only person whom agency counsel *really* needs to consult with as to what was reviewed and relied on to issue the May 19 Directive, to post the May 27 video on X, and to change the CDC's childhood immunization schedule to SCDM two days later. It's that simple. If Defendants are ordered to file another status report, agency counsel should state whether they have consulted *directly* with the Secretary as to what he reviewed and relied upon to issue the May 19 Directive, to make the May 27 video, and as to why the Directive's instruction to remove the Covid-19 vaccine from the childhood schedule was changed to SCDM. In addition, Defendants should be ordered to state in this status report whether the Secretary consulted with anyone outside of the U.S. government about the May 19 Directive, or any other action challenged in this action. If the Secretary consulted with anyone outside of the U.S. government on any of the challenged actions through electronic means, then those outside parties should be identified so that they may be subpoenaed for those communications. Defense counsel should be ordered to send a

preservation notice to any outside organization whom the Secretary consulted with about any of the actions challenged in this case. The AR on this claim should be produced before Plaintiffs' response to Defendants' motion to dismiss is due on December 3.

2. The SCDM Designation of the Covid-19 Vaccine for Adults

The AR on this final agency action also should be easily compiled. The ACIP voted on September 19 to make the Covid-19 vaccine SCDM for everyone under 65. Unlike votes taken by previous ACIPs on the Covid-19 vaccine, the Secretary's reconstituted ACIP did not apply the GRADE criteria or the EtR framework,[11] did not consult with the Covid-19 Work Group, and did not publish guidance on how clinicians should engage in SCDM with patients. *See* ECF 139, ¶¶ 73-75. Therefore, it is likely that GRADE and EtR data analyses supporting the ACIP's September 19 vote do not exist. Any materials relied on for the September vote on the Covid-19 vaccine are thus likely to be minimal and easily compiled. In addition, Defendant Acting CDC Director O'Neill adopted the ACIP's vote on October 6, a mere eleven working days later, and so whatever Defendant O'Neill considered during this short time span also should be easily compiled and produced when the AR on the May 19 Directive is produced.

3. The Reconstitution of the ACIP

This challenge *could* have a more voluminous AR, but that AR should be readily accessible. First, this challenge involves the Secretary's decision to terminate 17 ACIP members "for persistent conflicts of interest," so presumably the Secretary performed a careful review of

[11] *See* Exhibit 5 to Declaration of James J. Oh: Jessica Karins, *Former ACIP Members Criticize Abandonment of Scientific Process*, Inside Health Policy, October 24, 2025, pp.1-2 ("Between 2008 and 2010, they participated in an ACIP work group to bring the committee's standard of evidence in line with recommendations from the Institute of Medicine (now the National Academy of Medicine). ACIP officially adopted the proposed process, known as the GRADE process, in 2010. … Beginning in 2019, ACIP adopted an Evidence to Recommendation (ETR) process that included information on the magnitude of the public health problems being addressed, costs and benefits, feasibility, views of community and professional stakeholders, and effects on equity in addition to efficacy and safety.").

the then 17 members' conflicts of interest before he terminated them. Second, presumably, the Secretary and/or his designees performed a careful review of the conflicts forms that the new ACIP members were required to file with the ACIP Secretariat, the Federal Advisory Committee Management Branch, and the Office of General Counsel at CDC before appointing any new member. Indeed, as current ACIP member Dr. Malone has stated, he underwent three months of conflicts vetting, so presumably the other ACIP members were as carefully vetted. If the Court orders Defendants to file another status report, the Court should order agency counsel of record in this case to report on the status of collection of the OGE450 forms and Confidential Disclosure Reports from the 17 ACIP members who were terminated, the ACIP members appointed this year, and from anyone else considered for appointment to the current ACIP.

IV. CONCLUSION

As Plaintiffs now challenge three final agency actions, two of which are related to each other and one that is conceptually different, this case now presents complex case management issues. Accordingly, Plaintiffs respectfully request that the Court schedule an in-person status conference as soon as possible to discuss a manageable and expeditious path forward in this case, not only for production of the AR, but also for resolution of the claims on the merits. Counsel for the Plaintiffs are available to attend an in-person status conference before the Thanksgiving holiday next week.

Dated: November 18, 2025

Respectfully submitted,

By: */s/ James J. Oh*

James J. Oh (*admitted pro hac vice*)
Kathleen Barrett (*admitted pro hac vice*)
Carolyn O. Boucek (*admitted pro hac vice*)
Lydia Pincsak (*admitted pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
227 W. Monroe Street, Suite 4500
Chicago, IL 60606

Tel: 312.499.1400
Fax: 312.845.1998
Email: joh@ebglaw.com
kbarrett@ebglaw.com
cboucek@ebglaw.com
lpincsak@ebglaw.com

Elizabeth J. McEvoy (BBO No. 683191)
EPSTEIN BECKER & GREEN, P.C.
One Financial Center, Suite 1520
Boston, MA 02111
Tel: 617.603.1100
Fax: 617.249.1573
Email: emcevoy@ebglaw.com

Richard H. Hughes IV (*admitted pro hac vice*)
Stuart M. Gerson (*admitted pro hac vice*)
Robert Wanerman (*admitted pro hac vice*)
William Walters (*admitted pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
1227 25th Street, N.W., Suite 700
Washington, DC 20037
Tel: 202.861.0900
Fax: 202.296.2882
Email: rhhuges@ebglaw.com
sgerson@ebglaw.com
rwanerman@ebglaw.com
wwalters@ebglaw.com

Marguerite Stringer (*admitted pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
6000 Poplar Avenue, Suite 250
Memphis, TN 38119
Tel: 901.712.3200
Fax: 615.691.7715
Email: mstringer@ebglaw.com

Jeremy A. Avila (*admitted pro hac vice*)
EPSTEIN BECKER & GREEN, P.C.
57 Post Street, Suite 703
San Francisco, CA 94104
Tel: 415.398.3500
Fax: 415.398.0955
Email: javila@ebglaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 18th day of November 2025:

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 Centers for Disease Control and Prevention

c/o Leah Belaire Foley, US Attorney
Michael L. Fitzgerald
Office of the US Attorney for the District of Massachusetts
1 Courthouse Way, Suite 9200
Boston, Massachusetts 02210
michael.fitzgerald2@usdoj.gov

c/o Isaac Belfer
Trial Attorney
Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044-0386
Isaac.C.Belfer@usdoj.gov

/s/ James J. Oh
James J. Oh