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

DECLARATION OF JAMES J. OH

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the following is true and correct:

1. I am lead trial counsel for Plaintiffs in the above-titled action.

2. Attached hereto as Exhibit 1 are excerpts from the transcript of the October 30, 2025 hearing in this matter.

3. Attached hereto as Exhibit 2 is the resignation letter of Demetre Daskalakis posted on X on August 27, 2025.

4. Attached hereto as Exhibit 3 is a letter dated November 7, 2025 that I emailed to agency counsel of record for the Defendants, Isaac C. Belfer.

5. Attached hereto as Exhibit 4 is email correspondence between me and Mr. Belfer on November 7, November 10, and November 12.

6. Attached hereto as Exhibit 5 is an article from Inside Health Policy dated October 24, 2025 titled "Former ACIP Members Criticize Abandonment of Scientific Process."

I declare under penalty of perjury that the foregoing is true and correct.

Executed on November 18, 2025.

/s/ James J. Oh
James J. Oh

EXHIBIT 1

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,
Plaintiffs,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services, *et al.*,
Defendants.

Civil Action
No. 1:25-cv-11916-WGY

October 30, 2025
10:04 a.m.

TRANSCRIPT OF MOTION HEARING
BEFORE THE HONORABLE BRIAN E. MURPHY
UNITED STATES DISTRICT COURT
JOHN J. MOAKLEY U.S. COURTHOUSE
1 COURTHOUSE WAY
BOSTON, MA 02210

JESSICA L. BISAILLON, RPR, CRI
Official Court Reporter
John J. Moakley U.S. Courthouse
1 Courthouse Way, Room 5205
Boston, MA 02210
jsteno99@gmail.com

Your Honor, in an order that they be compiling the record now and that we get the administrative record within a very short time period after the hearing, if necessary.

MR. BELFER: So I think we are -- our proposal would be that the Court set a schedule for further proceedings after it decides the motion to dismiss, because, at that point, the Court will know what, if anything, is left of the case.

So we propose when the Court resolves the motion to dismiss, at that point the Court can set a schedule for -- for any necessary further proceedings. And then the parties can -- can repropose something at that point, too.

THE COURT: And so I'm probably fine with doing that.

I would like -- if -- 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.

I think just one more point. I think our view is that the Court doesn't have the jurisdiction, and so there's no basis to require us to produce the administrative record.

THE COURT: Right.

MR. BELFER: So that's --

THE COURT: I understand. I have not reviewed the motion to dismiss in as much depth as I will when it gets filed again. I understand that.

If I grant the motion to dismiss, the whole case is over, which is why I'm not going to tell you to spend hundreds of hours of effort putting together an administrative record. But if it is really several minutes and, you know, a few dozen

And have I made what I'm looking for in that status report clear?

MR. BELFER: Sorry?

THE COURT: 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 hours work, then I just want it produced by December 1st.

MR. BELFER: So we'll describe how much work is necessary to produce the administrative record.

THE COURT: Perfect. Great. Thank you very much.

Is there anything else I can do from the government's perspective?

MR. BELFER: No. That's all. Thank you.

THE COURT: Okay. And from the plaintiffs' perspective?

MR. OH: No, no. Other than thank you, again, Your Honor, for scheduling this hearing.

THE COURT: Of course. Thank you both. I appreciate your time.

THE CLERK: All rise.

(Adjourned at 12:12 p.m.)

EXHIBIT 2

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EXHIBIT 3

EPSTEIN
BECKER
GREEN

Attorneys at Law

James J. Oh
t 312.499.1470
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JOh@ebglaw.com

November 7, 2025

VIA EMAIL

Isaac C. Belfer
Trial Attorney
Enforcement & Affirmative Litigation Branch
U.S. Department of Justice
450 5th Street, NW, Suite 6400-South
Washington, DC 20044-0386
Isaac.C.Belfer@usdoj.gov

Re: ***American Academy of Pediatrics, et al. v. Kennedy, et al.:***
Production of the Administrative Record

Dear Isaac:

At the October 30, 2025 hearing on the motion to lift the stay, Judge Murphy ordered "Defendants to file a status report by 11/12/2025 re the compilation time line for disclosing the administrative record to plaintiffs." (ECF # 134). I offer the following for your consideration before you submit Defendants' report to the Court.

As you know, Plaintiffs filed a Third Amended Complaint two days ago on November 5, 2025 (ECF # 139) (the "TAC"). In the TAC, Plaintiffs challenge three Final Agency Actions:

(i) designation of the Covid-19 vaccine for children as Shared Clinical Decision Making ("the First SCDM Decision");

(ii) the designation of the Covid-19 vaccine for adults as SCDM (the "Second SCDM Decision"); and

(iii) the Secretary's reconstitution of the Advisory Committee on Immunization Practices (the "ACIP Claim").

The Administrative Record ("AR") on the SCDM Decisions

The complaints that Plaintiffs filed before the TAC challenged one Final Agency Action—the Secretarial Directive dated May 19, 2025 ("Directive"), which instructed the Centers for Disease Control and Prevention ("CDC") to remove the recommendations that pregnant women and children receive the Covid-19 vaccine. As you know, even though the Directive instructed the CDC to remove entirely the Covid-19 vaccine recommendation for children, the CDC's immunization schedule was changed, not by removing that recommendation, but by changing the designation of the childhood Covid-19 vaccine to SCDM. Thus, the AR on the First SCDM Decision should include documents that influenced the issuance of the Directive, the removal of the Covid-19 recommendation for pregnant people, and the designation of the Covid-19 vaccine for children as SCDM. This includes but is not limited to documents pertaining to evidence, decision-making, or instructions.

At the July 31, 2025 Case Management Conference ("CMC"), Judge Young understood the initial challenge to the Directive to be a "discrete determination" and that he "wouldn't think that the administrative record in support of that changed recommendation is extensive or hard to ferret out." (Transcript of 7/31 CMC at 7:23-8:5). At the CMC, you indicated that "the agency thinks that it can compile the records within 8 weeks." (*Id*. at 8:25-9:1). A reason that you gave the eight week number was that "the administrative record will probably include documents from all of those subagencies. And so that's what takes time, to recover records from three different subagencies,[1] and maybe other offices." (Id. at 8:18-23). Judge Young asked you if the record could be produced by September 26, and your response was "That works for us, your Honor." (*Id*. at 9:6-8). At the hearing on the Motion to Lift Stay on October 30, Judge Murphy asked you the status of producing the AR on the Directive, and you stated: "I think some work has been done, but there is more work to do. I don't know exactly how much more." (Transcript of 10/30 Hearing at 18:17-18).

Plaintiffs believe that the AR on the Directive could have been compiled by now, seven weeks after the government said it could produce the AR, and request that it be produced immediately, *i.e.*, next week (with the possible exception of electronically-stored information ("ESI") such as emails and text messages discussed in the next paragraph). By the time your status report is due next Wednesday, it will be 15 weeks after the CMC when you indicated you needed eight weeks to produce the AR on the Directive. Further, the TAC dropped NIH and FDA as Defendants, so there now is only one subagency to collect documents from. And since there was no ACIP meeting prior to the Directive to vote either on removing the Covid-19 recommendation for pregnant people, recommending the removal of the Covid-19 vaccine for children from the CDC's schedules, or changing the designation of the Covid-19 vaccine for children to SCDM, the burden cannot be great to collect documents from the CDC that "might have influenced the agency's decision, whether directly or indirectly." *Forest County Potawatomi Community v.*

[1] The operative complaint at that time named Health and Human Services ("HHS"), the Food and Drug Administration ("FDA"), the National Institutes of Health ("NIH"), and the CDC.

United States, 270 F.Supp. 3d 174, 178 (D.D.C. 2017) (administrative record should include materials considered directly or indirectly by the agency).

In this age of electronic communication, Plaintiffs expect that there are emails and text messages that influenced the decision makers on both SCDM decisions challenged here. *See Bimini Superfast Operations LLC v. Winkowski*, 994 F.Supp.2d 103, 106 (D.D.C. 2014) (holding emails were properly included in administrative record as documents that were directly or indirectly considered in decision making). Since the ACIP and CDC leadership such as Dr. Susan Monarez and Dr. Demetre Daskalakis were not consulted about the Directive (see TAC ¶¶ 64-72), Plaintiffs are entitled to know whom the Secretary consulted with and the evidence relied upon to issue the Directive. Indeed, as Dr. Daskalakis stated in his resignation letter, he asked the Secretary for the "data analyses that supported" the Directive, but nothing was shared with him "despite my respectful requests to HHS and other leadership." (TAC ¶ 72). Presumably, Dr. Daskalakis made those requests in writing by email, since, as Dr, Daskalakis has stated: "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 to us." Accordingly, Plaintiffs expect to see in the AR on the First SCDM Decision, at a minimum: (a) Dr. Daskalakis' requests for data analyses; (b) the electronic communications about the Directive from anyone involved in that decision; (c) data analyses and the "good science"[2] relied on to make the First SCDM Decision. If Defendants have yet to begin collecting ESI from those who were involved in that decision, then please let me know immediately so that we can schedule a call to discuss an ESI protocol that would ensure the forensically-sound collection and production of ESI. For efficiency sake, I will have an ESI vendor on the call with me.

ESI may be a reason that Defendants cannot produce the *entire* AR on the First SCDM Decision next week. But, in the meantime, other documents that were directly or indirectly considered with regard to the First SCDM Decision – such as data analyses, studies, articles, and PowerPoint presentations – should be produced now. *See Ammex, Inc. v. U.S.*, 62 F.Supp.2d 1148, 1156 (Ct. Int'l Trade 1999) ("If the relevant agency decisionmakers considered, even indirectly, any internal guidelines, memoranda, manuals or other materials in reaching its decision, those materials should be included in the record."). After all, on July 31, you told Judge Young that it was feasible to do so in eight weeks, *i.e.*, by September 26, and we are now seven weeks past that date.

Like the First SDCM Decision, it should not be difficult collecting and producing the AR on the Second SCDM Decision. On September 18, the ACIP voted in favor of the following proposition:

> It is the sense of the committee that in conversations with patients before COVID-19 vaccination, authorized healthcare providers

[2] In the May 27 video posted on the Secretary's official X account in which the Secretary announced the Directive, NIH Director Jay Bhattacharya stated that the Directive was supported by "good science." The AR should include the "good science" that Director Bhattacharya was referring to.

> discuss the risks and benefits of the vaccination for the individual patient. The discussion should consider known risk factors for severe outcomes from COVID-19, such as age, prior infections, immunosuppression, and certain comorbidities identified by the CDC, and include a discussion of the potential benefits and risks of vaccination and related uncertainties, especially those outlined in the vaccine information statement, as part of informed consent.

On October 6, Defendant O'Neill adopted this recommendation of the ACIP, and the CDC's immunization schedule for adults under 65 was changed to SCDM. There are ten business days between September 18 and October 6. One would think that the documents that Defendant O'Neill reviewed in that short span to make his October 6 decision are readily identifiable and producible. Of course, if he reviewed relevant documents related to the Second SCDM Decision before the September 18 vote, those documents should be included in the AR on the Second SCDM Decision as well.

The Administrative Record on the ACIP Claim

Plaintiffs recognize that they asserted the ACIP Claim for the first time only two days ago. We do not think, however, that assertion of the ACIP Claim should delay production of the AR on the SCDM Claims. Accordingly, I would ask that we meet and confer as soon as possible on staggering the production of the AR on the First and Second SCDM Decisions and the ACIP Claim.

In the interest of expedition, when we meet and confer, set forth below is a list of categories of evidence that Plaintiffs believe should be included in the AR on the ACIP Claim. Generally, the categories of documents that Plaintiffs think should be collected for production of the AR on the ACIP Claim include, but are not limited to:

- Conflicts of interests disclosures for the current members of the ACIP (hereafter "Current ACIP Members") and the conflicts of interest disclosures for the 17 ACIP members terminated on June 9, 2025 (hereafter "Former ACIP Members");

- The "nomination packages" referenced on page 17 of the Advisory Committee on Immunization Policies and Procedures dated June 2022 for the Former ACIP Members and the Current ACIP Members;

- All communications seeking recommendations for membership on the ACIP after the Secretary was confirmed on February 2025;

- All documents submitted by Former ACIP Members and Current ACIP Members relating to or in support of their application for and membership on the ACIP;

- All documents, including but not limited to electronic communications by or between the Secretary or anyone else, regarding the decision to terminate the Former ACIP Members;

- All documents, including but not limited to electronic communications by or between the Secretary or anyone, else regarding the Current ACIP Members;

- All documents, including but not limited to electronic communications by or between the Secretary or anyone else, regarding the Directive;

- All documents, including but not limited to electronic communications by or between the Secretary or anyone else, regarding the decision to change to SCDM the Directive's instruction to the CDC to remove the Covid-19 vaccine recommendation from the CDC's immunization schedule

- All documents, including but not limited to electronic communications by or between the Secretary or anyone else, regarding the decision to put up for a vote at the September 2025 ACIP meeting whether to designate the Covid-19 vaccine as SCDM for all individuals;

- All documents, including but not limited to electronic communications by or between the Secretary or anyone else, regarding the decision to appoint any of the current ACIP members to the ACIP;

- All documents, including but not limited to electronic communications by or between the Secretary or anyone else, regarding the decision to terminate the Former ACIP Members;

Anticipating that Defendants will assert the deliberative process privilege with respect to at least some of the categories of documents listed above, I note that the deliberative process privilege cannot prevent a party from obtaining proof of their claims. *See New York v. Salazar, 701 F.Supp.2d 224, 237 (N.D.N.Y.* 2010) (citing *Children First Foundation, Inc. v. Martinez*, No. 04-CV-0927, 2007 WL 4344915, at *7 (N.D.N.Y. 2007)). Where the decision-making process "is *at the heart of the action*…the deliberative process privilege imposes no restriction on plaintiffs' access to pre-decisional materials, and all documents withheld from the administrative record on this basis must therefore be produced." *Id.* at 237 (holding documents could not be withheld on basis of deliberative process privilege) (emphasis added). Documents reflecting deliberations, if any, over the terminations of the Former ACIP Members and the appointments of the Current ACIP Members are, to be sure, at the heart of the ACIP Claim. Similarly, deliberations on the First and Second SCDM Decisions are at the heart of those claims. Accordingly, an assertion of the deliberative process privilege with regard to any of the Final Agency Actions challenged here would be legally dubious. Moreover, in his welcome remarks to HHS Staff on February 18, 2025, a few days after he was sworn in as

Secretary, the Secretary pledged to "launch a new era of radical transparency." Hiding behind the deliberative process privilege in this case would break that pledge.

Meet and Confer Request

Given that this "is clearly a case that's of national importance" and "[i]t's one that needs to get addressed" (Transcript of October 30 hearing at 17:7-9), it is incumbent on all of us involved in this case to move this case forward as expeditiously as possible. Again, Plaintiffs believe that collection and production of the more voluminous AR on the ACIP Claim should not delay production of the AR on the SCDM Claims. Accordingly, we would like to meet and confer about staggering production of the AR on Monday or Tuesday of next week. Please let me know available times for a meet and confer call on Monday, November 10 or Tuesday November 11.

Thank you, and I hope you have a nice weekend.

Sincerely,

Jimmy

James J. Oh

EXHIBIT 4

From: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Sent: Wednesday, November 12, 2025 4:54 PM
To: James J. Oh; Fitzgerald, Michael (USAMA)
Cc: Kathleen Barrett; Richard H. Hughes IV; Robert Wanerman
Subject: RE: AAP, et al. v. RFK, Jr.: Letter re Administrative Record and Meet and Confer on Melinda Wharton

***** EXTERNAL EMAIL *****

Jimmy,

Thank you for reaching out. With respect to your November 7 letter, Defendants believe it would be premature to produce the administrative record before the Court has resolved Defendants' forthcoming motion to dismiss for lack of subject-matter jurisdiction. A decision granting Defendants' motion in full would obviate the need for an administrative record, and a decision granting Defendants' motion in part may narrow the scope of the record by determining which of Plaintiffs' claims are properly before the Court. Thus, we do not think it would be productive to meet and confer about the administrative record at this time.

We would also note that your letter contains several legal and factual errors. For example, the administrative record should not include information protected by the deliberative process privilege. *See Town of Norfolk v. U.S. Army Corps of Eng'rs*, 968 F.2d 1438, 1458 (1st Cir. 1992). There is also no basis for your assertion (on page 2) that Defendants should be ready to produce "the AR on the Directive" now. As we have discussed, any challenge to the Directive is now moot. Moreover, although the Court originally set the AR deadline for September 26, 2025, ECF No. 83, that deadline was extended to October 10, 2025, ECF No. 97, and later vacated, ECF No. 112 ("The Court will set a hearing date for the motion to dismiss" and "will, if necessary, set a date for the production of the administrative record at that time."). In light of the lapse in appropriations, Defendants have not been permitted to work on the AR since October 1, 2025.

With respect to your November 10 email, Defendants oppose Plaintiffs' request to depose former HHS official Melinda Wharton. In an APA case, "the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court." *Camp v. Pitts,* 411 U.S. 138, 142 (1973); *see* 5 U.S.C. § 706; ECF No. 80 at 2 ("Because the claims at issue involve alleged violations of the Administrative Procedure Act, 5 U.S.C. §706(2)(A), (D), the parties agree that this case is subject to the record review rule."). Any attempt to obtain extra-record discovery before Defendants have produced the record, much less before the Court has ruled on Defendants' forthcoming motion to dismiss, is premature. Furthermore, should Plaintiffs contact Dr. Wharton, Defendants ask to be involved in the communication to ensure that information subject to the rights and privileges of the United States (e.g., attorney-client privilege, deliberative process privilege) remains protected. As a former official, Ms. Wharton is not authorized to waive these rights and privileges, which belong to the government itself.

Thanks,
Isaac

From: Belfer, Isaac C.
Sent: Monday, November 10, 2025 4:23 PM
To: 'James J. Oh' <JOh@ebglaw.com>; Fitzgerald, Michael (USAMA) <Michael.Fitzgerald2@usdoj.gov>
Cc: Kathleen Barrett <KBarrett@ebglaw.com>; Richard H. Hughes IV <RHHughes@ebglaw.com>; Robert Wanerman

<RWanerman@ebglaw.com>
Subject: RE: AAP, et al. v. RFK, Jr.: Letter re Administrative Record and Meet and Confer on Melinda Wharton

Jimmy,

Thank you for your email and November 7 letter. Tomorrow is Veterans Day, but we will respond on Wednesday.

Thanks,
Isaac

From: James J. Oh <JOh@ebglaw.com>
Sent: Monday, November 10, 2025 12:57 PM
To: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>; Fitzgerald, Michael (USAMA) <Michael.Fitzgerald2@usdoj.gov>
Cc: Kathleen Barrett <KBarrett@ebglaw.com>; Richard H. Hughes IV <RHHughes@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: [EXTERNAL] FW: AAP, et al. v. RFK, Jr.: Letter re Administrative Record and Meet and Confer on Melinda Wharton

Isaac,

Plaintiffs would like to speak to and depose Melinda Wharton. Based on the government's previous objection to Plaintiffs speaking to and deposing Drs. Monarez and Daskalakis, I assume that the government objects both to Plaintiffs speaking to and deposing Dr. Wharton absent court permission. Please confirm. Please also let me know if I may represent in a motion that Plaintiffs have satisfied their obligation to meet and confer on the deposition of Melinda Wharton.

Thank you.

Jimmy

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From: James J. Oh
Sent: Friday, November 7, 2025 12:56 PM
To: Belfer, Isaac C. <isaac.c.belfer@usdoj.gov>; Fitzgerald, Michael (USAMA) <michael.fitzgerald2@usdoj.gov>
Cc: Kathleen Barrett <KBarrett@ebglaw.com>; Richard H. Hughes IV <RHHughes@ebglaw.com>; Robert Wanerman <rwanerman@ebglaw.com>
Subject: AAP, et al. v. RFK, Jr.: Letter re Administrative Record

Isaac and Michael,

Please see the attached letter and please let me know if you can meet and confer on Monday or Tuesday of next week.

Thank you.

Jimmy

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EXHIBIT 5

InsideHealthPolicy
An Inside Washington news service

Former ACIP Members Criticize Abandonment Of Scientific Process

By Jessica Karins / October 24, 2025 at 5:20 PM

Post Share

Two former members of CDC's vaccine advisory panel say in a Wednesday (Oct. 22) article the committee has largely disregarded evidence processes they helped develop that were intended to "prevent exactly what happened at the first 2 meetings this year: presentation of anecdotes, selective quoting of single studies, and a lack of in-depth evaluation of some of the evidence presented."

The article by former ACIP members was published Wednesday (Oct. 22) in the *Journal of the American Medical Association* by Doug Campos-Outcalt of the University of Arizona College of Medicine and Jonathan Temte of the University of Wisconsin School of Medicine and Public Health. They call on the new ACIP members hand-tapped by HHS Secretary Robert F. Kennedy Jr. to explain why they are overhauling long-standing ACIP processes.

Robert Malone, one of the members of the Advisory Committee for Immunization Practices (ACIP) appointed by Kennedy earlier this year after its previous membership was dismissed, recently indicated at a conference hosted Patriots for Europe, a far-right bloc in the European Parliament, more major changes to vaccine policy are coming, including a full reexamination of the U.S. vaccine schedule. Malone is scheduled to speak next week at another conference in the Netherlands alongside far-right and anti-vaccine figures.

ACIP is starting up a new work group that will revisit the childhood and adolescent vaccination schedules and consider anti-vaccine talking points such as whether aluminum adjuvants are harmful and whether coadministration of vaccines increases risks of adverse events.

Retsef Levi, another new member of ACIP who is heading the panel's COVID-19 work group, appeared Oct. 16 on a podcast hosted by React 19, a group for patients who believe they were injured by COVID-19 vaccines. The podcast's host asked how Levi approaches ACIP meetings "already knowing the (CDC scientists') data you have is either incomplete or simply wrong."

Levi agreed data from CDC about COVID-19 vaccines and vaccine injuries is unreliable, saying members of the work group have "deep commitments" to addressing vaccine injuries, many of which he said are not captured by vaccine surveillance systems.

Asked about a recent National Academies report that found CDC vaccine surveillance worked well during the COVID-19 pandemic, Levi said he hadn't read the report but believes CDC is failing to identify people with vaccine injuries. He said the new members of ACIP are not just focused on making recommendations for or against vaccines -- the panel's statutory role -- but will aim to figure out how to diagnose and support vaccine injuries, including, he said, injuries that may occur long after vaccination.

Levi also suggested government insurance programs should cover treatments some patients believe are helpful for vaccine injuries but which have not received support from mainstream medicine, including intravenous immunoglobulin treatment.

The former ACIP officials who authored the new journal article were instrumental in setting ACIP's previous standards that they say are now being discounted. 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.

"Since 2010, decisions about new vaccines have, with rare exceptions, been accompanied by a set of 5 tables, developed by multidisciplinary work groups, that include a clear description of the outcomes assessed (benefits and harms), the results of a comprehensive search of relevant databases, a list describing all of the data included in the review, an assessment of potential biases of each study, a meta-analysis of all included studies with quantification of observed benefits and harms, and an overall rating of the quality of the evidence," Campos-Outcalt and Temte wrote.

That information was provided to all ACIP members prior to each vote and posted on the ACIP website.

Beginning in 2019, ACIP adopted an Evidence to Recommendation (ETR) process that included information on the magnitude of the public health problem being addressed, costs and benefits, feasibility, views of community and professional stakeholders, and effects on equity in addition to efficacy and safety. Documents describing each consideration were produced and posted on ACIP's website.

"Every step and decision has been completely transparent to clinicians, researchers, and the public at large," the former members wrote, and training was provided to new ACIP members on the GRADE and ATR processes.

Campos-Outcalt and Temte said the previous processes have been largely abandoned by the new ACIP members appointed by Kennedy.

"Much attention has been focused on the new members and potential conflicts of interest. Much less attention has been focused on the processes used by the committee to make decisions," they wrote. "There have been 4 major decisions made in those 2 meetings. Two did not involve any work group deliberations. Two were not accompanied by a description of the methods used to gather and assess the information presented. No ETR documents were provided at the meetings or in advance for committee and public consideration, and only 2 decisions were based on a GRADE assessment of the quality of the evidence."

The former ACIP members said the new members do not appear to have received training on ACIP policies and processes and CDC staff have not consistently followed them, likely as a result of high turnover of staff at the agency.

"The evidence-based processes used by the ACIP were adopted to prevent exactly what happened at the first 2 meetings this year: presentation of anecdotes, selective quoting of single studies, and a lack of in-depth evaluation of some of the evidence presented," Temte and Campos-Outcault wrote. "If the newly constituted ACIP does not want to continue the evidence-based process used for the past 15 years, it should explain why and what it intends to replace the current process with. To be credible, this should be consistent and transparent and meet IOM standards. Lacking this, future ACIP recommendations will likely not be endorsed by professional medical organizations, leading to contradictory recommendations, public confusion, increased vaccine hesitancy, and, ultimately, increased rates of vaccine-preventable infections." -- *Jessica Karins* (jkarins@iwpnews.com)

151522

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