

**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' Response to Plaintiffs' Supplemental Declarations

As the Court permitted, Defendants hereby respond to Plaintiffs' three new declarations. ECF Nos. 242, 243, 244. The fear of Drs. Kressly and Berman that the vaccines recommended based on shared clinical decision-making will be removed from the Vaccines for Children ("VFC") Program is purely speculative and unable to establish irreparable harm. And the outreach from a private party to Dr. Zuckerman about potential interest in serving on the Advisory Committee on Immunization Practices ("ACIP") does not constitute a violation of the Federal Advisory Committee Act of 1972 ("FACA"). Thus, these declarations do not establish that Plaintiffs are entitled to preliminary relief.

During the hearing, the Court also invited further submissions regarding the ACIP Membership Balance Plan. The Membership Balance Plan is not required by law, and the Secretary was not required to follow it in selecting ACIP members. As Defendants demonstrated in their opposition to Plaintiffs' preliminary injunction motion, Plaintiffs are not likely to succeed on their FACA claim.

I. The New Declarations Do Not Support Preliminary Relief

Plaintiffs primarily rely on their new declarations to claim irreparable harm based on a

fear that certain vaccines will be removed from the VFC Program. ECF No. 243, ¶ 5; ECF No. 244, ¶ 3. Under the VFC Program, the federal government purchases doses of vaccines and distributes them to states and localities for distribution to healthcare providers, who then administer the vaccines to eligible children free-of-charge.

A two-step process determines which vaccines are available through the VFC Program. First, ACIP passes a resolution to include a vaccine in VFC, separate from the vote to recommend the vaccine (which recommendations are reviewed by the CDC Director and, if adopted, are published as official CDC/HHS recommendations, *see* ACIP Charter, <https://perma.cc/8W76-JTTS> (Dec. 3, 2025)). *See, e.g.*, ACIP, June 25–26, 2025 ACIP Meeting Summary, at 48–49, <https://perma.cc/WEP5-K2LD> (separate ACIP votes for RSV vaccine recommendation and for RSV vaccine VFC resolution).

Second, CDC uses the ACIP’s VFC resolutions “for the purpose of the purchase, delivery, and administration of pediatric vaccines” under the VFC Program. 42 U.S.C. § 1396s(e); *see also* ACIP Charter, *supra*. Specifically, the agency enters into contracts with vaccine manufacturers to purchase the vaccines identified by the ACIP’s resolutions. 42 U.S.C. § 1396s(d)(1). The agency has discretion, however, to “decline to enter into such contracts and may modify or extend such contracts.” *Id.* § 1396s(d)(2). A vaccine is considered a “qualified pediatric vaccine” covered by the VFC Program only if “a contract is in effect” for the agency to purchase that vaccine. *Id.* § 1396s(h)(8).

The new Kressly and Berman declarations focus on VFC coverage for the vaccines currently recommended based on shared clinical decision-making: hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19. ECF No. 243, ¶ 5; ECF No. 244, ¶ 3; ECF No. 185-18, at 8. Each of these vaccines has a VFC resolution from the ACIP in place.

See CDC, *Vaccines Provided by the VFC Program*, <https://perma.cc/ES7Y-HXXD>. And CDC currently has contracts with vaccine manufacturers to purchase these vaccines for the VFC Program. See CDC, *Pediatric/VFC Vaccine Price List* (Jan. 27, 2026), <https://perma.cc/DR3Z-DB7Y>; CDC, *Pediatric Influenza Vaccine Price List* (Jan. 27, 2026), <https://perma.cc/HQ9N-NG9F>; CDC, *Pediatric COVID-19 Vaccine Price List* (Jan. 27, 2026), <https://perma.cc/MHH9-MCVU>; see also CDC, *Current CDC Vaccine Price List* (Jan. 1, 2026), <https://perma.cc/RS24-GCJV>. Thus, as the January 2026 decision memorandum explained, all these vaccines “continue to be covered” by “the Vaccines for Children Program.” ECF No. 185-18, at 2–3; see HHS, *Fact Sheet: CDC Childhood Immunization Recommendations*, <https://perma.cc/DSL3-HWAJ> (last reviewed Jan. 5, 2026).

The new declarations express “concern[.]” that, at an ACIP meeting scheduled for February 25–27, 2026, ACIP will “remove” the vaccines recommended based on shared clinical decision-making “from the VFC program entirely.” ECF No. 243, ¶ 5; see ECF No. 244, ¶ 3. However, “irreparable harm must be grounded on something more than conjecture, surmise, or a party’s unsubstantiated fears of what the future may have in store.” *Charlesbank Equity Fund II v. Blinds To Go, Inc.*, 370 F.3d 151, 162 (1st Cir. 2004); see *City of Lowell v. Enel N. Am., Inc.*, 705 F. Supp. 2d 116, 120 (D. Mass. 2010) (requiring “evidence” of irreparable harm); see also *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 383 (2024) (no standing based on “speculative links” in the chain of causation).

Declarants’ concern arose from a “public statement[.]” made by ACIP Vice Chair Robert Malone that “the ACIP will need to vote during their next meeting to approve language aligning the Congressionally mandated Vaccines for Children program with the new schedule.” ECF No. 243, ¶ 3. It is not clear what Dr. Malone meant by “aligning” the VFC Program with the CDC

immunization schedule. In any event, the ACIP’s VFC resolutions are not required to match CDC’s immunization schedule. ACIP may take no action on VFC coverage at the February meeting, leaving in place its existing VFC resolutions. Moreover, contrary to Dr. Kressly’s suggestion, the list of vaccines covered by the VFC Program does not automatically update to “align” with new CDC vaccine recommendations. *Id.*, ¶ 4.

Next, Dr. Kressly speculates that “the agenda for the February ACIP meeting, when it is published, will include that ACIP will consider a vote related to the [VFC] program.” ECF No. 243, ¶ 3. But the agenda for the February ACIP meeting has not yet been set, so it is speculative whether it will include a vote, or even discussion, about VFC resolutions. And even if the ACIP voted to “align[]” its VFC resolutions with the current immunization schedule, there is no indication that would involve “remov[ing]” the vaccines recommended based on shared clinical decision-making “from the VFC program entirely.” ECF No. 243, ¶ 5; *see* ECF No. 244, ¶ 3. After all, CDC did not remove those vaccines from the schedule; it simply recategorized them from “Immunizations Recommended for All Children” to “Immunizations Based on Shared Clinical Decision-Making.”¹

“Vaccines provided through the VFC Program must be administered according to the guidelines outlined by the [ACIP] in VFC Program resolutions.” *Vaccines Provided by the VFC Program, supra.*² Those guidelines can include recommendations that vaccines be administered through shared clinical decision-making. For example, the ACIP’s VFC resolution for vaccines to prevent meningococcal disease states that “[c]hildren aged 16 through 18 years who are not at

¹ Several vaccines were moved to the “shared clinical decision-making” category before January 2026. The COVID-19 vaccine was moved in October 2025, and the hepatitis B vaccine was moved in December 2025.

² Providers may also administer VFC Program vaccines “according to State school attendance laws.” *Vaccines Provided by the VFC Program, supra.*

increased risk for serogroup B meningococcal disease may also be vaccinated when shared clinical decision-making favors administration of” serogroup B meningococcal vaccines. ACIP, Resolution No. 04/25-1, *Vaccines for Children Program: Vaccines to Prevent Meningococcal Disease*, at 3 (Apr. 16, 2025), <https://perma.cc/VS3G-95PS>. It further provides that “[c]hildren aged 16 through 18 years for whom both [Meningococcal Conjugate Vaccines] and [Serogroup B Meningococcal Vaccines] are indicated to be given at the same time and shared clinical decision-making favors administration of MenB vaccine” are eligible to receive the combination pentavalent serogroup A, C, W, Y, and B meningococcal vaccine. *Id.* at 4.

Thus, the shared clinical decision-making recommendation for the hepatitis A, hepatitis B, rotavirus, meningococcal disease, influenza, and COVID-19 vaccines does not necessarily mean those vaccines should be “remove[d]” from “the VFC program entirely.” ECF No. 243, ¶ 5; *see* ECF No. 244, ¶ 3. Instead, as in the existing VFC resolution for vaccines to prevent meningococcal disease, these vaccines can be included in the VFC Program with resolutions recommending shared clinical decision-making. Because the Kressly and Berman declarations offer only “conjecture, surmise, [and the declarants’] unsubstantiated fears” that these vaccines will be removed from the VFC Program, they do not show irreparable harm. *Charlesbank Equity Fund II*, 370 F.3d at 162; *see Enel N. Am.*, 705 F. Supp. 2d at 120; *see also All. for Hippocratic Med.*, 602 U.S. at 383.

The declarations are also deficient for several additional reasons. Plaintiffs cannot show irreparable harm by speculating about what documentation ACIP may provide in support of hypothetical future VFC resolutions. ECF No. 244, ¶¶ 7–8. The declarations also rely on alleged harms to third parties, such as “VFC-eligible children,” ECF No. 243, ¶ 6, and to abstract notions, such as “equity” and “the broader public health infrastructure,” *id.* ¶¶ 8, 10. Yet only

“irreparable harm to the movant rather than to one or more third parties” counts. *CMM Cable Rep., Inc. v. Ocean Coast Props., Inc.*, 48 F.3d 618, 622 (1st Cir. 1995). Similarly, the Kaiser Family Foundation poll regarding “trust in the CDC,” ECF No. 243, ¶ 13, does not show “irreparable harm to the movant,” *CMM Cable Rep.*, 48 F.3d at 622. Nor is it relevant to Plaintiffs’ likelihood of success on the merits, which must be evaluated based on “the information available to the agency when it made the [challenged] decision.” *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 547 (1978); see *Berkey Int’l, LLC v. EPA*, No. CV 24-1106 (CVR), 2024 WL 3517721, at *2–3 (D.P.R. July 24, 2024).

Finally, the Zuckerman Declaration purports to describe the process by which new ACIP members were selected. ECF No. 242. Assuming solely for purposes of argument some connection between the private party’s outreach to Dr. Zuckerman and the Secretary, this would not show a violation of FACA. FACA does not prescribe the process by which advisory committee members are identified and vetted. All that matters is that the advisory committee “be fairly balanced” and not “inappropriately influenced by the appointing authority or by any special interest.” 5 U.S.C. § 1004(b)(2)–(3), (c). As discussed in Defendants’ opposition to Plaintiffs’ preliminary injunction motion, the ACIP’s current membership amply satisfies FACA’s requirements. ECF No. 232 at 24–30. Thus, the Zuckerman Declaration does not show Plaintiffs are likely to succeed on their FACA claim.

II. Plaintiffs Have Not Shown Any Violation of Law Based on the ACIP Membership Balance Plan

During Friday’s hearing, the Court also asked several questions about the legal effect of the ACIP Membership Balance Plan and whether it might support an Administrative Procedure Act (“APA”) claim. Neither FACA nor any Department of Health and Human Services regulation requires membership balance plans. Rather, such plans emanated from policy guidance of the

General Services Administration (“GSA”) to other agency heads about how to implement FACA. *See* 41 C.F.R. §§ 102-3.5 and 102-3.60 (July 1, 2025 ed.).

Among other things, GSA asked agencies to prepare, for each advisory committee, a plan for “attain[ing] fairly balanced membership” and then upload that plan to GSA’s FACA database. *Id.* § 102-3.60(b)(3) (July 1, 2025 ed.). But in so doing, GSA expressly did not “create any right . . . , substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies or entities.” *Id.* § 102-3.5 (July 1, 2025 ed.). Furthermore, although published in the Code of Federal Regulations, GSA’s FACA “guidelines” did not “carry[] the force of law.” *Pub. Citizen v. U.S. Dep’t of Just.*, 491 U.S. 440, 465 n.12 (1989). Thus, even if the Secretary deviated from the process set forth in the ACIP Membership Balance Plan for identifying candidates when he appointed new members starting in June 2025, that would not constitute a violation of any binding regulation, FACA, or the APA.

At the hearing, Plaintiffs directed the Court to the discussion of a membership balance plan in *Western Organization of Resource Councils v. Bernhardt*, 412 F. Supp. 3d 1227 (D. Mont. 2019). But that case misunderstood GSA to dictate what “an agency is required to” do, *id.* at 1238, and thereby neglected the Supreme Court’s admonition that GSA “guidelines” do not “carry[] the force of law,” *Pub. Citizen*, 491 U.S. at 465 n.12. If anything, a membership balance plan is akin to an internal guidance document about advisory committee management, which *Bernhardt* ruled “cannot provide a basis for” a FACA or APA “claim.” 412 F. Supp. 3d at 1237.

Furthermore, effective December 15, 2025, GSA no longer asks agencies to prepare or submit membership balance plans. *See* 90 Fed. Reg. 58,408, 58,408 (Dec. 16, 2025) (revising 41 C.F.R. Part 102-3 by “removing portions of the regulation that are not required by statute and removing outdated provisions”). GSA now advises agencies simply to “make informed decisions

on the areas of expertise or perspectives that would advance the work of the advisory committee.” 41 C.F.R. § 102-3.60(b) (as of Feb. 12, 2026). That removes any possible argument by Plaintiffs that the Secretary’s discretion to identify and appoint ACIP members is subject to any legal constraints besides those in FACA itself.

But even if the Secretary’s deviation from the Membership Balance Plan violated FACA and the APA, the Court still must take “due account . . . of the rule of prejudicial error.” 5 U.S.C. § 706. Although the Membership Balance Plan set out procedures for identifying potential candidates, the Secretary retained discretion to decide whom to appoint, including individuals who were not identified through those precise procedures. And “[t]here is no reason to think that” the Secretary would have exercised his statutory discretion to appoint to ACIP anyone other than whom he ultimately selected. *Ali v. United States*, 849 F.3d 510, 515 (1st Cir. 2017). Accordingly, Plaintiffs cannot show “how their preferred procedure” for identifying candidates under the Membership Balance Plan—a concept now abandoned by GSA—“would have made any difference,” as necessary to prevail on their APA claim. *Id.*

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For these reasons, and those stated in Defendants’ opposition, ECF No. 232, and at the preliminary injunction hearing, the Court should deny Plaintiffs’ preliminary injunction motion.

February 18, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

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February 18, 2026

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