

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

vs.

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

Defendants.

Case No. 1:25-cv-11916 (BEM)

**PLAINTIFFS' SUPPLEMENTAL BRIEF ON THE LEGAL CONSEQUENCES
OF THE JANUARY 5, 2026, ACTION CHANGING
THE CDC'S CHILDHOOD IMMUNIZATION SCHEDULE**

I. INTRODUCTION

In ECF No. 241, the Court noted that the parties could “file additional briefing regarding the legal consequence of the January guidance no later than February 18, 2026.” Advisory Committee on Immunization Practices (“ACIP”) Vice-Chair Robert Malone has publicly stated “the ACIP will need to vote during their next meeting to approve language aligning the Congressionally mandated Vaccines for Children Program [VFC] with the new schedule.”¹ As of the filing of this brief, no agenda has been posted for the next ACIP meeting, which is currently scheduled to begin one week from today, on February 25, 2026, and run through February 27, 2026.² If an agenda is posted after this brief is filed, Plaintiffs anticipate that the agenda will

¹ Robert W. Malone, HHS, CDC to Make Announcement on Children’s Health Tomorrow, SUBSTACK (Dec. 18, 2025) <https://www.malone.news/p/hhs-cdc-to-make-announcement-on-childrens> [<https://perma.cc/Z7J7-T2VX>]; *see also* Second Suppl. Decl. Susan J. Kressly, M.D., FAAP, ECF No. 243, ¶¶ 3–11, Feb. 17, 2026.

² Advisory committee meeting notices “must be published [in the Federal Register] at least 7 calendar days prior to an advisory committee meeting.” 41 C.F.R. § 102-3.150(a).

include a vote on the VFC program to, as Dr. Malone indicated, align the VFC list of covered immunizations (“VFC List”) with the Centers for Disease Control and Prevention’s (“CDC”) Childhood and Adolescent Immunization Schedule (the “Childhood Schedule”). Aligning the VFC List with the Childhood Schedule would mean downgrading the following immunizations on the VFC List from “routine” to “non-routine”: hepatitis A, hepatitis B, rotavirus, influenza, and meningococcal. The Covid-19 vaccine has already been classified as non-routine in the VFC Operations Guide. Downgrading these immunizations on the VFC List threatens the public interest because it will cut off access to these immunizations for many children covered under the VFC program. In addition, because the ACIP Vice Chair has forecasted a vote to align the VFC List with the Childhood Schedule at the next ACIP meeting, health care providers have had to plan for this eventuality and, as a result, have been irreparably harmed.

II. THE VFC PROGRAM

The VFC program is a federally funded entitlement program created by Congress in 1993. 42 U.S.C. § 1396s. Congress established this program in response to measles outbreaks linked to under-immunization of children due to cost barriers. The VFC program provides vaccines recommended by the ACIP at no cost to VFC-eligible children.³ The Office of Management and Budget (“OMB”) approves funding for the VFC program. The Centers for Medicare and Medicaid Services (“CMS”) then makes those funds available to the CDC to procure vaccines from manufacturers at a negotiated or discounted rate and supplies them to VFC-program awardees for distribution.⁴ Program awardees (63 state, local, and territorial immunization programs) operate

³ *About the Vaccines for Children (VFC) Program*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 30, 2025), <https://www.cdc.gov/vaccines-for-children/about/index.html> [<https://perma.cc/5MZ7-YPMT>].

⁴ CTRS. FOR DISEASE CONTROL & PREVENTION, *VFC Operations Guide (July 1, 2025 - June 30, 2026)* 15 (2025), <https://www.cdc.gov/vaccines-for-children/media/pdfs/2025/07/vfc-ops-guide-508.pdf> [<https://perma.cc/E4L3-B86A>].

and oversee the VFC program, including provider enrollment, vaccine distribution, and program administration.⁵

The VFC statute, 42 U.S.C. § 1396s, establishes patient eligibility criteria and provider enrollment parameters. VFC-eligible children are defined as children 17 years of age or younger who are Medicaid-eligible, uninsured, underinsured,⁶ or American Indian or Alaska native. 42 U.S.C. § 1396s(b). Nearly half of all children in the United States are VFC-eligible.⁷ Providers who wish to participate in the VFC program must enroll with their state, local, or territorial immunization program and sign a VFC Provider Agreement that sets forth federal and state VFC program requirements that include specific storage and handling standards for vaccines procured through the VFC program, inventory tracking, screening and documentation of patient eligibility, and periodic program audits.⁸ Providers must also comply with the immunization schedule set and revised by the ACIP “regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines” 42 U.S.C. § 1396s(c). Children, and their parents, do not

⁵ *Id.* at 15–16.

⁶ Underinsured means that the child has health insurance, but the insurance policy does not cover vaccines generally, does not cover recommended vaccines, does not provide first-dollar coverage for vaccines (e.g., requires a deductible for recommended vaccines), or does cover vaccines but has a fixed dollar limit for payment. Underinsured children may only be vaccinated under the VFC program at Federally Qualified Health Centers. *See Vaccines for Children (VFC) Program: Information for Parents*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 30, 2025), <https://www.cdc.gov/vaccines-for-children/vfc-information-for-parents/index.html> [<https://perma.cc/NV7V-FMKV>].

⁷ Allyson Crays et al., *Kids Lose When Vaccine Coverage Rules Are Unclear—Understanding Recent Changes in Federal Vaccine Guidance*, THE COMMONWEALTH FUND (Jan. 29, 2026), <https://www.commonwealthfund.org/blog/2026/kids-lose-when-vaccine-coverage-rules-are-unclear>.

⁸ CTRS. FOR DISEASE CONTROL & PREVENTION, *VFC Operations Guide (July 1, 2025 - June 30, 2026)* (2025), <https://www.cdc.gov/vaccines-for-children/media/pdfs/2025/07/vfc-ops-guide-508.pdf> [<https://perma.cc/E4L3-B86A>].

need to show proof of eligibility.⁹ Providers may not charge patients for the vaccine itself, but they may charge a nominal administration fee that is capped by the state immunization program.¹⁰

The VFC statute incorporates reliance on the ACIP to establish which immunizations are covered under the statute: “[t]he Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices.” 42 U.S.C. § 1396s(e). When the ACIP votes on the recommended use for a new vaccine or a change in recommended use, the ACIP votes on a VFC resolution to update the VFC List per the VFC Operations Guide.¹¹ Providers must adhere to a VFC resolution that the ACIP passes.

The VFC Operations Guide provides comprehensive, detailed guidance to immunization programs and VFC-enrolled providers about the day-to-day administration of the program and expectations for provider participation.¹² The VFC Operations Guide treats non-routine vaccines, including those recommended under shared clinical decision-making (“SCDM”), differently from routinely recommended vaccines.¹³ In particular, providers are required to stock and offer all routinely recommended vaccines on the VFC List. They are not, however, required to stock non-routine vaccines on the VFC List. The Guide permits providers to order such non-routine vaccines based on anticipated need rather than as part of their core, required inventory.¹⁴

⁹ See *Vaccines for Children (VFC) Program: Information for Parents*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 30, 2025), <https://www.cdc.gov/vaccines-for-children/vfc-information-for-parents/index.html> [<https://perma.cc/NV7V-FMKV>].

¹⁰ See *id.*; *Vaccines for Children (VFC) Program: Information for Providers*, CTRS. FOR DISEASE CONTROL & PREVENTION (Sept. 30, 2025), <https://www.cdc.gov/vaccines-for-children/hcp/information-for-providers/index.html> [<https://perma.cc/UYP9-7DPH>].

¹¹ CTRS. FOR DISEASE CONTROL & PREVENTION, *VFC Operations Guide (July 1, 2025 - June 30, 2026)* (2025), <https://www.cdc.gov/vaccines-for-children/media/pdfs/2025/07/vfc-ops-guide-508.pdf> [<https://perma.cc/E4L3-B86A>].

¹² See *id.*

¹³ See *id.*

¹⁴ See *id.*

Historically, the ACIP has voted on VFC resolutions when a new vaccine is being introduced into the U.S. market or when the ACIP has voted on modifications to recommendations for how a vaccine is administered. For example, at the June 21–23, 2023 ACIP meeting, presentations were made on “economic analysis and public health impact of PCV20 use in children...; a comparison of cost-effectiveness analyses on PCV20 use in children...; and a summary of the [Work Group’s] interpretation on EtR and policy options...” The ACIP then took five votes on the pneumococcal vaccines, with the first vote being on “Routine PCV Use for All Children aged 2–23 months,” which passed 14–0. The fifth vote was a “VFC Resolution” vote to “[a]pprove the Vaccines for Children (VFC) resolution for pneumococcal pneumonia,” which also passed 14–0.¹⁵

For another example, in February 2024, the sole U.S.-based manufacturer of a vaccine against tetanus and diphtheria (“Td”) discontinued making this vaccine, which the ACIP anticipated would lead to “the supply of Td vaccine in the US market . . . be[ing] constrained during 2024.”¹⁶ With the sole U.S.-based Td vaccine manufacturer leaving the market, only one manufacturer of a US-licensed Td vaccine remained and was taking steps to augment the available supply of Td vaccines in the U.S. At that time, the routine vaccination schedule for children recommended a primary series of the pediatric diphtheria-, tetanus-, and pertussis-containing

¹⁵ CTRS. FOR DISEASE CONTROL & PREVENTION, *Meeting of the Advisory Committee on Immunization Practices (ACIP), June 21–23, 2023 Meeting Summary*, 41–44 (2025), <https://www.cdc.gov/acip/downloads/minutes/summary-2023-06-21-23-508.pdf> [<https://perma.cc/AW2M-HKEL>]; *Advisory Committee on Immunization Practices, Vaccines For Children Program, Vaccines To Prevent Pneumococcal Disease*, CTRS. FOR DISEASE CONTROL & PREVENTION (Jul. 2023), <https://www.cdc.gov/vaccines-for-children/downloads/06-23-2-pneumo-508.pdf> [<https://perma.cc/23UW-LZZ7>].

¹⁶ CTRS. FOR DISEASE CONTROL & PREVENTION, *Meeting of the Advisory Committee on Immunization Practices (ACIP), February 28–29, 2024 Meeting Summary*, 27–28 (2024), <https://www.cdc.gov/acip/downloads/minutes/summary-2024-02-28-29-508.pdf> [<https://perma.cc/4US3-T87L>]; *Advisory Committee on Immunization Practices, Vaccines For Children Program, Vaccines To Prevent Diphtheria, Tetanus And Pertussis*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 2024), <https://www.cdc.gov/vaccines-for-children/downloads/DTaP-508.pdf> [<https://perma.cc/5JZ5-K9NN>].

vaccines (DTaP) for children < 7 years of age. The DTaP vaccines were included on the VFC List. For children < 7 years of age who developed a contraindication to pertussis-containing vaccines, the Td vaccine was recommended instead, but the Td vaccine was not included on the VFC List. Accordingly, at the February 28–29, 2024 ACIP meeting, the ACIP voted on a VFC resolution titled “Vaccines for Children Program to Prevent Diphtheria, Tetanus and Pertussis,” with the purpose of the resolution being “to (1) add Td vaccine for use in children < 7 years of age for whom receipt of the pertussis component is contraindicated and to (2) update the language regarding the Tdap booster to align with ACIP recommendations.”¹⁷ Adding Td to the VFC List ensured that the small, high-need group of children for whom pertussis-containing vaccine was contraindicated would be able to get the Td vaccine through the VFC program.

III. The Harm To VFC Providers from the January 5 Action and Other Downgrades of Immunizations to SCDM.

In July 2025, the CDC updated the 2025–2026 VFC Operations Guide to reflect that the Covid-19 vaccine for children was no longer a routine vaccine but instead was a non-routine vaccine.¹⁸ Prior to May 2025, no childhood vaccine on the VFC list had been downgraded in this manner. Defendants downgraded five other immunizations on the Childhood Schedule from routine to SCDM on January 5, 2026.

The harms to VFC providers like Dr. Suzanne Berman, who owns a pediatric practice in rural Tennessee, are immediate. As she attests in her second supplemental declaration (ECF No.

¹⁷ *Advisory Committee on Immunization Practices, Vaccines For Children Program, Vaccines To Prevent Diphtheria, Tetanus And Pertussis*, CTRS. FOR DISEASE CONTROL & PREVENTION (Feb. 2024), <https://www.cdc.gov/vaccines-for-children/downloads/DTaP-508.pdf> [<https://perma.cc/5JZ5-K9NN>].

¹⁸ *Compare CTRS. FOR DISEASE CONTROL & PREVENTION VFC Operations Guide (July 1, 2024 - June 30, 2025)* (2024), <https://www.cdc.gov/vaccines-for-children/media/pdfs/2025/07/vfc-ops-guide-508.pdf> [<https://perma.cc/VVH3-LEAH>] *with CTRS. FOR DISEASE CONTROL & PREVENTION, VFC Operations Guide (July 1, 2025 - June 30, 2026)* (2025), <https://www.cdc.gov/vaccines-for-children/media/pdfs/2025/07/vfc-ops-guide-508.pdf> [<https://perma.cc/E4L3-B86A>].

244, ¶¶ 3–5), if the ACIP votes at its next meeting to “align” the VFC List with the Childhood Schedule:

The consequences of such a vote would be immediate. VFC providers may not administer federally supplied vaccine outside the VFC program. If these vaccines are removed from the program, my practice must immediately stop using VFC inventory for those vaccines. That would require us either to cease offering the vaccines to Medicaid-insured children or to purchase private stock at our own expense.

Vaccine procurement is not instantaneous. It requires advance ordering, minimum purchase quantities, and upfront payment. Because the February ACIP Meeting is imminent and the agenda remains unpublished, I must divert my time and resources to make purchasing decisions now without knowing whether these vaccines will remain covered under VFC. That uncertainty itself is disruptive to me and my practice. If I reduce orders to limit financial exposure, I risk shortages for children who present for vaccination in the coming weeks. If I purchase additional private inventory in anticipation of removal from VFC, I assume significant financial risk that cannot later be undone.

If vaccines are removed from VFC, Medicaid reimbursement mechanisms are unlikely to immediately absorb those costs at market rates. Many vaccines cost my practice \$100, \$200, or more per dose outside the VFC program. My experience with non-VFC vaccines demonstrates that Medicaid reimbursement frequently falls below acquisition cost. For example, a vaccine costing \$120 to acquire may be reimbursed at \$80; a vaccine costing \$30 may be reimbursed at \$20. When multiplied across a high-volume pediatric population, those losses compound rapidly. If vaccines are removed from VFC following the February ACIP Meeting, each administration to a Medicaid-insured child would generate a direct financial loss. Those losses cannot later be recovered from families due to federal billing restrictions—as a Medicaid-participating provider, I am prohibited from charging Medicaid families more than a nominal copay. They also cannot realistically be recouped through retroactive reimbursement adjustments. Once vaccine inventory is purchased or administered at a loss, the financial harm is complete.

An ACIP vote to align the VFC List with the Childhood Schedule will further erode trust in pediatricians who are members of the American Academy of Pediatrics and puts those physicians in an ethical dilemma:

These changes create direct harms to VFC providers because they prevent us from doing what we know we are ethically obligated to do to: follow the science and protect the child. If the organization a physician works for can no longer provide the downgraded vaccines through the VFC program, the physician may

be unable to provide these vaccines to VFC-eligible families who want to be vaccinated. That breaks the promise to treat the child to the best of our ability. It also goes against HHS's insistence that "[n]o family will lose access." These issues erode families' trust in their physicians and in our public health systems.

Removing downgraded vaccines from the VFC program will create a serious equity problem. VFC providers are required to maintain separate inventories of VFC-supplied and privately purchased vaccines. If a vaccine is no longer available through the VFC program but is available to privately insured patients, children seen in the same practice will face different access to that vaccine solely based on their insurance coverage status: privately insured children can receive the vaccine without cost-sharing, while VFC-eligible patients will be forced to pay out of pocket. That forces pediatricians to provide a different level of care to different populations, which is professionally and ethically untenable.

Second Suppl. Decl. Susan J. Kressly, M.D., FAAP ¶¶ 7–8, ECF No. 243.

Participation in the VFC program entails substantial economic and administrative burdens for providers, as detailed above. Even without an ACIP vote, if the January 5 Childhood schedule changes remain in place, then VFC providers are no longer required to stock these vaccines per the VFC Operations Guide.¹⁹ Many will predictably choose not to carry them, and some may reconsider whether to remain enrolled in VFC at all. In addition to reducing access to downgraded vaccines for low-income children, this shifts workload and expense onto providers who choose to stay in the VFC-program. Remaining VFC-providers will shoulder higher uncompensated administrative work, more time-intensive counseling under SCDM across a growing set of vaccines, added inventory and ordering unpredictability and complexity, and greater financial pressure because VFC administration fees are capped and do not cover staffing time, storage, and other compliance costs. Second Suppl. Decl. Susan J. Kressly, M.D., FAAP §§ 9-11, ECF No. 243.

¹⁹ CTRS. FOR DISEASE CONTROL & PREVENTION, *VFC Operations Guide (July 1, 2025 - June 30, 2026)* (2025) 91, <https://www.cdc.gov/vaccines-for-children/media/pdfs/2025/07/vfc-ops-guide-508.pdf> [<https://perma.cc/E4L3-B86A>]

IV. Irreparable Harm

The January 5, 2026, final agency action to change the CDC's Childhood Schedule (the "January 5 Action") has and will continue to cause irreparable harm if that action is not set aside. The Plaintiff organizations and their individual members are suffering harm now because they have already expended resources to plan for what Defendants have forecast is coming at the next ACIP meeting. *See Washington v. United States Dept. of Health and Human Services*, 2025 WL 3002366, at *23 (D. Or. Oct. 27, 2025) ("A threat of public harm is sufficiently immediate to warrant preliminary injunctive relief if the plaintiff is likely to suffer irreparable harm before a decision on the merits can be rendered." (citation modified)). Courts around the country have held that "[a]gency actions that increase public health risks may result in irreparable harm. *See, e.g., Washington*, 2025 WL 3002366 at *28 (granting preliminary injunction and finding irreparable harm resulting from "a significantly impaired ability to protect the public health"); *State v. Bureau of Land Mgmt.*, 286 F.Supp.3d 1054, 1074 (N.D. Cal. 2018) (finding irreparable harm from agency rule that "will have irreparable consequences for public health") (citation omitted); *Cigar Masters Providence, Inc. v. Omni Rhode Island, LLC*, 2017 WL 4081899, at *14 (D.R.I. Sept. 14, 2017) ("Threats to public health and safety constitute irreparable harm that will support an injunction"); *Sierra Club v. Dep't of Agriculture, Rural Utils. Serv.*, 841 F.Supp.2d 349, 358 (D.D.C. 2012) (finding irreparable harm from agency action that increases public exposure to pollutants resulting in an increased threat to public health).

V. Conclusion

The January 5 Action was arbitrary and capricious, not in accordance with law, and was not committed to agency discretion. That action, in turn, has led to an imminent vote of the ACIP to change the VFC List to align with the Childhood Schedule. That vote would be tainted because it was the vote of a federal advisory committee that was constituted and that has been operating in

violation of the Federal Advisory Committee Act. The January 5 Action has caused and will continue to cause harm to the Plaintiffs and to public health. Accordingly, it should be set aside, and the next ACIP meeting enjoined.

Dated: February 18, 2026

Respectfully submitted,

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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 February 2026:

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as Secretary of Health and Human Services

Jim O'Neill, in his official capacity as Acting
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