No. 26-1503

UNITED STATES COURT OF APPEALS
FOR THE FIRST CIRCUIT

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, JANE DOE 2, and JANE DOE 3;

Plaintiffs-Appellees,

v.

ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; UNITED STATES FOOD & DRUG ADMINISTRATION; JAY BHATTACHARYA, in his official capacities as Director of the National Institutes of Health and as Acting Director of Centers for Disease Control and Prevention; NATIONAL INSTITUTES OF HEALTH; CENTERS FOR DISEASE CONTROL AND PREVENTION; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; KYLE DIAMANTAS, in the official capacity as Acting Commissioner of the Food and Drug Administration, DOES 1– 50, Inclusive,

Defendants-Appellants.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

Case No. 1:25-cv-11916

HON. BRIAN E. MURPHY

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CORPORATE DISCLOSURE STATEMENT

Plaintiffs-Appellees submit this Disclosure Statement pursuant to Federal Rules of Appellate Procedure 26.1:

1. Plaintiff–Appellee American Academy of Pediatrics is a nonprofit corporation, has no parent corporation, and no publicly held corporation owns any interest in the American Academy of Pediatrics.

2. Plaintiff–Appellee American College of Physicians has no parent corporation, and no publicly held corporation owns any interest in American College of Physicians.

3. Plaintiff–Appellee American Public Health Association is a 501(c)(3) nonprofit membership organization, has no parent corporation, and no publicly held corporation owns any interest in American Public Health Association.

4. Plaintiff–Appellee Infectious Diseases Society of America is a nonprofit corporation, has no parent corporation, and no publicly held corporation owns any interest in Infectious Diseases Society of America.

5. Plaintiff–Appellee Massachusetts Public Health Association is a nonprofit corporation, has no parent corporation, and no publicly held corporation owns any interest in Massachusetts Public Health Association.

6. Plaintiff–Appellee Society for Maternal-Fetal Medicine is a nonprofit corporation, has no parent corporation, and no publicly held corporation owns any interest in Society for Maternal-Fetal Medicine.

7. Plaintiff–Appellee Massachusetts Chapter of the American Academy of Pediatrics is a nonprofit corporation, is a member chapter of the American Academy of Pediatrics, and no publicly held corporation owns any interest in Massachusetts Chapter of the American Academy of Pediatrics.

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STATEMENT REGARDING ORAL ARGUMENT

The Government did not request oral argument in its opening brief. Plaintiffs-Appellees view oral argument as unnecessary. But if the Court concludes that argument would be helpful, Plaintiffs-Appellees would welcome the opportunity to defend the district court's stay order.

INTRODUCTION

For decades, the Advisory Committee on Immunization Practices ("ACIP") has served as the gold standard for evidence-based, transparent vaccine recommendations. The ACIP's role in providing advice and guidance regarding use of vaccines depends upon it being comprised of experts in the use of vaccines and immunologic agents in clinical practice or preventive medicine, public health, and other relevant topics. As a committee subject to the Federal Advisory Committee Act ("FACA"), it must be "fairly balanced in terms of the points of view represented and the functions to be performed." 5 U.S.C. §§ 1001, et seq.

Since his confirmation as Secretary of the United States Department of Health and Human Services ("HHS"), Defendant Robert F. Kennedy, Jr. (the "Secretary") along with HHS and the subagencies and officials acting under his leadership (collectively the "Government"), have taken deliberate actions to undermine the ACIP's role as a body of experts providing independent advice. This began on June 9, 2025, when the Secretary terminated all sitting members of the ACIP, each of whom had relevant subject-matter expertise and credentials. Since then, the Government has appointed new members that fail to meet the minimum requirements for expertise and fair balance set forth in the statute and in the ACIP's own operative Membership Balance Plan ("MBP") and charter.

The reconstituted ACIP promptly took actions that directly threaten public health. For example, the reconstituted ACIP voted to downgrade the recommendation for the hepatitis B ("HepB") vaccine, including the birth dose. ACIP's landmark 1991 recommendation to immunize all infants at birth for HepB reduced pediatric HepB cases by 99% (from 16,000 to fewer than 20 annually), preventing tens of thousands of cases of cirrhosis, liver cancer, and death.[1] Reverting to pre-1991 individual-based decision-making is likely to increase the incidence of infection and associated chronic disease and vaccine-preventable death.[2]

The Government's brief is notable for what it does not argue. It does not contend that the current ACIP is fairly balanced. Nor does it dispute that the challenged ACIP votes and changes to the recommended vaccine schedule are likely unlawful, arbitrary, and capricious. Instead, the Government challenges only the

[1] Melissa Jenco, *Report: Hepatitis B vaccine safe; delaying would lead to increased infections*, AM. ACAD. OF PEDIATRICS (Dec. 2, 2025), https://publications.aap.org/aapnews/news/33888/Report-Hepatitis-B-vaccine-safe-delaying-would?autologincheck=redirected (last visited July 16, 2026); *Dozens of Public Health and Policy Experts, Along with the American Public Health Association, Urge the CDC to Maintain Universal Newborn Hepatitis B Vaccination*, MILKEN INST. OF PUB. HEALTH (Dec. 2, 2025) https://publichealth.gwu.edu/dozens-public-health-and-policy-experts-along-american-public-health-association-urge-cdc-maintain [https://perma.cc/C9SA-C3PX].

[2] *Id.*

district court's determination[3] that plaintiffs are likely to succeed on their claims regarding the Government's decision to fire all of the ACIP members and replace them with new appointees, many of whom appear to lack the qualifications for ACIP membership.

The Government characterizes its appeal as a narrow one. In reality, however, if the Government's appeal succeeds, the Secretary could simply reinstate the appointments previously stayed and leverage the reconstituted ACIP to give a patina of regularity to the Secretary's ultimate objective of radically changing the childhood immunization schedule and U.S. vaccine policy more broadly. Indeed, a recent Executive Order that directs the Centers for Disease Control ("CDC") and the ACIP to "take any appropriate steps to update the United States childhood and adolescent vaccine schedule" to align with "best practices from peer, developed countries" appears designed to accomplish just that.[4]

Additionally, the Government's brief is notable for its bald mischaracterization of the district court's stay order. The Government asserts that the stay order "freezes federal vaccine policy" by preventing the Government from reconvening the ACIP "without judicial permission." Gov't. Br. 16; *see also id.* at

[3] App'x 816, District Ct. Dkt. No. 291 (hereafter, the "Order").
[4] Exec. Order No. 14407, 91 Fed. Reg. 33575 (June 3, 2026) https://www.whitehouse.gov/presidential-actions/2026/05/realigning-united-states-core-childhood-vaccine-recommendations-with-best-practices-from-peer-developed-countries/ [https://perma.cc/5GMF-C75R].

1. It also asserts that the district court "conducted a de novo credentialing trial" and concluded "member by member" that appointees lacked the required expertise. Gov't. Br. 15; *see also id.* at 2. Contrary to the Government's assertions, the district court expressly stated that "it would be inappropriate" to "enjoin the ACIP from meeting" or to "select-by-veto a different ACIP, as Defendants suggest." App. 859, District Ct. Dkt. No. 291 at 44. The district court also stated that "it is the agency's job and prerogative" to fairly balance the ACIP's members. *Id.* In short, the district court's stay order leaves the Secretary free to take a range of possible actions to meet the statutory "fairly balanced" requirement.

JURISDICTIONAL STATEMENT

This Court should dismiss for lack of appellate jurisdiction. The district court's stay order is not a "final decision[]" appealable as of right under 28 U.S.C. § 1291 because the district neither granted nor refused to grant an injunction. Rather, the district court chose a less intrusive remedy and stayed the challenged appointments. App. 86, District Ct. Dkt. No. 291. Stays of agency actions are not injunctions, as the Supreme Court has recognized. *E.g.*, *Nken v. Holder*, 556 U.S. 418, 429–30 (2009).

The Government nevertheless argues that the stay order is immediately appealable because it has the "practical effect" of an injunction, risks "serious, perhaps irreparable, consequence[s]," and can be "effectually challenged" only

through immediate appeal. *Carson v. Am. Brands, Inc*., 450 U.S. 79, 83–84 (1981). The Government bears the burden of satisfying each requirement, and failure to establish any one of them defeats appellate jurisdiction. *See, e.g.*, *Calvary Chapel of Bangor v. Mills*, 984 F.3d 21, 27 (1st Cir. 2020).

The Government has not carried its burden. It argues that the stay order has the practical effect of an injunction because it allegedly prevents ACIP from achieving a quorum and "command[s] that the CDC Director not change the immunization schedule without ACIP involvement." Gov't Br. 4-5. That is incorrect. The stay order does not prohibit the CDC Director from making lawful changes to an immunization schedule, nor does it prohibit the Secretary from undertaking a lawful appointment process that would result in a fairly balanced advisory committee as required by FACA. This Court has previously dismissed appeals for lack of appellate jurisdiction where, as here, there were alternative means available to address the alleged harm. *See, e.g.*, *Calvary Chapel*, 984 F.3d at 29.

This Court should dismiss this appeal for lack of appellate jurisdiction.

STATEMENT OF THE ISSUES

1. Whether the district court correctly concluded that Plaintiffs have Article III standing to challenge unlawful appointments to the ACIP.

2. Whether the Secretary's appointments to reconstitute the ACIP are reviewable as final agency action.

3. Whether Plaintiffs are likely to succeed on the merits of their unfairly balanced claim under FACA.

4. Whether a stay of ACIP appointments that does not prevent the Secretary from making lawful new appointments to the ACIP at his discretion is a permissible exercise of the district court's remedial discretion.

STATEMENT OF THE CASE

A. Statutory and Regulatory Framework

1. The ACIP

The Advisory Committee on Immunization Practices ("ACIP") is a globally respected authority on vaccination policy and a model for similar advisory bodies around the world.[5] Its success is rooted in its status as "a recognized body of health experts" who can provide evidence-based, transparent vaccine recommendations. App'x 835, District Ct. Dkt. No. 291 at 20.

For more than 25 years before the establishment of the ACIP, the main body that made recommendations on vaccine use in the United States was appellee American Academy of Pediatrics' ("AAP") Committee on Infectious Diseases ("COID", then called the Committee on Immunization Procedures).[6] As new

[5] Jason L. Schwartz & Adel Mahmoud, *A Half-Century of Prevention — The Advisory Committee on Immunization Practices*, 371 NEJM 1953, 1953 (2014).
[6] L. Reed Walton, Walter A. Orenstein & Larry K. Pickering, *The history of the United States Advisory Committee on Immunization Practices (ACIP)*, 33 VACCINE 405, 406 (2015).

vaccines came to market and federal immunization programs expanded, "it was evident that decision making on use of vaccines required a greater degree of continuity of expert technical advice rather than formation of ad hoc committees to address national immunization policy."[7] Therefore, the Surgeon General established the ACIP in March 1964 under section 222 of the Public Health Services Act, which authorizes the appointment of advisory committees.[8] The committee was "charged with the responsibility of advising the Surgeon General regarding the most effective application in public health practice of specific preventive agents which may be applied in communicable disease control."[9] That mission has remained essentially unchanged to date.[10]

In 1972, the ACIP was designated a federal advisory committee under the Federal Advisory Committee Act, 5 U.S.C. § 1001, et seq. ("FACA"), which sets forth legal requirements for operations of federal advisory committees. By law, a federal advisory committee "shall not meet or take any action until an advisory committee charter has been filed . . . with— (i) the head of the agency to whom the

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[7] Jean Clare Smith, Alan R. Hinman & Larry K. Pickering, *History and Evolution of the Advisory Committee on Immunization Practices – United States, 1964-2014*, 63 MORBIDITY & MORTALITY WKLY. REP. 955, 955 (2014).
[8] 42 U.S.C. § 217a–1 ("All appointments to advisory committees established to assist in implementing the Public Health Service Act . . . shall be made without regard to political affiliation.").
[9] *Id.*
[10] *Id.*

advisory committee reports; and (ii) the standing committees of the Senate and House of Representatives having legislative jurisdiction over the agency."[11] The charter also must be filed in the U.S. General Services Administration FACA database.[12] The operative ACIP Charter in this case is dated April 1, 2024.[13]

The FACA regulations in effect at the time of the challenged ACIP appointments required discretionary advisory committees like the ACIP to have a Membership Balance Plan ("MBP").[14] The operative MBP in this case is dated

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[11] 5 U.S.C. § 1008(c)(1). *See also Federal Advisory Committee Act (FACA): Committee Establishment and Termination*, CONG. RSCH. SERV. (June 5, 2023), https://www.congress.gov/crs_external_products/IF/PDF/IF12102/IF12102.3.pdf [https://perma.cc/9XBY-2275] ("All federal advisory committees subject to FACA must submit charters to the GSA Administrator in order to be formally established. . . . A committee cannot meet or take action without filing a charter, which must also be refiled every two years (5 U.S.C. §1008).").

[12] *Federal Advisory Committee Charters*, U.S. GEN. SERVS. ADMIN. (Oct. 16, 2024), https://www.gsa.gov/policy-regulations/policy/faca-overview/advice-and-guidance/federal-advisory-committee-charters [https://perma.cc/LZ4J-3NB6]; *see also GSA Federal Advisory Committee Act (FACA) Database*, U.S. GEN. SERVS. ADMIN., https://www.facadatabase.gov/FACA/s/ [https://perma.cc/G7VV-CBDX].

[13] *See ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 1, 2024), https://gsa-geo.my.salesforce.com/sfc/p/#t0000000Gyj0/a/3d000002n0vR/v5Bk.tLFdWd3s5nsKV5cvV_UC2H80LQUfinwVsSBgfU [https://perma.cc/M6LE-WF5V]. Three weeks after the district court's March 16, 2026, decision, the CDC published in the Federal Register a notice of charter renewal, which it subsequently withdrew. 91 Fed. Reg. 17279 (Apr. 6, 2026); 91 Fed. Reg. 29139 (May 19, 2026). A new ACIP charter was posted on the CDC's website on June 24, 2026. *See ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (June 24, 2026), https://www.cdc.gov/acip/about/acip-charter.html [https://perma.cc/JMU3-GS9Q].

[14] 89 Fed. Reg. 27682 (Apr. 18, 2024) (requiring a "description of the agency's plan to attain fairly balanced membership, as appropriate based on the nature and functions of the advisory committee, as documented through the agency's

January 29, 2024, and mandates that individual members be selected based upon "expertise in the field of immunization practices"; "multi-disciplinary expertise in public health"; "expertise in the use of vaccines and immunologic agents"; or "knowledge of vaccine development, evaluation, safety and delivery."[15] The "Candidate Identification Process" section of the MBP requires widespread solicitation and ACIP Steering Committee review of proposed ACIP members.[16]

2. The Vaccine Recommendation Process in the United States

The ACIP is charged with providing "advice and guidance to the Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States."[17] ACIP's role begins before a vaccine is approved by the U.S. Food & Drug Administration ("FDA"). While the Biologics License Application ("BLA") is under review at the FDA, an ACIP Work Group thoroughly reviews all available scientific information about the vaccine, including the data submitted in the BLA,

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Membership Balance Plan (MBP). The MBP must be updated to the FACA database when the agency files the Federal advisory committee charter with the Secretariat.").

[15] Supp'l App. 2667; App. 519-23, District Ct. Dkt. No. 260 at 76-80.

[16] Supp'l App. 2668; App. 519-23, District Ct. Dkt. No. 260 at 76-80.

[17] *See ACIP Charter*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 1, 2024), https://gsa-geo.my.salesforce.com/sfc/p/#t0000000Gyj0/a/3d000002n0vR/v5Bk.tLFdWd3s5nsKV5cvV_UC2H80LQUfinwVsSBgfU [https://perma.cc/M6LE-WF5V]. ("Objective and Scope of Activities").

so that the Work Group will be prepared to present information to the ACIP at the next public meeting of the ACIP after the vaccine is licensed.[18]

The ACIP and its Work Groups historically adhered to well-established frameworks to develop evidence-based recommendations. In 2010, the ACIP adopted the "GRADE" approach—Grading of Recommendations, Assessment, Development, and Evaluation—which provides a framework for assessing the certainty (*i.e.*, quality or confidence) of the evidence and moving from evidence to decision making (*i.e.*, recommendations);[19] in 2018, the ACIP adopted the Evidence to Recommendation ("EtR") framework, which helps panels making recommendations move from evidence to decisions and provides transparency around the impact of additional factors on deliberations when considering a recommendation.[20]

The CDC Director has the authority to adopt ACIP recommendations, and, once adopted, the CDC publishes all ACIP recommendations on its website and in

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[18] 21 U.S.C. § 360bbb-4 note ("Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices … shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting").

[19] *See Introduction in ACIP GRADE Handbook*, CTRS. FOR DISEASE CONTROL & PREVENTION (April 22, 2024), https://www.cdc.gov/acip-grade-handbook/hcp/chapter-1-introduction/index.htm.

[20] *See ACIP Evidence to Recommendation User's Guide*, CTRS. FOR DISEASE CONTROL & PREVENTION 1, 3 (Oct. 1, 2020), https://www.cdc.gov/acip/media/pdfs/2024/09/acip-etr-users-guide_october-1-2020.pdf [https://perma.cc/3VDX-WET4].

the Morbidity and Mortality Weekly Report ("MMWR"). 45 C.F.R. § 147.130(a)(1)(ii).

3. Congress' Incorporation of ACIP Recommendations Into Statutes

As the district court acknowledged, "Congress has . . . recognized the importance and value of having independent experts involved in setting our national public health agenda by cementing ACIP's role in the CDC's issuance of immunization schedules, which—among other things—determines which vaccines are available to patients through insurers and government healthcare programs." App. 817–18, District Ct. Dkt. No. 291 at 2–3. Legislative bodies around the country at all levels have incorporated ACIP recommendations into legislation, "with nearly 600 statutes and regulations across 49 states, three territories, and Washington, D.C. referencing ACIP recommendations and tying them to essential public health programs and insurance coverage mandates."[21]

The United States Congress has incorporated ACIP recommendations into 13 different statutes:

- Vaccines for Children Program, 42 U.S.C. §§ 1396d, 1396s.
- Amendment to Immigration and Nationality Act – Vaccine Preventable Diseases, 8 U.S.C. § 1182(a)(1)(A)(ii).

[21] *Impact of the Advisory Committee on Immunization Practices Recommendations on State Law*, ASS'N OF STATE AND TERRITORIAL HEALTH OFFS. (June 23, 2025), https://www.astho.org/topic/resource/impact-of-acip-recommendations-on-state-law/ [https://perma.cc/94RU-SEUA].

- Veterans' Benefits – Preventive Health Services, 38 U.S.C. §§ 1701(9)(G), 1701(10).
- Education and outreach campaign regarding preventive benefits, 42 U.S.C. § 300u-12.
- Affordable Care Act – Coverage of preventive health services, 42 U.S.C. § 300gg-13(a)(2).
- Medicare Part B – Annual Wellness Visit (Assessment of Vaccination Status), 42 U.S.C. § 1395x(hhh)(2).
- Community Preventive Services Task Force, 42 U.S.C. § 280g-10.
- Medicaid Definition of "Medical Assistance," 42 U.S.C. § 1396d(a)(13)(B).
- Program for distribution of pediatric vaccines, 42 U.S.C. § 1396s(e).
- 21st Century Cures Act – Predictable Review Timelines of Vaccines by the ACIP, 21 U.S.C. § 360bbb-4 note, Public Law 114-255.
- The Coronavirus Aid, Relief, and Economic Security Act (CARES) Act – Qualifying Coronavirus Preventative Service, statutory note to 42 U.S.C. § 300gg-13.
- Inflation Reduction Act – Coverage of Adult Vaccines, 42 U.S.C. § 1396o(a)(1)(j).
- Public awareness campaign on the importance of vaccinations, 42 U.S.C. § 245(d)(4)(B).

B. The Secretary's Reconstitution of the ACIP.

On June 9, 2025, an Opinion Commentary written by the Secretary appeared in the online version of the *Wall Street Journal*. In the column, the Secretary announced he was "totally reconstituting the Advisory Committee for Immunization

Practices (ACIP)" and "retiring the 17 current members of the committee."[22] The Secretary claimed that the ACIP had "been plagued with persistent conflicts of interest," had "become little more than a rubber stamp for any vaccine," were corrupt, and were "directly work[ing] for the vaccine industry."

Two days later, the Secretary announced the appointment of eight new members to the ACIP. On September 11, 2025, the Secretary announced four more appointments to the ACIP. The Secretary's appointees did not possess the requisite qualifications or expertise, and many of his appointees had publicly stated anti-vaccine views that align with the Secretary's.

The reconstituted ACIP took the following actions in 2025:

- At the June 2025 meeting, ACIP voted to remove thimerosal from all influenza vaccines distributed in the U.S. No new data or study on the presence of thimerosal in vaccines was presented at the meeting. Instead, an outside presenter resuscitated the long-debunked, settled issue of whether thimerosal in vaccines caused autism and made unsupported and misleading claims that thimerosal is not an effective preservative and was never adequately tested before widespread use.
- At the September 2025 meeting, ACIP voted to change the Covid-19 vaccine recommendation for adults and children to Shared Clinical Decision-Making ("SCDM"), referring to a process where a vaccine is not routinely recommended for everyone in an age group or risk group, but instead recommendations are individually based on a patient's specific circumstances. In a departure from the very limited other instances where ACIP previously recommended SCDM, the

[22] Robert F. Kennedy, Jr., *HHS Moves to Restore Public Trust in Vaccines*, WALL ST. J. (June 9, 2025, 4:00 PM), https://www.wsj.com/opinion/rfk-jr-hhs-moves-to-restore-public-trust-in-vaccines-45495112 [https://perma.cc/L2AD-EB7X].

CDC never provided any guidance as to how clinicians should engage with their patients on whether a Covid-19 vaccine is appropriate.

- At the December 2025 meeting, ACIP voted to change the Hepatitis B ("HepB") vaccine recommendation for all doses for children born to HepB negative mothers to individual-based decision-making. Previously, the HepB vaccine was recommended for *all* newborns at birth, a policy credited with reducing pediatric HepB cases by 99% (from 16,000 to fewer than 20 annually) and preventing tens of thousands of cases of cirrhosis, liver cancer, and death.[23]

In taking these actions, the reconstituted ACIP did not consult with the relevant Work Groups and did not apply the GRADE approach or the EtR framework. Additionally, the reconstituted ACIP promptly terminated liaison representatives from participation in ACIP Work Groups. App. 395, District Ct. Dkt. No. 245 at 41. Among those liaison representatives terminated were Organizational Plaintiffs American Academy of Pediatrics ("AAP"), American College of Physicians ("ACP"), and Infectious Diseases Society of America ("IDSA").

[23] Melissa Jenco, *Report: Hepatitis B vaccine safe; delaying would lead to increased infections*, AM. ACAD. OF PEDIATRICS (Dec. 2, 2025), https://publications.aap.org/aapnews/news/33888/Report-Hepatitis-B-vaccine-safe-delaying-would?autologincheck=redirected (last visited July 16, 2026); *Dozens of Public Health and Policy Experts, Along with the American Public Health Association, Urge the CDC to Maintain Universal Newborn Hepatitis B Vaccination*, MILKEN INST. OF PUB. HEALTH (Dec. 2, 2025) https://publichealth.gwu.edu/dozens-public-health-and-policy-experts-along-american-public-health-association-urge-cdc-maintain [https://perma.cc/C9SA-C3PX].

Additionally, despite Congress' clear command to use ACIP in crafting vaccine policy, HHS has also taken steps to sidestep the ACIP. Although Congress requires ACIP to weigh in on vaccine recommendation, Secretary Kennedy unilaterally issued a Directive on May 27, 2025 modifying the recommended Covid-19 vaccine administration for children and pregnant women. App. 358, District Ct. Dkt. No. 245 at 4. And on January 5, 2026, the Acting Director of the CDC issued a Decision Memo revising the Childhood and Adolescent Immunization Schedule. App. 356, District Ct. Dkt. No. 245 at 2.

C. Procedural History

Plaintiffs—several medical associations, public health organizations, and three Jane Does with direct interests in the Nation's vaccine policy[24]—initially brought suit under the Administrative Procedure Act on July 7, 2025, challenging Secretary Kennedy's May 27, 2025 directive that the CDC stop recommending the Covid-19 vaccine for pregnant women and "healthy" children. Suppl. App'x 1, District Ct. Dkt. No. 1. Following several amendments to the initial complaint to add plaintiffs, additional factual allegations, and claims, Counts II and III of the

[24] The Organizational Plaintiffs include AAP, ACP, the American Public Health Association ("APHA"), IDSA, the Massachusetts Public Health Association d/b/a the Massachusetts Public Health Alliance ("MPHA"), the Society For Maternal-Fetal Medicine ("SMFM"), and the Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP").

operative complaint challenges as unlawful the reconstitution of ACIP and three votes ACIP took in 2025. App. 436-439, District Ct. Dkt. No. 245 at 82-85.

On January 6, 2026, the district court denied the Government's motion to dismiss, including as to Count II. App. 119, District Ct. Dkt. No. 168. The district court concluded in relevant part that AAP and the other Organizational Plaintiffs satisfied the injury-in-fact requirement for organizational standing, the organizational plaintiffs' members had standing sufficient to provide the organizations with associational standing, and Plaintiffs had plausibly alleged that the current ACIP composition did not comport with FACA's requirements. *Id.*

Plaintiffs then moved for preliminary relief, seeking in part to set aside the reconstituted ACIP's actions, enjoin future ACIP meetings, and enjoin Defendants from relying on the three 2025 ACIP votes taken by the reconstituted committee described *supra* at 13-14. App. 162, District Ct. Dkt. No. 229.

Following two hearings, the district court granted in part Plaintiffs' request for preliminary relief. App. 816, District Ct. Dkt. No. 291. Relevant to this appeal, the district court found Plaintiffs are likely to succeed on their claim that the reconstituted ACIP violates the FACA's "fairly balanced" requirement because only a handful of the newly appointed members have relevant vaccine-related expertise and that the appointment process as to each member bypassed ACIP's own membership balance plan and outreach procedures. *Id.* The district court reasoned

that ACIP's reconstitution caused Plaintiffs' irreparable harm due to the diversion of organizational resources, and determined that the balance of equities and public interest favored preliminary relief. *Id.* Consistent with its findings, the district court stayed the appointments of the thirteen ACIP members appointed in June 2025, September 2025, and January 2026 and stayed all votes taken by the reconstituted ACIP. *Id.* The Government appealed. Suppl. App'x 2663, District Ct. Dkt. No. 306.

SUMMARY OF ARGUMENT

I. The district court correctly held that Plaintiffs satisfy all three elements of Article III standing. ACIP's reconstitution – whether viewed as individual appointments or as a reconstitution of the entire Committee – caused cognizable injuries to Plaintiffs that are redressable by a court.

A. Plaintiff Organizations have established organizational standing. It is well established that an organization can establish Article III standing by showing an injury-in-fact to itself. Here, Plaintiff Organizations meet that test because ACIP's reconstitution forced them to divert time and resources from their core public health missions. Following ACIP's reconstitution, Plaintiff Organizations have been forced to spend time and limited resources on correcting vaccine misinformation, developing a new vaccine schedule and policy statements, and fielding a surge in

member inquiries. The district court properly concluded this diversion constitutes a sufficient injury for organizational standing.

B. Plaintiff Organizations have also established associational standing. Organizations have associational standing when at least one member of the organization has standing, the interests asserted are germane to the organizations' purposes, and individual member participation is unnecessary. Here, Plaintiff Organizations have established associational standing through their members' concrete financial harms. The Government does not contest that members have been injured. Instead, the Government contends such harms are not traceable to ACIP's reconstitution. But those injuries are fairly traceable to ACIP's reconstitution because it was entirely predictable that the wholesale reconstitution of the ACIP would alter its vaccine recommendations and reduce patient vaccine uptake, leaving members with unused vaccine for which they cannot be reimbursed by Medicaid or other government payors.

C. Plaintiffs have an additional basis for standing. As this Court has made clear, FACA's fair-balance requirement is judicially enforceable through the APA. *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020). When the Government violates that requirement, entities with a direct interest in the FACA-regulated committee's work suffer an injury-in-fact sufficient to confer standing. Organizational Plaintiffs are among the stakeholders most directly

affected by ACIP's recommendations because their work is directly affected by ACIP's recommendations. As courts have recognized, this interest gives Organizational Plaintiffs standing to challenge the fair-balance requirement.

II. The Government's final agency action argument is both forfeited and meritless.

A. The Government did not argue to the district court that ACIP's reconstitution was not final agency action. Instead, the Government argued only that the ACIP appointments did not violate any law. The Government's forfeiture is all the more glaring because it argued that other challenged actions lacked finality. Accordingly, the Court should treat the Government's finality argument as forfeited.

B. The Government's finality argument also fails on the merits. The ACIP reconstitution—whether viewed as a series of individual appointments or as a reconstitution of the entire Committee—is final agency action subject to review under the APA. The Government does not contest that each ACIP appointment marked the "consummation" of HHS's decision to name the appointed individual to the ACIP. These appointments are "final" because they determine "rights or obligations" from which "legal consequences flow." *Bennett v. Spear*, 520 U.S. 154, 178 (1997). Each appointment directly confers legal rights on the appointed persons that otherwise would not exist, and each appointee incurs several legal obligations through the appointment. The ACIP reconstitution considered as a whole is also a

final agency action because it is a "discrete" agency decision altering the composition of the ACIP.

III. The district court review followed this Court's decision in *Wheeler* and was appropriately deferential. The district court expressly recognized that "many different balances" can be struck and that it is the agency's prerogative to strike that balance in the first instance, consistent with this Court's framework in *Wheeler*. Applying ACIP's own MBP and FACA's implementing regulations, the district court found that only a handful of the newly appointed members had relevant vaccine expertise and that the appointment process bypassed the MBP's outreach and vetting procedures.

IV. The district court's interim relief was appropriate and within its remedial authority. The Government's challenge rests principally on its final agency action argument, which fails for the reasons outlined in Part II. The district court's stay order does not micromanage the appointment process; it expressly disclaims any intent to select a different ACIP by veto and leaves the agency free to strike its own balance among many permissible options. The Government cannot credibly attack a remedy that is a less intrusive variant of the very relief it proposed below.

Nor does the stay order conflict with *Kennedy v. Braidwood Management*, Inc., 606 U.S. 748 (2025). That case addressed the President's removal power over inferior officers exercising executive authority. Reliance on *Braidwood* is misplaced

when considering a FACA-governed advisory committee and a stay order that does not limit the agency's power to remove members of the committee. The district court's stay order permits the Secretary to lawfully rebalance ACIP.

STANDARD OF REVIEW

This Court reviews stay orders for abuse of discretion. *Becky's Broncos, LLC v. Town of Nantucket*, 138 F.4th 73, 77–78 (1st Cir. 2025). The district court's factual findings are reviewed for clear error. *See Ross-Simons of Warwick, Inc. v. Baccarat, Inc.*, 102 F.3d 12, 15 (1st Cir. 1996) (affording "considerable deference" to the district court's evaluation of the preliminary-relief factors). Questions of law are reviewed *de novo*. *See Murthy v. Missouri*, 603 U.S. 43, 58 (2024).

ARGUMENT

I. Plaintiffs Have Article III Standing to Challenge ACIP's Reconstitution.

The district court correctly determined that Plaintiffs meet the requirements for Article III standing. To establish standing, a plaintiff must show that it has "suffered, or will suffer, an injury that is '[1] concrete, particularized, and actual or imminent; [2] fairly traceable to the challenged action; and [3] redressable by a favorable ruling.'" *Murthy*, 603 U.S. at 57 (citation omitted). The organizational Plaintiffs have established that ACIP's reconstitution has caused concrete injury to them and their members that is traceable to that action and redressable by the court.

The Government faults the district court for not addressing standing separately for each count of the complaint. Gov't Br. 17–18. But as the district

court noted, "[n]either party" argued that the standing analysis differed for each claim. App. 127, District Ct. Dkt. No. 168 at 9 Indeed, the standing analysis is largely the same for each claim, because the Plaintiffs' concrete and particularized harms—including diversion of resources and financial injury—flow predictably from the Government's shifting vaccine policy, of which the wholesale reconstitution of ACIP is an integral part. To the extent the standing analysis differs for the ACIP reconstitution claim, it is because Plaintiffs have an additional basis for establishing their standing to assert that claim: They have a direct interest in the work of the ACIP and therefore have standing to challenge a violation of FACA's fair balance requirement.

A. Plaintiff Organizations Have Organizational Standing.

The district court properly concluded that Plaintiff Organizations have organizational standing. "An organization with individual members may establish Article III standing by satisfying the three elements of such standing based on an 'injury in fact' of its own." *Doe v. Trump*, 157 F.4th 36, 47 (1st Cir. 2025) (citation omitted). Plaintiff Organizations satisfy these criteria. As the district court determined, ACIP's reconstitution – whether viewed as individual appointments or as a reconstitution of the entire Committee – required Plaintiff Organizations to divert valuable time and resources away from their critical public health missions. That diversion is an injury sufficient for Article III standing.

Organizational Plaintiff the American Academy of Pediatrics ("AAP") provides a representative example.[25] AAP is a professional organization for pediatric medicine that seeks to promote children's health. App. 359, District Ct. Dkt. No. 245 at 5 Since its founding in 1930, AAP's mission has been "to attain optimal physical, mental, and social health and well-being for all infants, children, adolescents and young adults."[26] In service of that mission, AAP focuses on educating medical professionals, including providing clinical skill development; publishing evidence-driven, nonpartisan, rigorously reviewed, science-backed recommendations on pediatric health; and engaging in public policy advocacy to advance the health and well-being of all youth.[27]

As the district court twice concluded, AAP has established injury in fact because ACIP's reconstitution has diverted valuable time and resources away from AAP's critical work. App. 119, District Ct. Dkt. No. 168; App. 816, District Ct.

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[25] As the district court concluded, each of the Plaintiff Organizations—the American College of Physicians, Inc. ("ACP"), the American Public Health Association ("APHA"), the Infectious Diseases Society of America ("IDSA"), the Massachusetts Public Health Association d/b/a the Massachusetts Public Health Alliance ("MPHA"), the Society For Maternal-Fetal Medicine ("SMFM"), and the Massachusetts Chapter of the American Academy of Pediatrics ("MCAAP")—have been required to divert time and resources away from their usual activities following ACIP's reconstitution. App. 851, District Ct. Dkt. No. 291 at 36.

[26] *American Academy of Pediatrics Mission and Strategic Plan*, Am. Acad. of Pediatrics (Sept. 16, 2024) https://www.aap.org/en/about-the-aap/strategic-plan/?srsltid=AfmBOopwHjMNkQwpmb_zhH_w9WX_emUEd3k26g3Fllu6GfGfWKnVidwE [https://perma.cc/QCL9-23B3].

[27] *Id.*

Dkt. No. 291. Since ACIP's reconstitution, AAP has had to expend significant time and resources to fill the public health gaps ACIP's reconstitution has caused. Supp'l App. 449 District Ct. Dkt. No. 146-15 at 2. For example, AAP has had to invest time and resources correcting misinformation about vaccines spread at ACIP meetings by newly appointed ACIP members. Suppl. App. 1846-47, District Ct. Dkt. No. 185-27 at 14-15. In addition, at least twelve AAP employees have "spent many hours" developing a new vaccine schedule in response to ACIP's changes to vaccine recommendations, and at least ten others "spent a significant amount of time" developing new policy statements and other publications. Supp'l. App. 450, District Ct. Dkt. No 146-15, at 3. Indeed, since ACIP's reconstitution, AAP has had to "field[] additional calls and email from AAP members seeking clarification" about vaccine policy, with one AAP executive estimating that "the volume of text, instant, and email messages in her inbox, and the number of meetings, has doubled" in recent months. *Id.* As the district court found, this resource diversion represents a "sufficient injury to AAP's core business activity" because it has come at the expense of AAP's "usual tasks and initiatives aimed at children's health." App. 128, District Ct. Dkt. No. 168 at 10. Those injuries flowed directly and immediately from

the individual appointments and collective reconstitution of ACIP and thus confer standing to challenge ACIP's reconstitution.[28]

The Government's attempt to narrow *Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982), is unpersuasive. The Government argues that *Havens Realty* is distinguishable because there the allegedly unlawful conduct "operated directly" on the organization's core service activity, while here the Government's actions indirectly affect AAP. Gov't Br. 22. But that is not what *Havens Realty* held. There, the Supreme Court held that an organization has standing when the challenged actions "perceptibly impaired" the organization's core service activities. 455 U.S. at 379. That is what happened here: AAP's core mission of supporting children's health through its member-doctors was directly impaired by changes the reconstituted ACIP made to the vaccine recommendations, requiring AAP to divert resources away from its core organizational activities. The fact that AAP's

[28] AAP has also been forced to expend time and manpower "holding multiple meetings" with staff and AAP's executive team to assess the legal consequences of their recommendations. Supp'l. App. 447, District Ct. Dkt. No 146-15, at 2. The day AAP published its own immunization schedules, Secretary Kennedy publicly stated that "doctors and hospitals" that chose to follow vaccine recommendations like AAP's "that diverge from the CDC's official list are not shielded from liability under the 1986 Vaccine Injury Act." *See* Robert F. Kennedy, Jr., @SecKennedy, X (Aug. 19, 2025, 9:17 PM), https://x.com/SecKennedy/status/1957914911415153107 [https://perma.cc/WKG8-DS4V]. AAP was thus forced to divert time and attention away from its pediatric health mission to "discuss the implications of AAP's own immunization (IZ) schedule diverging from that of the CDC." Supp'l. App. 449, District Ct. Dkt. No 146-15, at 2.

responsive counseling implicated issues of a similar nature to AAP's prior work is proof positive that the Government's actions directly affected and interfered with AAP's core organizational activities.

The Government's reliance on *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), is misplaced. Gov't Br. 22. In that case, plaintiff doctors challenging FDA approval of a drug lacked standing because they neither prescribed nor used that drug in their medical practices. *Alliance for Hippocratic Med.*, 602 U.S. at 385. Here, however, the government's reconstitution of ACIP immediately and directly interfered with AAP's core organizational operations. AAP members administer vaccines every day, in addition to educating medical providers about recommended vaccine schedules. ACIP's reconstitution and subsequent actions cut to the core of AAP's mission.

B. Organizational Plaintiffs Have Associational Standing.

The district court also correctly concluded AAP and the other Organizational Plaintiffs have associational standing based on their members' injuries. Associational standing allows an organization to sue on behalf of its members when (a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit. *In re Fin. Oversight & Mgmt. Bd. for P.R.*, 110 F.4th 295,

308 (1st Cir. 2024). Only one member of an organization must have individual standing for that organization to satisfy the first factor. *See Draper v. Healey*, 827 F.3d 1, 3 (1st Cir. 2016).

The Government does not dispute that the Organizational Plaintiffs' members have suffered concrete financial harm, and for good reason: The record contains ample evidence of such harm. For example, AAP member Dr. Suzanne Berman, a pediatrician in rural Western Appalachia, submitted a declaration describing how ACIP's reconstitution caused her financial harm. *See e.g.*, Supp'l. App. 429, District Ct. Dkt. No. 146-12 at 1; Supp'l. App. 2339, 2334, 2346–48, District Ct. Dkt. No 287 at 2, 7, 9–11; Supp'l. App. 2320-21, District Ct. Dkt. No. 244 at 2–3. Dr. Berman declared that 70–75% of her patients are vulnerable children enrolled in Medicaid or the Children's Health Insurance Program ("CHIP") who rely on the Vaccines for Children ("VFC") program for coverage of vaccinations. Supp'l. App. 2339, District Ct. Dkt. No 287 at 2. As she explained, she must stock vaccines, including the COVID-19 vaccine, at hundreds of dollars per dose because her practice's isolated location means that there are few, if any, other nearby locations that stock that vaccine in her area. *See* Supp'l. App. 426, District Ct. Dkt. No. 146-11 at 4; Supp'l. App. 2348–49, District Ct. Dkt. No 287 at 11–12. But ACIP's reconstitution has predictably resulted in reduced uptake of the vaccine, leaving her with unused vaccine for which she cannot be reimbursed by either Medicaid, other

government programs, or the manufacturer. *See* Supp'l. App. 1930, District Ct. Dkt. No. 185-31 at 3; Supp'l. App. 2346–47, District Ct. Dkt. No 287 at 9–10. She has also experienced a material increase in the frequency and duration of counseling parents of patients about the Covid-19 vaccine—time for which she is not paid when parents decline to vaccinate their children. Supp'l. App. 2339-41, District Ct. Dkt. No 287 at 2–4. It is unsurprising that the Government does not contest these financial injuries.

Instead, the Government contends that those financial injuries are not fairly traceable to ACIP's reconstitution, but solely "to the CDC-adopted schedule changes." Gov't Br. 18–19, 23. This argument fails because it was entirely predictable that wholesale changes to ACIP's composition would alter ACIP's vaccine recommendations, which would directly impact patients' vaccine uptake.

The Supreme Court has recently made clear that unregulated parties have standing to challenge government actions where, as here, it is "likely that third parties will react to government regulation "in predictable ways that will likely cause … the plaintiff's injury." *Diamond Alt. Energy, LLC v. Env't Prot. Agency*, 606 U.S. 100, 112 (2025) (cleaned up). Here, it was entirely "predictable" that ACIP's reconstitution would cause changes to patients' vaccine uptake. And because government payors like Medicaid will only reimburse doctors for vaccines they administer, these financial injuries from uptake changes are fairly traceable to

ACIP's reconstitution. *See, e.g.*, *Center for Biological Diversity v. EPA*, 168 F.4th 1164, 1176 (9th Cir. 2026) (holding that CBD had standing to challenge EPA's non-binding § 304(a) recommendations because it was "predictable" that States would adopt the recommendations).

The Government does not address *Diamond Alternative Energy*. Instead, the Government relies on out-of-circuit, decades-old cases to suggest that "[o]ther courts have rejected similar causal chains in the FACA context." Gov't Br. 23-24. But these cases—*Physicians' Education Network v. Department of HEW*, 653 F.2d 621 (D.C. Cir. 1981), *Metcalf v. National Petroleum Council*, 553 F.2d 176 (D.C. Cir. 1997), and *Mulqueeny v. National Commission on the Observance of International Women's Year*, 549 F.2d 1115, 1121 (7th Cir. 1977)—involved speculative efforts to trace injury from advisory committee activity to uncertain downstream decisions, such as economic harm that rescinding a committee's work product would not redress, consumer injury from allegedly biased advice, or the possibility that relief against an advisory body might influence later legislative action. Here, however, ACIP's recommendations are embedded in a statutory and regulatory framework governing vaccine coverage, reimbursement, and liability. *See supra* pp. 11-12. The reconstituted ACIP has already produced recommendations adopted into CDC immunization schedules, and Plaintiff Organizations' members have already experienced concrete financial harms from those changes. *See supra* pp. 26-27.

Unlike in the Government's cited cases, Plaintiff Organizations' financial injuries are traceable to ACIP's reconstitution.

C. Plaintiffs Have Standing to Challenge a Violation of FACA's Fair Balance Provision Because They Have a Direct Interest in the ACIP's Work.

Plaintiffs have an additional basis for standing to challenge the reconstitution of the ACIP. As this Court has recognized, "FACA requires [an agency] to maintain a fair balance on its committees and to avoid inappropriate influences by both the appointing authority and any special interest." *Wheeler*, 954 F.3d at 20. This fair-balance requirement is reviewable under the APA. *See id.* When the Government violates that requirement, persons (or groups) who have a direct interest in the FACA-regulated committee's work suffer an injury-in-fact sufficient to confer standing. *See, e.g.*, *Am. First Legal Found. v. Cardona*, 630 F. Supp. 3d 170, 180 (D.D.C. 2022); *see also Nat'l Ass'n of Consumer Advocs. v. Uejio*, 521 F. Supp. 3d 130, 144–45 (D. Mass. 2021); *NAACP Legal Def. Fund, Inc. v. Barr*, 496 F. Supp. 3d 116, 129 (D.D.C. 2020) (collecting cases); *accord Nat'l Anti-Hunger Coal. v. Executive Committee*, 711 F.2d 1071 (D.C. Cir. 1983); *Cargill, Inc. v. United States*, 173 F.3d 323, 335−36 (5th Cir. 1999) (holding fair balance requirement is justiciable).

Plaintiff Organizations clearly have a direct interest in the work of the ACIP. ACIP recommendations shape clinical practice, patient counseling, vaccine

availability, coverage, reimbursement, and public-health guidance. *See supra* pp. 22–24. Indeed, AAP and the other Organizational Plaintiffs are among the stakeholders most directly affected by ACIP's recommendations because their work is directly affected by ACIP's recommendations.

ACIP's reconstitution caused AAP and the other Plaintiff Organizations a concrete representational injury. The reconstituted ACIP lacks the fair balance and relevant expertise FACA requires and has so far excluded the very medical and public health perspectives Congress intended the advisory process to include—and that the Plaintiff Organizations share. *See supra* pp. 6–10.

ACIP's refusal to use the Work Groups provides an example of this failure. Previously, ACIP formed subgroups of committee members known as "Work Groups" to develop vaccine recommendations. These Work Groups presented findings at ACIP's meetings to help inform ACIP's vaccine recommendations. As the district court observed, AAP previously participated in these Work Groups, helping to inform the Nation's approach to vaccines. App. 840-41, District Ct. Dkt. No. 291 at 25-6. But under the reconstituted ACIP, ACIP has not used the Work Groups and has recommended changes to vaccine schedules without the advice and findings of AAP and other Work Group members. Contrary to the Government's representations, AAP does not claim it is "entitled" to a Work Group seat. Gov't Br.

21. It simply asserts its interest in protecting the balance of viewpoints and expertise within ACIP on the whole, which the reconstitution blatantly rejects.

The Government tries to minimize the significance of the cases recognizing that persons with a direct interest in an FACA-regulated committee's work have standing to challenge the fair-balance requirement. Gov't Br. 20-22 (citing, *e.g.*, *Cardona*, 630 F. Supp. 3d at 180). In so doing, the Government (at 21) mischaracterizes the nature of Plaintiff Organizations' injury as solely "financial and downstream." Gov't Br. 21. But as explained above, Plaintiff Organizations do not rely solely on downstream financial harms—they also suffer harm from the denial of a fairly balanced advisory process for a committee whose work directly affects their mission, their members and the members' patients, and clinical practice. The district court correctly concluded that is sufficient to confer standing.

II. The Government's Final Agency Action Argument Is Forfeited And Lacks Merit.

On appeal, the Government asserts that Count II is not "justiciable" because it is not final agency action subject to review under the APA. Gov't Br. 26. The Government is wrong. To start, the Government's finality argument is forfeited because the Government failed to raise it in the district court. But even if it were properly preserved, the Government's argument fails because ACIP's reconstitution – whether viewed as a series of individual appointments or as a reconstitution of the

entire Committee – is the consummation of HHS's decision making process from which legal consequences flow.

A. The Government's Final Agency Action Argument Is Forfeited.

The Government argues for the first time on appeal that reconstitution of the ACIP is not a "final agency action" subject to challenge under the APA. Gov't. Br. 5. Arguments not raised in the district court are forfeited. *See, e.g.*, *Reyes-Colon v. United States*, 974 F.3d 56, 62 (1st Cir. 2020) ("The Federal Reporter is brimming with opinions from us saying things like: 'arguments not seasonably advanced below cannot be raised for the first time on appeal.'"). This Court has specifically "held that the APA's finality argument is not jurisdictional in nature" and is thus subject to forfeiture. *Nulankeyutmonen Nkihtaqmikon v. Impson*, 503 F.3d 18, 33 (1st Cir. 2007) (citing *R.I. Dep't of Envtl. Mgmt. v. United States*, 304 F.3d 31, 40 (1st Cir. 2002)).

In the district court, the government argued only that the ACIP appointments "did not violate any law." Gov't Br. 26. The forfeiture is especially clear because the government argued in the district court that a *different* agency action challenged by Plaintiffs was not a "final agency action." *See* App. 257-59, District Ct. Dkt. No. 232. The government's passing invocation of *Singleton v. Wulff*, 428 U.S. 106 (1976), does not excuse its forfeiture. *Singleton* "declined to announce a 'general rule' of waiver or forfeiture" and instead left courts of appeals a "broad grant of

authority to … establish rules governing waiver and forfeiture." *Mullane v. United States Department of Justice*, 113 F.4th 123, 132 (1st Cir. 2024). Under this Court's "traditional approach to waiver and forfeiture," no exception applies because the government identifies no gross miscarriage of justice, exceptional circumstance, or important constitutional issue requiring review. *Id.* (citations omitted). Accordingly, the Court should treat the Government's finality argument as forfeited.

B. The Government's Final Agency Action Argument Lacks Merit.

Even if this Court were to consider the Government's late-breaking finality argument, it should reject it. The ACIP reconstitution—whether viewed as a series of individual appointments or as a reconstitution of the entire Committee—is final agency action subject to review under the APA.

A final agency action is one that represents "the 'consummation' of the agency's decision making process," and determines "'rights or obligations'" from which "'legal consequences will flow.'" *Harper v. Werfel*, 118 F.4th 100, 116 (1st Cir. 2024), *cert. denied*, 145 S. Ct. 2867 (2025) (quoting *Bennett v. Spear*, 520 U.S. 154, 178 (1997)). Courts take a "'pragmatic' approach" to finality. *U.S. Army Corps of Eng'rs v. Hawkes Co.*, 578 U.S. 590, 599 (2016) (quoting *Abbott Lab'ys v. Gardner*, 387 U.S. 136, 149 (1967)). The ACIP's reconstitution, as well as each appointment that contributed to the wholesale reconstitution, meets the definition of a final agency action.

The Government does not contest that each ACIP appointment marked the "consummation" of HHS's decision to name the appointed individual to the ACIP. Gov't Br. 28-29. Instead, the Government argues that the appointments do not determine any "rights or obligations" from which "legal consequences flow." Gov't Br. 28-29. Relying on *Dalton v. Specter*, 511 U.S. 462 (1994), the Government argues that individual ACIP appointments do not determine rights or obligations because ACIP recommendations are not self-executing and become effective only after adoption by the CDC Director. Gov't Br. 28-30.

The Government's argument misses the mark. The challenged appointments have direct legal consequences. Each appointment directly confers legal rights and obligations on the appointed person that otherwise would not exist. For example, an appointee gains the legal right to participate in ACIP meetings and vote on matters considered by ACIP. Appointees also become subject to several legal obligations, such as limitations on their employment, required financial disclosures, and a prohibition on receiving compensation for speaking or writing about their official ACIP work outside of Committee or Work Group meetings.[29] The appointments thus meet the definition of a final agency action.

[29] *Advisory Committee on Immunization Practices Policies and Procedures*, ACIP (June 2022), https://www.cdc.gov/acip/downloads/Policies-Procedures-508.pdf [https://perma.cc/G3D2-VZX4].

The ACIP reconstitution considered as a whole is also a final agency action. It is a "circumscribed, discrete" agency decision altering the composition of the ACIP. *See, e.g.*, *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 62-64 (2004); *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 890-94 (1990). As the Government recognizes (at 6), FACA regulates ACIP's membership. Gov't Br. 6. This Court has explained that "FACA requires [an agency] to maintain a fair balance on its committees and to avoid inappropriate influences by both the appointing authority and any special interest." *Wheeler*, 954 F.3d at 20; *see also* 5 U.S.C. § 1004(b)(2). The statutory duty attaches to ACIP's composition, so the agency action subject to challenge can be viewed as the Secretary's decision to reconstitute the ACIP by replacing all of its members. *Wheeler*, 954 F.3d 11.

The Government's attempts to distinguish this Court's decision in *Wheeler* fail to persuade. As the Government recognizes, *Wheeler* confirmed that FACA's fair-balance requirement is judicially enforceable through the APA. Gov't Br. 32. The government tries to limit the availability of judicial review by differentiating between a formal exclusion directive and a wholesale reconstitution of committee membership. *Id.* But that elevates form over substance. Both a formal exclusion directive and a wholesale reconstitution can violate FACA's fair balance requirement. If only formal exclusion directives were reviewable, agencies could

evade *Wheeler* by doing through appointments what they could not do through a written directive.

The Government also argues that ACIP's reconstitution was not final because it involved appointments made in batches over several months and because "seats remained open when the court intervened." *Id.*; *see also* Gov't Br. 26. That ACIP's reconstitution unfolded in several steps does not immunize it from review under the APA. Agencies often implement final decisions through multiple acts across multiple months. *See, e.g.*, *Biden v. Texas*, 597 U.S. 785, 793, 807 (2022) (treating DHS memoranda as final agency action even though DHS directed additional implementation steps). Moreover, HHS's reconstituted committee was fully operational. It convened and voted—issuing recommendations that have independent legal effect, *see supra* at 13-14—on three occasions before the district court intervened. The fact that the Secretary could make additional appointments does not change the fact that the reconstituted committee as challenged by the Plaintiffs likely violates the fair balance requirement, and has issued multiple recommendations that are likely arbitrary and capricious. As a practical matter, the reconstitution is complete.

III. The District Court Applied the Correct Standard to Determine That Plaintiffs Are Likely to Succeed on Their FACA Claim.

The Government argues that judicial review of an agency's compliance with FACA should be deferential, and that the district court departed from deferential

review by engaging in "member-by-member credentialing" of the new ACIP members. Gov't Br. 36-44. Contrary to the Government's argument, the district court was appropriately deferential to the agency. It recognized that "[t]there are many different balances that can be struck in a committee's membership" and that "in the first instance it is an agency's job and prerogative to strike that balance" App. 859, District Ct. Dkt. No. 291 at 44. (internal quotation and citation omitted). In addition, the district court expressly stated that "it would be inappropriate" to "select-by-veto a different ACIP, as Defendants suggest." App. 859, District Ct. Dkt. No. 291 at 44. Moreover, the court was guided by the agency's own operative documents governing the ACIP. As this Court has held, "FACA requires [an agency] to maintain a fair balance on its committees and to avoid inappropriate influences by both the appointing authority and any special interest." *Wheeler*, 954 F.3d at 20. The prevailing consideration for a court in determining whether a committee satisfies FACA is whether, in light of "the functions assigned to [the] committee[,] . . . its balance is fair." *Wheeler*, 954 F.3d at 20. This is the framework the district court applied.

The district court began by evaluating the ACIP's function. App. 842, District Ct. Dkt. No. 291 at 27. According to the then-operative charter and MBP, the ACIP's task is "develop[ing] recommendations on the use of vaccines in the civilian population of the United States" and "provid[ing] advice and guidance to the

Director of the CDC regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States."[30]

The district court proceeded to evaluate whether the committee as reconstituted was "fairly balanced in terms of . . . the functions to be performed." 5 U.S.C. § 1004(b)(2);); App. 841, District Ct. Dkt. No. 291 at 26. Courts recognize that if an agency "announces and follows—by rule or by settled course of adjudication—a general policy by which its exercise of discretion will be governed," they can supply standards for judicial review. *I.N.S. v. Yueh-Shaio Yang*, 519 U.S. 26, 32 (1996). Here, federal regulations and the ACIP's MBP provide a framework for a court to apply in conducting this analysis. *See Wheeler*, 954 F.3d at 14 (relying on regulations set out by the U.S. Office of Government Ethics); *see also Nat. Res. Def. Council v. Dep't of Interior*, 410 F. Supp. 3d 582, 605 (S.D.N.Y. 2019) (stating that "the Court need not rely on [FACA's] language and purpose alone" because "the relevant regulations and guidance provide even more concrete direction still for judicial review"); *NAACP Legal Def. & Educ. Fund, Inc. v. Barr*, 496 F.Supp.3d 116, 134 (D.D.C. 2020) ("FACA's implementing regulations provide further law to apply").

[30] *General Committee-Related Information*, CDC (Aug. 12, 2025), https://www.cdc.gov/acip/about/index.html [https://perma.cc/QQ9V-8CU8]*; ACIP Charter at 2*

As relevant here, FACA's implementing regulations explicitly provide that "[a]dvisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed by the committee." 41 C.F.R. § 102-3.60(b)(1). At the time the Secretary reconstituted ACIP, federal regulations also expressly required a "description of the agency's plan to attain fairly balanced membership as appropriate based on the nature and functions of the advisory committee, as documented through the agency's Membership Balance Plan (MBP)." 41 C.F.R. § 102-3.60(b)(3) (eff. through Dec. 15, 2026). Thus, the MBP is likewise relevant to assessing whether the ACIP was properly reconstituted.

To ensure that the ACIP can adequately provide advice and guidance "regarding use of vaccines and related agents for effective control of vaccine-preventable diseases in the civilian population of the United States," Supp'l App. 2666; App. 519-23, District Ct. Dkt. No. 260 at 76-80; Supp'l App. 1742, Dkt. 185-21 at 2, and to achieve the fair balance mandated by FACA, the MBP provides objective criteria for membership selection. Specifically, the "Points of View" section explicitly states that "ACIP members are selected based on their expertise and experience and qualifications necessary to contribute to the accomplishments of the Committee's objectives." Supp'l App. 2667; App. 519-23, District Ct. Dkt. No. 260 at 76-80. The requisite expertise and experience is captured through the four-

part criteria upon which members are selected: "(1) expertise in the field of immunization practices;" (2) "multi-disciplinary expertise in public health;" (3) "expertise in the use of vaccines and immunologic agents;" (4) "knowledge of vaccine development, evaluation, safety and delivery;" or (5) "[in the case of a consumer representative] knowledge about consumer perspectives and/or social and community aspects of immunization programs." *Id.* And the "Other Balance Factors" provides for consideration of "[g]eographic balance" and "[b]alance of specialty areas." Supp'l App. 2668; App. 519-23, District Ct. Dkt. No. 260 at 76-80.

Furthermore, the MBP includes detailed processes for the solicitation and vetting of potential candidates. The Candidate Identification Process provides three methods through which the Secretary can solicit names for new ACIP members: (1) email solicitation "distributed widely on an annual basis, sent to all 30 ACIP liaison organizations, ex officio members, current and past ACIP members, professional organizations [], academic centers, and other contacts in the field of vaccinology"; (2) annual postings in the Federal Register; (3) announcements at ACIP meetings via a web link broadcast to all virtual attendees." *Id.* Applications for membership are to be "reviewed in-depth by the ACIP Steering Committee," which is directed to review, for each candidate, a current, complete CV and at least one letter of recommendation from a non-HHS source. *Id.* Finally, the ACIP Steering

Committee "selects two proposed candidates for each vacant position based on the quality of the candidate's technical expertise, balance of specialty areas . . . . and geographic distribution of recommended candidates." *Id.*

Citing "glaring gaps," the district court correctly concluded that Plaintiffs have demonstrated a strong likelihood of prevailing on the merits of their fairly balanced claim. Gov't Br. 29, 34. According to the district court, "even under the most generous reading, only six [appointees] appear to have any meaningful experience in vaccines—the *very focus of ACIP*." App. 844, District Ct. Dkt. No. 291 at 29 (emphasis in original). And as the district court concluded, such a committee cannot plausibly be "fairly balanced in terms of . . . the functions to be performed." 5 U.S.C. § 1004(b)(2); App. 844, District Ct. Dkt. No. 291 at 29. This was not undeferential micromanagement of the Secretary's appointments; instead, it was application of the agency's own standards in the most generous possible way.

The district court also correctly concluded that the Secretary's appointments of new ACIP members did not follow the framework established by the MBP or FACA's requirement that "standards and uniform procedures should govern the establishment . . . of advisory committees." 5 U.S.C. § 1002(b)(4)); App. 848, District Ct. Dkt. No. 291 at 33. As the district court determined on the basis of the record before it, for each set of appointments, no email solicitations were sent out, including none to liaison organizations, who were all terminated and cut off from

participation by June 9, 2025. App. 847-48, District Ct. Dkt. No. 291 at 32-33. No notices were posted in the Federal Register. App. 848, District Ct. Dkt. No. 291 at 33. No applications were reviewed by the ACIP Steering Committee nor, upon information and belief, were two candidates identified for each vacancy before selecting one. App. 847-48, District Ct. Dkt. No. 291 at 32-33. Rather, "on the current record, the most generous description of the appointment process is that it took a few months and involved some limited outreach to candidates . . . . This ad hoc outreach fails to comply with the spirit or letter of the FACA regulations governing outreach, all of which seek to promote FACA's overarching goal of public accountability and transparency." App. 848, District Ct. Dkt. No. 291 at 33.

The Government accuses the district court of "invert[ing] the burden of proof," Gov't Br. 40, but the district court did no such thing. Instead, it reviewed the evidence available to it at this preliminary stage of the case and determined that even on the most generous reading of that evidence many of the appointees appear to be unqualified. App. 844, District Ct. Dkt. No. 291 at 29. Relatedly, the Government claims that the district court erred because "there was no administrative record to review." Gov't. Br. 49. But at the preliminary injunction stage, it is often the case that the district court lacks the benefit of a complete administrative record. Moreover, Plaintiffs sought an expedited production of the Administrative Record

in this case, and the Government delayed producing it for many months.[31] When the Government believes the administrative record will assist its opposition to preliminary relief, it can—and often does—submit at least some record materials to support its arguments. The Government did not avail itself of that option in this case. Having made that choice, the Government cannot use it as a shield on appeal.

In a single paragraph that does not cite a single case, the Government asserts that the district court's order "presents a freestanding separation of powers problem" because the President's Appointment Power under Article II "includes the authority to determine what qualifications an appointee should possess and whether a particular individual meets them." Gov't Br. 43. The Government did not raise this argument in the district court and cannot do so for the first time on appeal. And even if the argument could be heard now, it sweeps far too broadly. Among other things, it implies that the "fair balance" provision of FACA is unconstitutional, that *Wheeler* was wrongly decided, and that courts are powerless to police an agency's failure to follow its own procedures and requirements for making appointments to advisory committees. A single paragraph lacking a single case citation is an utterly insufficient way to present such a radical argument.

[31] Even now, Plaintiffs do not believe the administrative record is complete, and plan to file a motion with the district court to complete the record.

IV. The District Court's Interim Relief Is Appropriate.

The Government incorrectly asserts that the district court's remedial order exceeds the court's authority. Gov't Br. 44-54. The Government begins by repeating its argument that the Secretary's appointments to the ACIP are not reviewable final agency action. *See* Gov't Br. 45 (arguing that "[t]he breadth of the remedy is not a separate misstep. It is the consequence of reviewing a non-final action."). As explained in Part II above, however, the Government's final agency action argument is both forfeited and lacking in merit. Accordingly, this challenge to the district court's interim relief fails.

The Government next argues that the district court's remedy exceeds the court's authority because the district court did not merely "remand for the agency to restore balance" but instead has asserted authority to "micromanage the appointment process." Gov't Br. 46. The Government misreads the district court's order, which specifically disclaims such effect. The order expressly states that "it would be inappropriate for the Court either to enjoin ACIP from meeting … or to effectively select-by-veto a different ACIP." App. 859, District Ct. Dkt. No. 291 at 44. The district court also noted that "[t]here are many different balances that can be struck" and "in the first instance it is the agency's job and prerogative to strike that balance." *Id.* For these reasons, the district court crafted a remedy – an interim stay of the challenged appointment – that leaves maximum leeway "for *the agency* to restore

balance." Gov't Br. 46. In fact, notably, in the district court the *Government* proposed staying the appointment of particular appointees as the proper remedy. App. 288, District Ct. Dkt. No. 232 at 44 Having proposed that remedy, the government is not in a position to challenge a variant of it on appeal. *See Sexual Minorities Uganda v. Lively*, 899 F.3d 24, 33-34 (1st Cir. 2018) (applying judicial estoppel where a party's position on appeal contradicts the position it took below).

The Government's argument fails for an additional reason: in the district court, it did not clearly explain how its proposed remedy would work. *Cf. Doe v. Trump*, 157 F.4th 36, 82 (1st Cir. 2025) (rejecting a challenge to the scope of preliminary relief where the Government failed to "flesh[] out how any narrower injunction would work" (citation omitted)). The district court reasonably concluded that "[i]dentifying specific members of the ACIP who should not have been appointed, based on an incomplete record, or assuming that HHS is wholly incapable of assembling a lawful ACIP at this stage and enjoining it from doing so, would impose a far greater intrusion on Defendants' operation than merely staying the current appointments." App. 859, District Ct. Dkt. No. 291 at 44. The Government has not established that the district court exceeded its remedial discretion.

The Government suggests (Br. 53) that the district court's order creates a problem with approval of the annual flu vaccine for the 2026-2027 flu season. The Government did not raise this issue before the district court, it has presented no

evidence of a problem, and there are strong reasons to believe that no such problem exists. First, FDA's Vaccines and Related Biological Products Advisory Committee has already finalized its strain recommendations for the 2026-2027 season.[32] ACIP and CDC play no role in this process. Second, federal laws do not require the ACIP to issue recommendations annually for coverage requirements to be triggered.[33]

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[32] U.S. Food & Drug Admin., *Influenza Vaccine Composition for the 2026-2027 U.S. Influenza Season* (Mar. 13, 2026) https://www.fda.gov/vaccines-blood-biologics/vaccines/influenza-vaccine-composition-2026-2027-us-influenza-season (last visited July 16, 2026).

[33] "[F]or the purpose of the purchase, delivery, and administration" of VFC vaccines, federal law directs the CDC to use "the list established (and periodically reviewed and as appropriate revised) by" the ACIP. 42 U.S.C. § 1396s(e). This provision refers to the ACIP's VFC resolutions, not the annual recommendations on appropriate use as incorporated into CDC's Immunization Schedules. ACIP's influenza VFC resolution was last updated in 2024 and remains effective. *See Advisory Committee on Immunization Practices Vaccines for Children Program Vaccines to Prevent Influenzas*, Ctrs. for Disease Control & Prevention (Oct. 23, 2024), https://www.cdc.gov/vaccines-for-children/downloads/Influenza-508.pdf [https://perma.cc/2XG2-N829]. Indeed, the Pediatric Influenza Vaccine Price List has already been published for the 2026-2027 season. *See Pediatric Influenza Vaccine Price List*, Ctrs. for Disease Control & Prevention (2026), https://www.cdc.gov/vaccines-for-children/media/pdfs/2026/03/Pediatric-Influenza-Vaccine-Price-List-03-02-26-508.pdf [https://perma.cc/NP43-63CF]. Additionally, the ACA requires all non-grandfathered commercial health plans and issuers to cover, without cost sharing, "immunizations that have in effect a recommendation from the [ACIP] with respect to the individual involved." 42 U.S.C. § 300gg-13(a)(2). The implementing regulations at 45 C.F.R. § 147.130 state that coverage is required for immunizations "for routine use" that have a recommendation "in effect," defined as an ACIP recommendation adopted by the CDC Director and listed in the MMWR. Currently, the ACIP's June 2025 vote on the flu vaccine is listed in the MMWR and remains operative. Lisa Grohskopf, *et al*., *Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2025–26 Influenza Season*, 74 MORBIDITY & MORTALITY WKLY. REP. 500

Third, a trade association of health insurance companies has committed that health plans will continue to cover all ACIP-recommended immunizations that were recommended as of September 1, 2025, including updated formulations of the COVID-19 and influenza vaccines, with no cost-sharing for patients through the end of 2027.[34] If the Government nevertheless believes there is a problem, it is free to return to the district court to seek a modification of the stay order. It has not done so. It also waited 45 days to file a notice of appeal and an additional 43 days to file a motion to expedite the appeal, suggesting that it does not perceive an urgent problem with the 2026-2027 flu vaccine.

The Government's argument that the district court's remedy conflicts with *Braidwood*, 606 U.S. 748, fails for several reasons. First, to the extent that the Government is seeking to raise a constitutional separation-of-powers challenge to the district court's remedy, it did not properly raise that challenge in the district court and should not be permitted to do so on appeal. *See supra* at 31-32 (discussing forfeiture). Second, *Braidwood* addressed the Secretary's power to remove inferior officers of the United States. 606 U.S. at 764-70. Here, the district court's order does not limit the Secretary's power to remove ACIP members (and, indeed,

(Aug. 28, 2025) https://www.cdc.gov/mmwr/volumes/74/wr/mm7432a2.htm [https://perma.cc/K3Z9-ERDU].

[34] AHIP, *AHIP Statement on Vaccine Coverage* (May 1, 2026) https://www.ahip.org/news/press-releases/ahip-statement-on-vaccine-coverage [https://perma.cc/WE76-QJFH].

Plaintiffs have not challenged the Secretary's mass *firing* of all the ACIP members). Third, the Government recognizes that the ACIP is an advisory committee and therefore its members may not exercise Executive authority in the constitutional sense. In contrast, the Task Force at issue in *Braidwood* was not subject to FACA. *See* 606 U.S. at 766 n.3 (the Task Force "is not subject to the provisions of chapter 10 of title 5"). Fourth, *Braidwood* does not deprive Congress of authority to establish qualifications for members of advisory committees, or even for officers of the United States. For example, the court did not question the validity of the statutory requirement that members of that Task Force must have "appropriate expertise." *See id.* at 781 (recognizing that the official charged with convening the Task Force "is required to ensure that members . . . meet certain qualifications, such as 'appropriate expertise'" (quoting 42 U.S.C. § 299b-4(a)(1))).

Finally, the Government contends that "the proper relief" in this case is to lift the stay of the 13 appointments to the ACIP so that "the Secretary can rebalance the ACIP." Gov't Br. 53. But the district court's order leaves the Secretary completely free to rebalance the ACIP lawfully, and it expressly recognizes that many different balances can be struck. App. 859, District Ct. Dkt. No. 291 at 44. The district court's interim relief, which the district court reasonably viewed as a less intrusive variation of the relief the Government itself proposed, did not exceed the district court's remedial authority.

CONCLUSION

This Court should dismiss for lack of appellate jurisdiction. If it exercises jurisdiction, it should affirm the district court's order.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

1. This Brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(b) because it contains 10,629 words, excluding the parts of the Brief exempted by Federal Rule of Appellate Procedure 32(f).

2. This Brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point, Times New Roman font.

July 16, 2026 /s/ *James J. Oh*

CERTIFICATE OF SERVICE

I certify that on July 16, 2026, I electronically filed the foregoing document with the Clerk of the Court of the United States Court of Appeals for the First Circuit by using the appellate CM/ECF system. I certify that all participants in this case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

/s/ DRAFT