UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAUL THOMAS, M.D.; KENNETH P. STOLLER, M.D.; and STAND FOR HEALTH FREEDOM,

Plaintiffs,

v. Case No. 1:25-cv-02685-JMC

JAY BHATTACHARYA, in his official capacity as Acting Director, Centers for Disease Control and Prevention,

Defendant.

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANT'S MOTION TO DISMISS

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INTRODUCTION

The government asks this Court to dismiss a case in which two physicians lost their careers for practicing the medicine the Institute of Medicine repeatedly urged the CDC to investigate. The government says the injuries are not traceable to the CDC, that this Court cannot redress them, and that subsequent events have mooted the claims. None of that is correct.

The government argues that state medical boards acted independently when they disciplined Dr. Thomas and Dr. Stoller. Def. Mem. at 7–10. But the boards did not act independently. They said so themselves. The Medical Board of California found that "the standard of care for pediatricians in giving advice and making decisions about immunization is to follow the recommendations in the ACIP Guidelines and the AAP Red Book." *In re Stoller*, Cal. Med. Bd. Case No. 800-2017-034218, Proposed Decision, Finding 83 (adopted Feb. 16, 2021), aff'd, *Stoller v. Medical Bd. of Cal.*, 2021 Cal. Super. LEXIS 108488 (Sacramento Cnty. Super. Ct. Sept. 13, 2021). Oregon's regulations define "contraindication or precaution" as a diagnosis "in accordance with the current recommendations of the Advisory Committee on Immunization Practices." OAR 333-050-0210(8). The boards were not exercising independent judgment. They were applying a federal scheme incorporated into state law.

The government argues that the January 2026 schedule revision moots this case. Def. Mem. at 16–19. Yet in *AAP v. Kennedy*, Case No. 1:25-cv-11916 (D. Mass.), the American Academy of Pediatrics is seeking a preliminary injunction to restore the pre-January vaccine schedule, seeking to move the six reclassified vaccines back from shared clinical decision-making to universal recommendation. Moreover, ACIP recommendations are not merely advisory as a matter of federal law: under 42 U.S.C. § 300gg-13(a)(2), they trigger mandatory

insurance coverage obligations for approximately 175 million Americans the moment the CDC Director adopts them. The government tells this Court there is "no reasonable expectation that the alleged violation will recur." In Massachusetts, the AAP is litigating to make it recur. The government is the defendant in that case.

On the merits, the government invites this Court to defer to the CDC's scientific judgment. Def. Mem. at 22–24. But the problem is that CDC did not exercise scientific judgment on the critical question. The Institute of Medicine told CDC in 2002 to study the cumulative safety of the childhood vaccine schedule. IOM repeated that recommendation in 2013, finding "no studies have compared the differences in health outcomes … between entirely unimmunized populations of children and fully immunized children." IOM 2013 at 9. CDC ignored both recommendations. When Dr. Thomas conducted precisely such a study, he lost his license within days. CDC refused to conduct the study. When a physician conducted one, it cost him his career. At the pleading stage, that states a claim. Plaintiffs' Complaint should not be dismissed.

ARGUMENT

THE SUPREME COURT HAS ALREADY CHARACTERIZED ACIP'S AUTHORITY AS BINDING.

The government characterizes ACIP recommendations as "merely advisory." Def. Mem. at 3, 7, 25. From that characterization, it argues the recommendations are too attenuated to cause injury, do not require notice-and-comment rulemaking, and cannot constitute final agency action. The Supreme Court has rejected the premise.

In *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025), the Court examined the Affordable Care Act's delegation to the U.S. Preventive Services Task Force ("PSTF") under

42 U.S.C. § 300gg-13(a)(1). That provision requires non-grandfathered health plans to cover, without cost-sharing, items and services rated "A" or "B" by the PSTF. The adjacent provision, § 300gg-13(a)(2), imposes an identical mandate for "immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices." The Court recognized the two provisions as parallel delegations to parallel entities within HHS. *See id.* at 753, 766–67.

The Court did not leave ACIP's status as an open question. In footnote 4 of the majority opinion, the Court examined ACIP by name and identified the regulatory mechanism through which its recommendations acquire legal force: "The body within HHS assigned to recommend immunization coverage requirements under the Affordable Care Act—the Advisory Committee on Immunization Practices—already operates under such a regulation. The regulation states that a recommendation of the Committee is not 'considered in effect' until 'it has been adopted by' the Director of the Centers for Disease Control and Prevention, who answers to the Secretary of HHS." *Id.* at 767 n.4 (citing 45 C.F.R. § 147.130(a)(1)(ii)). The Court held up ACIP's adoption process as the model for constitutionally adequate oversight, the "formal review process" that ensures binding recommendations do not take legal effect without review by an accountable officer. *Id.* at 767.

This characterization confirms what the Court stated more broadly in footnote 3: that the PSTF "ceased to be an advisory committee in 2010 when Congress enacted the Affordable Care Act and empowered the Task Force to issue binding recommendations." *Id.* at 766 n.3. ACIP operates under the identical statutory mechanism, § 300gg-13(a)(2). An entity whose recommendations go through a formal regulatory adoption process before they take effect is not issuing advice.

Braidwood was decided in 2025. The government filed its motion to dismiss in this case thereafter, yet its brief proceeds as if the decision does not exist. It argues that ACIP recommendations "are not, by themselves, binding on the states, or on physicians, or on anyone else," Def. Mem. at 3, while the Supreme Court describes the identical statutory mechanism as the power to issue binding recommendations that carry the force of law.

Braidwood affects every issue the government raises. If the Supreme Court has described ACIP's authority as binding, the government cannot argue that the resulting injury is too attenuated to establish standing. The same characterization undercuts the government's position on reviewability and notice-and-comment. And an action that triggers mandatory insurance coverage for 175 million Americans under federal statute carries the "legal consequences" required for final agency action. *Cf. Bennett v. Spear*, 520 U.S. 154, 178 (1997).

Braidwood's characterization also raises structural constitutional questions. If ACIP's recommendations are binding, the validity of the delegation (to a committee whose members are appointed by the CDC Director rather than nominated by the President and confirmed by the Senate) implicates the Appointments Clause concerns that animated *Braidwood* itself. *See* 606 U.S. at 765–68. This Court need not reach those questions to deny the motion to dismiss. But they confirm that the Recommended Schedule is not the innocuous advisory document the government portrays. It is a regulatory instrument with substantial practical consequence. The APA's procedural protections apply.

I. PLAINTIFFS HAVE ARTICLE III STANDING.

A. The Individual Plaintiffs' Injuries Are Fairly Traceable to the CDC's Conduct.

The government contends that Dr. Thomas's and Dr. Stoller's injuries are traceable to state medical boards rather than the CDC. Def. Mem. at 7–10. This argument fails because it

mischaracterizes the causal mechanism. The individual Plaintiffs do not allege an "attenuated chain of possibilities." They allege, and document, that state boards explicitly adopted ACIP recommendations as the governing standard of care and then disciplined physicians for deviation from that federally-defined standard.

1. Dr. Stoller: Documented State Adoption of the Federal Framework.

Dr. Stoller's case is straightforward on traceability. The Medical Board of California revoked Dr. Stoller's license for deviating from the ACIP standard of care, finding that "the standard of care for pediatricians in giving advice and making decisions about immunization is to follow the recommendations in the ACIP Guidelines and the AAP Red Book." *In re Stoller*, Cal. Med. Bd. Case No. 800-2017-034218, Proposed Decision, Finding 83 (adopted Feb. 16, 2021), aff'd, Stoller v. Medical Bd. of Cal., 2021 Cal. Super. LEXIS 108488 (Sacramento Cnty. Super. Ct. Sept. 13, 2021). That is not a "speculative" or "attenuated" causal chain. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013). A physician lost his license for deviating from ACIP, and a Superior Court judge affirmed. Recommendations that carry those consequences are not advisory.

The government's reliance on *Murthy v. Missouri*, 603 U.S. 43 (2024), is misplaced. Def. Mem. at 8–9. In *Murthy*, the question was whether social media platforms moderated content because of government jawboning or because of their own independent policies. *Id.* at 45. The Court found an insufficient causal link because the platforms had preexisting terms of service that independently motivated their decisions.

Here, there is no ambiguity. The state tribunal identified the source of its standard: ACIP. The Medical Board did not happen to agree with CDC. It incorporated CDC by explicit regulatory reference.

The correct framework is *Diamond Alternative Energy, LLC v. EPA*, 606 U.S. 100, 112–13 (2025). As the Supreme Court explained: "[A] court must conclude that 'third parties will likely react' to the government regulation (or judicial relief) 'in predictable ways' that will likely cause (or redress) the plaintiff's injury." *Id.* at 112–13 (quoting *All. for Hippocratic Med.*. Dr. Stoller's case is far stronger: he does not merely allege that third-party reactions were "predictable." He has a documented judicial ruling confirming the state board followed ACIP.

2. Dr. Thomas: Oregon Law Incorporates ACIP by Regulatory Definition.

Oregon's regulatory structure eliminates any traceability gap. OAR 333-050-0210(8) defines "contraindication or precaution" as "a medical diagnosis … in accordance with the current recommendations of the Advisory Committee on Immunization Practices." OAR 333-050-0270(d) provides that a medical exemption lacking an ACIP-compliant contraindication "lacks the required elements" and is facially invalid. Oregon wrote ACIP into the regulatory definitions themselves. Change the federal framework, and the state definitions change automatically.

Dr. Thomas was suspended within days of publishing a retrospective analysis of over 3,000 patients comparing health outcomes between vaccinated and unvaccinated children, the type of study IOM had recommended in 2002 and 2013 that CDC refused to conduct. Compl. ¶¶ 7, 12.

His individualized protocols deviated from the ACIP framework that Oregon law defines as the exclusive basis for medical exemptions. The timing and basis of his suspension confirm that the ACIP framework, not independent state judgment, drove the disciplinary action.

3. The Government's Decoupling Evidence Proves Plaintiffs' Case.

The government cites evidence that certain states have recently decoupled from CDC recommendations. Def. Mem. at 9–10. California passed a law in September 2025 freezing its baseline at the January 1, 2025, schedule. Oregon's Health Authority announced its requirements

are "independent of federal recommendations." Twenty-eight states publicly announced they would not follow the January 2026 changes. Id.

California had to pass a new law to freeze its baseline, which means before September 2025, California's requirements tracked CDC automatically. Oregon issued a public statement distinguishing its requirements from federal changes, which was necessary only because the default assumption was linkage. And twenty-eight states publicly announced their departure from the CDC schedule, which tells you their prior posture was to follow it.

All of this decoupling occurred after Dr. Thomas and Dr. Stoller lost their licenses. At the time of their discipline, both Oregon and California were operating under the default regime of ACIP incorporation. The government cannot use 2025–2026 legislative changes to argue that the 2020–2021 enforcement actions were not traceable to the federal framework in effect at the time.

4. The Involvement of Other Entities Does Not Defeat Traceability.

The government frames Plaintiffs' theory as a "speculative, attenuated causal chain" and invokes *Murthy v. Missouri*, 603 U.S. 43, 45 (2024), for the proposition that third-party conduct attributable to independent judgment cannot be traced to government action. Def. Mem. at 8. But *Murthy* held only that where social media platforms had preexisting policies that independently motivated their content moderation, the plaintiffs could not show the government's communications were the but-for cause. 603 U.S. at 60–62. The Court did not hold, and no authority holds, that government action becomes untraceable merely because third parties implement it.

Article III "requires no more than de facto causality," and traceability is established where third-party reactions to government action are "predictable." *Dep't of Commerce v. New*

York, 588 U.S. 752, 768 (2019). Where the government creates conditions under which third parties predictably cause injury, standing is established regardless of other actors in the causal chain. *Duke Power Co. v. Carolina Env't Study Grp.*, 438 U.S. 59, 76–78 (1978). The Supreme Court reaffirmed this in *Diamond Alternative Energy*, holding that "a court must conclude that 'third parties will likely react' to the government regulation (or judicial relief) 'in predictable ways' that will likely cause (or redress) the plaintiff's injury." 606 U.S. at 112–13 (quoting *All. for Hippocratic Med.*, 602 U.S. at 383).

Here, third-party reactions were not merely predictable. They were documented. The Complaint alleges, and the government does not dispute, that "nearly 600 statutes and regulations across 49 states" reference ACIP. Compl. ¶ 3 (quoting ASTHO). State boards applied the ACIP framework as their governing standard of care. *Supra* Sections I.A.1–2. That private professional organizations may also have promoted or incorporated that framework does not sever the causal chain. *See Duke Power*, 438 U.S. at 76–78; *Diamond Alt. Energy*, 606 U.S. at 112–13.

These legal consequences extend beyond state adoption. Under 42 U.S.C. § 300gg-13(a)(2), enacted as part of the Affordable Care Act, non-grandfathered group health plans must cover without cost-sharing "immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention." An ACIP recommendation comes "in effect" when adopted by the CDC Director. *See also* 45 C.F.R. § 147.130. This federal coverage mandate (affecting approximately 175 million Americans) operates automatically upon ACIP recommendation without any intervening state action. An agency recommendation that triggers mandatory insurance coverage obligations by force of federal statute is not the "non-binding" guidance the government describes. Def.

Mem. at 3. *Cf. Bennett v. Spear*, 520 U.S. 154, 178 (1997) (final agency action where "legal consequences" flow from agency determination).

B. A Favorable Decision Would Likely Redress Plaintiffs' Injuries.

Redressability does not require certainty that the injury will be cured. It requires a likelihood. The government argues that even a favorable ruling would not remedy Plaintiffs' injuries because reinstatement depends on third-party state boards. Def. Mem. at 11–12. That misstates the relief sought and the legal standard.

Redressability does not require certainty. The plaintiff must show that the injury is "likely to be redressed by a favorable judicial decision." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 338 (2016). Where third-party responses to judicial relief are "predictable," that standard is met. *Diamond Alt. Energy*, 606 U.S. at 112–13.

The relief Plaintiffs seek is a declaration that CDC's failure to test the cumulative schedule renders the rigid Category A framework arbitrary and capricious, coupled with reclassification to shared clinical decision-making. That relief would not merely "could lead to" reinstatement. It would eliminate the legal predicate for the state discipline. Under Oregon's OAR, if ACIP's framework changes, the regulatory definition of "contraindication or precaution" changes automatically, because the regulation incorporates ACIP by reference. OAR 333-050-0210(8).

A federal court declaration that the framework is legally deficient does not ask the state board to exercise discretion. It removes the federal standard the state board relied on. Reclassification to shared clinical decision-making would transform the individualized protocols that formed the basis for Plaintiffs' discipline from deviant practice into permissible medical judgment. Dr. Thomas's individualized vaccine protocols and Dr. Stoller's genetic-based

exemptions would no longer violate the governing standard. The governing standard would permit exactly that kind of individualized assessment. With the framework changed, Plaintiffs could seek reinstatement in their home states or apply for licensure in jurisdictions where shared clinical decision-making is already the norm under the Kennedy HHS reforms.

The government's argument that court-ordered studies might vindicate the schedule (Def. Mem. at 12) confuses redressability with the merits. Redressability requires only that a favorable decision would likely remedy the injury. Whether the studies ultimately support universal recommendation or individualized protocols is a question for the merits, not for Article III jurisdiction.

C. Stand for Health Freedom Has Organizational Standing.

The government argues that SHF cannot establish organizational standing under *FDA v. Alliance for Hippocratic Medicine*, 602 U.S. 367 (2024), because its resource expenditures constitute "self-inflicted budgetary choice[s]." Def. Mem. at 14–15. This argument conflates two distinct categories of organizational injury.

In *Alliance*, the plaintiff organizations were anti-abortion medical associations that did not prescribe, manufacture, or sell mifepristone. 602 U.S. at 385. They had no operational connection to the challenged FDA regulation. Their expenditures were purely ideological, spending money to oppose a policy they disagreed with. *Id.* at 394–95. The Court held that "an organization that has not suffered a concrete injury caused by a defendant's action cannot spend its way into standing simply by expending money to gather information and advocate against the defendant's action." *Id.* at 394.

SHF is not analogous to the *Alliance* plaintiffs. SHF's core mission is supporting families navigating school vaccine mandates, developing resources for parents seeking medical exemptions, and coordinating state-level advocacy for informed consent laws. Compl. ¶¶ 14, 32. The CDC's untested schedule is the operational environment SHF works in, not a policy it opposes. When the CDC maintains rigid Category A recommendations that states adopt as school-entry mandates, SHF must divert resources from its core programming to address the consequences: families excluded from school, parents denied informed consent, physicians unable to provide individualized guidance.

That is the distinction between ideological opposition (*Alliance*) and operational disruption (*Havens Realty Corp. v. Coleman*, 455 U.S. 363 (1982)). In *Havens*, the defendant's discriminatory practices "perceptibly impaired" the organization's ability to provide its core housing counseling services. 455 U.S. at 379.

SHF's injuries are of the same character. But for CDC's refusal to test the cumulative schedule and its maintenance of the rigid contraindications criteria, SHF would not need to divert resources from its core programming to supporting families facing school exclusion, hosting webinars presenting scientific evidence excluded from CDC's process, and developing educational materials to counter incomplete safety information. Compl. ¶ 32.

D. The Individual Plaintiffs Have Standing to Assert Constitutional Claims.

The government argues that Dr. Thomas and Dr. Stoller lack standing to assert Fifth Amendment claims because they are not parents or children. Def. Mem. at 11. That mischaracterizes the basis for their constitutional standing.

Dr. Thomas and Dr. Stoller assert due process claims based on their own constitutionally protected interests: their property interest in their medical licenses and their liberty interest in

practicing their profession. The Fifth Amendment protects against the deprivation of "life, liberty, or property, without due process of law." U.S. Const. amend. V. A medical license is a constitutionally protected property interest. *See Barry v. Barchi*, 443 U.S. 55, 64 (1979). The right to pursue one's chosen profession is a protected liberty interest. *See Greene v. McElroy*, 360 U.S. 474, 492 (1959). The parental rights allegations in the Complaint provide context for the systemic harm the CDC's framework inflicts. They are not the basis for Dr. Thomas's or Dr. Stoller's individual standing.

E. Each Plaintiff Independently Supports Standing for the Claims Asserted.

The government correctly notes that standing must be demonstrated for each claim. Def. Mem. at 11 (citing *Davis v. FEC*, 554 U.S. 724, 734 (2008)). Each Plaintiff satisfies that requirement. Dr. Stoller's documented discipline under the ACIP-incorporating California framework supports standing for the APA claims (arbitrary and capricious, notice-and-comment), the due process claim (deprivation of property and liberty interests in his medical license), and the First Amendment claim (professional discipline for deviating from the federal framework). Dr. Thomas's discipline under Oregon's ACIP-incorporating regulations independently supports standing for the same claims. SHF's organizational injuries support standing for the APA claims and the notice-and-comment claim. The Court need find standing for only one Plaintiff per claim. *See Davis*, 554 U.S. at 734.

II. PLAINTIFFS' CLAIMS ARE NOT MOOT.

Under the voluntary cessation doctrine, the government bears a "heavy burden" to demonstrate mootness. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs.*, 528 U.S. 167, 189 (2000). It must make "absolutely clear that the allegedly wrongful behavior could not reasonably be expected to

recur." *Id.* at 190. The government contends the January 5, 2026, schedule revision meets that standard. Def. Mem. at 16–19. It does not.

1. The Complaint Challenges the Structural Framework, not a Particular Schedule Version.

Plaintiffs do not challenge a specific list of vaccines. They challenge the CDC's failure to study the cumulative safety of the childhood vaccination schedule, a failure that persists regardless of how many vaccines are on the schedule. The January 2026 revision moved approximately six vaccines from universal recommendation to shared clinical decision-making or risk-based categories, reducing the universally recommended childhood vaccines from approximately eighteen to approximately eleven. But reducing the number of untested universal recommendations is not the same as eliminating the framework that produces them. Eleven vaccines are still universally recommended without the cumulative safety studies the IOM called for in 2002 and 2013. The basic problem (universal recommendations issued without cumulative safety testing) has not changed.

A case becomes moot only when the challenged conduct has been fully eliminated, not merely scaled back. The government has not studied the cumulative effects of the remaining schedule, has not revised the contraindications standards, and has not addressed the enforcement architecture that cost Plaintiffs their careers. Partial modification of a challenged practice does not moot a case. "It is well settled that a defendant's voluntary cessation of a challenged practice does not deprive a federal court of its power to determine the legality of the practice." *City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982).

The government emphasizes that "the Recommended Schedule overall is meaningfully different in 2026 than it was in 2025" because "the CDC removed approximately six vaccines

from its list of vaccines routinely recommended for all children." Def. Mem. at 17–18. But Plaintiffs do not challenge a vaccine list. They challenge the contraindications and precautions framework, the narrow criteria that determine when a physician may deviate from whatever vaccines remain on the schedule. That framework has not been modified by the January 2026 revision or any subsequent agency action. States that incorporated ACIP's contraindications by regulatory reference continue to enforce the identical criteria. OAR 333-050-0210(8). Plaintiffs were not disciplined for giving too few vaccines. They were disciplined for deviating from the contraindications standards that states had incorporated. That standard persists regardless of how many vaccines are on the schedule.

2. Active Federal Litigation Demonstrates a Reasonable Expectation of Recurrence.

The voluntary cessation doctrine provides that a case is not moot unless "(1) 'there is no reasonable expectation that the alleged violation will recur,' and (2) 'interim relief or events have completely or irrevocably eradicated the effects of the alleged violation.'" *Nat'l Black Police Ass'n*, 108 F.3d 346, 349 (D.C. Cir. 1997). Neither prong is satisfied here.

As to recurrence: the American Academy of Pediatrics is litigating *AAP v. Kennedy* in the District of Massachusetts, seeking a preliminary injunction to restore the pre-January vaccine schedule. AAP's proposed order would require the CDC to reinstate universal recommendation for all six reclassified vaccines and enjoin all future ACIP meetings of the current membership until final adjudication. If the AAP prevails, the entire schedule reverts, and the framework Plaintiffs challenge here is fully restored.

The government argues there is "no reasonable expectation" of recurrence. But it is currently defending against the AAP's lawsuit in Massachusetts, which seeks to produce that

recurrence. *See Akiachak Native Cmty. v. Dep't of Interior*, 827 F.3d 100, 106 (D.C. Cir. 2016) (mootness requires absence of evidence that the challenged action "likely will be reenacted"). The AAP's pending litigation is that evidence.

Nor is the AAP lawsuit the only pending action seeking to restore the prior schedule. On February 24, 2026, fifteen state attorneys general filed *State of California v. Kennedy*, No. 26-cv-01609 (N.D. Cal.), challenging the same January 5 Decision Memo and the reconstitution of ACIP. The states seek to enjoin and vacate the revised schedule and restore universal recommendation for all seven reclassified vaccines. This case is one of three pending federal actions addressing the Kennedy HHS administration's changes to the childhood immunization schedule. The AAP and the fifteen states are pushing to restore the pre-January schedule of eighteen universally recommended diseases. This case moves in the opposite direction, toward shared clinical decision-making for all childhood vaccines until the cumulative schedule has been tested for safety. The government's claim that this controversy is moot cannot be reconciled with the existence of two other federal lawsuits seeking to produce the very outcome Plaintiffs challenge.

As to eradication of effects: the injuries Plaintiffs suffered have not been eradicated. Dr. Thomas remains unable to practice. Dr. Stoller's license remains revoked. The contraindications framework that drove their discipline remains in force.

The schedule revision did not restore their licenses, compensate their losses, or change the standard under which they were disciplined.

III. PLAINTIFFS STATE VALID CLAIMS UNDER THE ADMINISTRATIVE PROCEDURE ACT.

A. The Recommended Schedule Is Reviewable Under the APA.

The APA creates a "strong presumption" favoring judicial review of administrative action. *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986). The exception for action "committed to agency discretion by law" is "a very narrow exception." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 410 (1971). The government invokes it here, arguing the Recommended Schedule is unreviewable under 5 U.S.C. § 701(a)(2). Def. Mem. at 20–21. If accepted, the argument would immunize from judicial review any agency action taken under a broad statutory delegation. That CDC operates under a broad grant to "assist" and "advise" states, 42 U.S.C. § 243, does not render its actions unreviewable. The APA's arbitrary-and-capricious standard supplies the judicially manageable standard the government claims is absent.

The First Circuit has held that FACA's requirements supply reviewable legal standards for advisory committee actions. *Union of Concerned Scientists v. Wheeler*, 954 F.3d 11, 20 (1st Cir. 2020). If the composition and procedures of ACIP are reviewable, so too are the substantive recommendations produced through those procedures.

B. The Recommended Schedule Constitutes Final Agency Action.

The government argues that the Recommended Schedule is not final agency action because it is merely advisory. Def. Mem. at 21–22. The statutory framework and the record say otherwise. The test for final agency action requires that (1) the action marks the consummation of the agency's decision making process, and (2) the action is one from which legal consequences flow. *Bennett v. Spear*, 520 U.S. 154, 178 (1997).

The Recommended Schedule satisfies both prongs. It represents the consummation of ACIP's deliberative process: the committee reviews evidence, votes, and the CDC Director formally adopts and publishes the schedule. Legal consequences flow from it. As the Complaint

alleges and the government's own decoupling evidence confirms, nearly 600 statutes and regulations across 49 states reference ACIP. Association of State and Territorial Health Officials (ASTHO), Impact of ACIP Recommendations on State Law (2025). When ACIP adopts a recommendation, state laws that incorporate ACIP by reference automatically give that recommendation the force of law. Automatic incorporation into state regulatory definitions is a direct legal consequence. See OAR 333-050-0210(8).

The Supreme Court confirmed this mechanism. In *Braidwood*, the Court specifically identified ACIP's regulation and noted that a recommendation "is not 'considered in effect' until 'it has been adopted by' the Director of the Centers for Disease Control and Prevention." 606 U.S. at 767 n.4 (citing 45 C.F.R. § 147.130(a)(1)(ii)). The Director's adoption is the discrete act that satisfies *Bennett*'s first prong, the "consummation of the agency's decisionmaking process." 520 U.S. at 178. The legal consequences that flow from that adoption (mandatory insurance coverage under § 300gg-13(a)(2), incorporation into nearly 600 state statutes, VFC compliance obligations, medical board enforcement) satisfy *Bennett*'s second prong.

The government contends that "nothing about the schedule changes States' authority" and that "CDC's recommendations remain non-binding." Def. Mem. at 21–22. But legal consequences flow from ACIP recommendations directly at the federal level, without any intervening state action. Under 42 U.S.C. § 300gg-13(a)(2), enacted as part of the Affordable Care Act, non-grandfathered group health plans must cover without cost-sharing "immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices." *See* 45 C.F.R. § 147.130.

Congress specifically identified ACIP recommendations as the trigger for mandatory insurance coverage obligations affecting the majority of privately insured Americans. When the

agency publishes a recommendation and the Director adopts it, legal rights and obligations attach by operation of federal law. That satisfies *Bennett*'s requirement of an action from which "legal consequences will flow." 520 U.S. at 178.

The government cites *Dalton v. Specter*, 511 U.S. 462, 469 (1994), for the proposition that a recommendation is not final agency action. Def. Mem. at 22. But *Dalton* involved a base-closure recommendation to the President, who retained independent authority to accept or reject it. *Id.* at 469–70. Here, there is no intervening decisional authority between an ACIP recommendation adopted by the CDC Director and the legal obligation it creates under § 300gg-13(a)(2). The insurance coverage mandate operates automatically. Congress did not treat ACIP recommendations as suggestions. It treated them as authoritative determinations with automatic legal force. This Court should do the same for purposes of the final agency action analysis.

C. The Recommended Schedule Is Arbitrary and Capricious.

Agency action is arbitrary and capricious when the agency has "entirely failed to consider an important aspect of the problem." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The government argues that Plaintiffs merely "read the data differently" and that this Court should defer to agency expertise. Def. Mem. at 22–24.

But Plaintiffs identify the absence of evidence, not a disagreement about what it shows. The CDC has never studied the cumulative safety of the childhood vaccine schedule. CDC never conducted the study. The IOM confirmed that gap in 2002. It confirmed it again in 2013, finding that "no studies have compared the differences in health outcomes … between entirely unimmunized populations of children and fully immunized children" and that "studies designed to examine the long-term effects of the cumulative number of vaccines or other aspects of the immunization schedule have not been conducted." IOM 2013 at 9–10.

The agency's only publicly articulated justification for not conducting these studies is a theoretical immunogenicity argument, the claim that infants can theoretically respond to 10,000 vaccines simultaneously. Offit PA, et al., "Addressing Parents' Concerns: Do Multiple Vaccines Overwhelm or Weaken the Infant's Immune System?", Pediatrics 2002;109(1):124–129. Compl. ¶ 8 & n.5.

This article was published in the official journal of the American Academy of Pediatrics by a lead author who served simultaneously on AAP's Committee on Infectious Diseases (which publishes the Red Book pediatric guidelines) and on the CDC's Advisory Committee on Immunization Practices. The article addressed immunological capacity (whether the immune system can generate antibody responses), not the clinical safety question the IOM identified: whether the cumulative schedule produces net health benefits across all health outcomes. The IOM's 2013 report was issued after this theoretical model was in wide circulation and specifically concluded that the existing evidence base was inadequate because no empirical studies had been done.

An agency that relies on a theoretical model that its own scientific advisors have declared insufficient, refuses to conduct the empirical studies those advisors recommended, and builds a rigid enforcement framework on the untested assumption has "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. The sequence is documented. It is not disputed.

The government cites *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1160 (2021), for the proposition that agencies need not have "perfect empirical or statistical data." Def. Mem. at 23–24. But *Prometheus* involved an agency that had some data and made a reasoned decision about how to use it. Here, the agency has no cumulative safety data: not imperfect data, not

incomplete data, but no data at all on the central question its own advisors identified. The agency never conducted the inquiry. There is nothing to defer to.

IOM recommends study of the cumulative schedule (2002, 2013). CDC refuses. Dr. Thomas conducts such a study (2020). Oregon suspends his license within days (2020). The government's position requires this Court to accept that the cumulative schedule does not need study, that the IOM was wrong to recommend it twice, and that the physician who conducted the recommended study committed professional misconduct. Accepting all well-pleaded facts as true, as the Court must on a motion to dismiss, the sequence states a plausible claim for arbitrary and capricious agency action.

D. The Recommended Schedule Required Notice-and-Comment Rulemaking.

The government argues that the Recommended Schedule is a non-binding recommendation that does not require notice-and-comment rulemaking. Def. Mem. at 25. But when agency "guidance" has binding practical effect, it must undergo rulemaking. *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1020 (D.C. Cir. 2000) ("The phenomenon we see in this case is familiar. Congress passes a broadly worded statute. The agency follows with regulations containing broad language, open-ended phrases, ambiguous standards and the like. Then as years pass, the agency issues circulars or guidance or memoranda, explaining, interpreting, defining and often expanding the commands in the regulations. One guidance document may yield another and then another and so on. Several words in a regulation may spawn hundreds of pages of text as the agency offers more and more detail regarding what its regulations demand of regulated entities. Law is made, without notice and comment, without public participation, and without publication in the Federal Register or the Code of Federal Regulations.").

That description fits CDC's vaccination system. The Recommended Schedule is nominally advisory, but nearly 600 state statutes and regulations incorporate it by reference. ASTHO, *supra*. Medical boards enforce it as the exclusive standard of care. Schools condition attendance on compliance. When a "recommendation" carries these consequences, it is a rule in substance and must satisfy the APA's procedural requirements.

The government points to the word "Recommended" in the schedule's title and asserts that "CDC communications are clear that the schedules are recommendations rather than mandates." Def. Mem. at 25. The label is not dispositive. *See Appalachian Power*, 208 F.3d at 1023 (agency's disclaimer that guidance "cannot be relied upon to create any rights" does not save it where "'rights' may not be created but 'obligations' certainly are"). When a "recommendation" triggers mandatory insurance coverage under 42 U.S.C. § 300gg-13(a)(2), determines what medical services insurers must provide at zero cost-sharing, and is incorporated by reference into the regulatory definitions of 49 states, it has, as a practical matter, a binding effect that distinguishes a legislative rule from a policy statement. *See id.* at 1021.

The government cites *Telecommunications Research & Action Center v. FCC*, 800 F.2d 1181, 1186–87 (1986), for the proposition that policy statements need not undergo rulemaking. Def. Mem. at 25. But *TRAC* involved an agency's internal case-processing guidelines that imposed no obligations on regulated parties. 800 F.2d at 1186. ACIP recommendations impose coverage obligations on every non-grandfathered health plan in the country by force of federal statute. The Supreme Court in *Braidwood* characterized this authority as the power "to issue binding recommendations." 606 U.S. at 766 n.3. An agency action the Supreme Court has characterized as "binding" is not the type of non-binding policy statement exempt from notice-and-comment under 5 U.S.C. § 553(b)(A). The Recommended Schedule has operated with the

force of law for over a decade without the procedural safeguard the APA requires. That is the "large advantage" the D.C. Circuit warned against in *Appalachian Power*. 208 F.3d at 1020.

IV. PLAINTIFFS STATE VALID CONSTITUTIONAL CLAIMS.

A. The CDC's Framework Violates Substantive Due Process.

This claim turns on whether the Recommended Schedule is "purely advisory." The government says it is, and argues it therefore implicates no fundamental liberty interest and passes rational basis review. Def. Mem. at 26–28.

The government cites *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), for the proposition that states may mandate vaccines. Def. Mem. at 27. But Plaintiffs do not challenge state vaccine mandates. They challenge the federal government's creation of medical standards without scientific basis that the federal government knows states will enforce coercively. *Jacobson* upheld a vaccine mandate supported by the scientific understanding of its era. It did not hold that the government may impose medical interventions while refusing to study whether they are safe in combination.

As to rational basis: the government has the burden to demonstrate a rational connection between its action and a legitimate interest. *Reno v. Flores*, 507 U.S. 292, 293 (1993). Plaintiffs allege that the CDC has maintained universal vaccination recommendations for 72+ doses while refusing to study whether the cumulative schedule is safe, a refusal its own scientific advisors have criticized for over two decades. Even under rational basis review, government action that is "so attenuated as to render the distinction arbitrary or irrational" violates due process. *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 446 (1985). Maintaining universal recommendations while deliberately refusing to investigate their cumulative safety states a plausible claim under this standard.

B. The CDC's Framework Violates Equal Protection.

Plaintiffs' equal protection claim does not depend on a facial classification. Def. Mem. at 28–29 argues that the Recommended Schedule makes no distinction between children. The CDC's refusal to classify (its insistence on treating all children identically despite mounting evidence that some are medically vulnerable to vaccine injury) is itself irrational.

The CDC admits it has never studied which children face higher risks from the cumulative schedule. It refuses to investigate whether genetic markers, family history, or prior adverse reactions predict future injury. Having declined to investigate differential risk, it treats all children as medically identical. That is a conclusion the agency can maintain only by not looking at the evidence. Even under rational basis review, that states a plausible equal protection claim. Compl. ¶¶ 93–95.

C. The CDC's Framework Violates the First Amendment.

The government argues that Plaintiffs have not alleged CDC directly enforced professional speech restrictions or issued threats comparable to *NRA v. Vullo*, 602 U.S. 175 (2024). Def. Mem. at 29–31. That is not the claim.

Plaintiffs do not allege that CDC telephoned state medical boards and directed them to revoke licenses. They allege something more structural: the CDC created a contraindications framework so narrow that any physician who exercises individualized clinical judgment (including publishing research questioning the schedule's safety) faces automatic professional consequences through the states that have incorporated that framework into binding law.

The CDC knows states adopt its standards wholesale. The CDC knows medical boards enforce it as the exclusive standard of care. The CDC knows physicians who deviate face discipline. *See*

Bantam Books, Inc. v. Sullivan, 372 U.S. 58, 67 (1963) (government action that achieves suppressive effect through "inform[al] sanctions" violates the First Amendment).

Dr. Thomas published peer-reviewed research (the type of study the IOM recommended) and lost his license within days. The Complaint alleges sufficient facts to state a plausible First Amendment claim that the CDC's framework operates as a system of viewpoint suppression, enforced not through direct federal action but through the predictable mechanism of state regulatory adoption. At the motion-to-dismiss stage, these allegations must be accepted as true.

CONCLUSION

Plaintiffs have standing. Their injuries are documented and traceable to the CDC's framework through explicit state regulatory adoption. The relief sought would redress those injuries. The case is not moot. The regulatory scheme Plaintiffs challenge remains in force, the AAP is litigating to restore the prior schedule in Massachusetts, and Plaintiffs' injuries have not been eradicated.

On the merits, Plaintiffs plausibly allege that CDC maintained universal vaccination recommendations for decades while refusing to conduct the cumulative safety studies its own advisors recommended. It then disciplined the physicians who tried to fill the gap.

The motion to dismiss should be denied.

Dated: March 5, 2026

Respectfully submitted,

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Attorney for Plaintiffs

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PAUL THOMAS, et al.,

Plaintiffs,

Civil Action No. 25-2685 (JMC)

v.

JAY BHATTACHARYA, in his official capacity as Acting Director of the Centers for Disease Control and Prevention,

Defendant.

CERTIFICATE OF SERVICE

I hereby certify that on March 5, 2026, I electronically filed the foregoing Plaintiffs' Memorandum in Opposition to Defendant's Motion to Dismiss with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

Counsel of record registered with CM/ECF will receive service through the Court's electronic filing system. No party requires service by any other means.

Dated: March 5, 2026

Respectfully submitted,

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[PROPOSED] ORDER

UPON CONSIDERATION of Defendant's Motion to Dismiss and Memorandum in Support Thereof, Plaintiffs' Memorandum in Opposition thereto, and the entire record herein, it is hereby

ORDERED that Defendant's Motion to Dismiss is DENIED.

SO ORDERED:

_____ _____

Date JIA M. COBB
United States District Judge