

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

AMERICAN ACADEMY OF PEDIATRICS, *et al.*,

Plaintiffs,

vs.

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

Defendants.

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

**PLAINTIFFS' SUPPLEMENTAL BRIEF REGARDING
THE APPLICABILITY OF THE FEDERAL ADVISORY COMMITTEE ACT TO THE
ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES**

I. INTRODUCTION

The Court has questioned whether the Advisory Committee on Immunization Practices (“ACIP”) functions as an advisory committee, such that it is governed and subject to the requirements of the Federal Advisory Committee Act (“FACA”). The answer is yes. Congress enacted FACA to regulate committees providing advice or recommendations to federal agencies. The ACIP does just that. From inception, the ACIP has consistently provided advice and recommendations regarding the control of vaccine-preventable diseases for the consideration and approval by the Centers for Disease Control and Prevention (“CDC”) Director. Unlike the U.S. Preventive Services Task Force (“PSTF”) at issue in *Kennedy v. Braidwood Management, Inc.*, 606 U.S. 748 (2025), which issued “A” and “B” ratings that on their own compelled insurance coverage determinations, the ACIP’s recommendations are not self-effectuating and only trigger coverage determinations when subsequently adopted by the CDC Director. That Congress has recognized this well-embedded two-step process for vaccine recommendations—the ACIP

recommendation followed by CDC endorsement—in various statutes does not convert the longstanding purpose of the ACIP from primarily advisory in function to operational. *Braidwood* does not alter the ACIP’s status as an advisory body subject to FACA nor did it address the question of FACA applicability.¹

II. UNLIKE PSTF, THE ACIP IS AN ADVISORY COMMITTEE WITHIN THE MEANING OF AND SUBJECT TO FACA.

There are multiple reasons why the ACIP qualifies as an advisory committee subject to FACA and that *Braidwood*’s analysis of the PSTF does not apply to the ACIP.

First, the ACIP and PSTF occupy entirely different roles within the Public Health Service. The PSTF is established by Congress in a specific statute, 42 U.S.C. § 299b-4, which explicitly mandates that its members and their recommendations shall be “independent and, to the extent practicable, not subject to political pressure”. In contrast, the ACIP was created through a delegation of the Secretary’s general authority under 42 U.S.C. § 217a(a) to establish “advisory councils or committees.” Congress provided that the Secretary may “delegate to [the ACIP] such advisory functions . . . as [he] determines to be appropriate.” 42 U.S.C. § 217a(c).

This distinction between the congressionally established PSTF and the ACIP, established pursuant to explicit “advisory committee” authority, is further codified in the Affordable Care Act’s preventive coverage requirement itself. While the PSTF is referenced in its own right, the ACIP is further characterized as “of the Centers for Disease Control and Prevention”. *See* 42 U.S.C. § 300gg-13(a)(1–2). This phrasing, consistent with other prior statutes referencing ACIP,

¹ Plaintiffs anticipate that the Government may rely on Footnote 3 of the *Braidwood* decision to argue that ACIP is no longer “advisory.” *See Kennedy v. Braidwood Mgmt., Inc.*, 606 U.S. 748, 766 n.3 (2025) (observing that “the [PSTF] ceased to be an advisory committee in 2010 when Congress enacted the Affordable Care Act and empowered the [PSTF] to issue binding recommendations. [PSTF] members are officers because, by operation of the ACA, their ‘A’ and ‘B’ recommendations are not purely advisory.” (citation modified). While the Court described the PSTF’s role under the Affordable Care Act as “not purely advisory,” this same description cannot automatically apply to the ACIP, and this Court should reject such a broad reading.

confirms that Congress views ACIP as a subordinate advisory arm of the CDC rather than as an independent decision-maker.²

Second, Congress expressly made FACA inapplicable to the PSTF, and there is no comparable exclusion of the ACIP. Thus, when enacting the very statutory framework at issue in *Braidwood* (42 U.S.C. § 300gg-13(a)), Congress simultaneously provided, in 42 U.S.C. § 299b-4(a)(5), an express exclusion of the PSTF from FACA. It did not similarly exempt the ACIP.

This silence is dispositive. Congress demonstrated that it knew exactly how to exempt an entity from FACA’s requirements. It chose not to do so with respect to the ACIP. Under the canon of *expressio unius est exclusio alterius*, the decision to exempt the PSTF while remaining silent on ACIP serves as a definitive legislative recognition that the ACIP remains an advisory committee. The PSTF was granted a unique, independent status that Congress saw fit to expressly exempt from FACA. The ACIP, however, was maintained as a traditional advisory body, fully subject to the public’s right to oversight. It is a fundamental principle of statutory interpretation that Congress is presumed to act intentionally and purposely when it includes particular language in one section of a statute but omits it in another.³

² See, e.g., 42 U.S.C. § 300gg-13(a)(2) (“immunizations that have in effect a recommendation from the Advisory Committee on Immunization Practices **of the Centers for Disease Control and Prevention** with respect to the individual involved” (emphasis added)); 42 U.S.C. § 1396d(a)(13)(B) (“with respect to an adult individual, approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting **through the Director of the Centers for Disease Control and Prevention**)” (emphasis added)); 42 U.S. Code § 1396s(e) (“The Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting **through the Director of the Centers for Disease Control and Prevention**).” (emphasis added)); 38 U.S. Code § 1701(10) (“The term ‘recommended adult immunization schedule’ means the schedule established (and periodically reviewed and, as appropriate, revised) by the Advisory Committee on Immunization Practices established by the Secretary of Health and Human Services and **delegated to the Centers for Disease Control and Prevention**.” (emphasis added)).

³ See *Russello v. United States*, 464 U.S. 16, 23 (1983) (observing that “[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.”) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972)); see also *United States v. Wooten*, 688 F.2d 941, 950 (4th Cir. 1982). This “short answer”—that “Congress did not write the statute that way,” *United States v. Naftalin*, 441 U.S. 768,

Third, FACA defines an “advisory committee” as any group established or utilized by an agency “in the interest of obtaining advice or recommendations”. 5 U.S.C. § 1001(2). The core question as to FACA’s applicability is whether ACIP performs “primarily advisory” functions. ACIP remains a primarily advisory body because its functions are deliberative rather than executive. Under long-standing FACA jurisprudence, the legal distinction between “advisory” and “operational” functions rests on whether the committee itself is the final decider or whether its output is a recommendation used by a separate executive actor. *See Jud. Watch, Inc. v. Clinton*, 76 F.3d 1232, 1233 (D.C. Cir. 1996) (limiting FACA to advice directed to government policy). “[T]he most important inquiry for FACA purposes is whether it is asked to render advice or recommendations.” *Pub. Emps. for Env’t Resp. v. Nat’l Park Serv.*, 605 F.Supp.3d 28, 52–53 (D.D.C. 2022) (citation modified).

The ACIP’s charge upon inception was “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.”⁴ Today, it continues to fulfill this fundamental purpose in providing recommendations to the Director of the CDC.

FACA regulations exempt “[a]ny committee established to perform primarily operational as opposed to primarily advisory functions . . . such as making or implementing Government decisions or policy.” 41 C.F.R. § 102-3.40(j); *See also Nat’l Res. Def. Council v. Env’t Prot. Agency*, 806 F.Supp. 275, 276 (D.D.C. 1992) (quoting 42 C.F.R. § 101-6.1004(g) [sic] (1992)

773 (1979)—applies with full force to the ACA’s preventive-services framework. While Congress explicitly provided that “the Federal Advisory Committee Act shall not apply to the [PSTF],” 42 U.S.C. § 299b-37(a)(6), it conspicuously omitted any such exemption for the ACIP. Following the Supreme Court’s instruction in *Russello*, this Court should “refrain from concluding” that the presence of an express FACA exemption for the [PSTF] and the absence of one for the ACIP was a “simple mistake in draftsmanship.” 464 U.S. at 23. Rather, it must be presumed that Congress intended for the ACIP to remain subject to the transparency mandates of FACA.

⁴ Jean Clare Smith et al., *History and Evolution of the Advisory Committee on Immunization Practices — United States, 1964–2014*, 63 MORBIDITY AND MORTALITY WKLY. REP. (MMWR) 955, 955–58 (Oct. 24, 2014), <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6342a5.htm> [<https://perma.cc/PFX4-M8JL>] (emphasis added).

(current version at 41 C.F.R. § 102-3.40(j) (2025))). This includes any committee for which “operational responsibilities give rise to or beget its advisory duties,” or for which “its advisory duties are paramount to its mission and a culmination of its operational duties.” *Emmerich Newspapers, Inc. v. Mississippi River Comm’n*, 2025 WL 1223098, at *10 (S.D. Miss. 2025) (slip opinion).

Operational bodies generally perform direct governmental services—such as adjudicating claims, managing public lands, or issuing binding regulations—none of which the ACIP performs.⁵ The ACIP does not manage the budget for vaccine procurement, nor does it enforce insurance mandates or possess the power to penalize non-compliance; rather, it provides the scientific basis for decisions made by others. ACIP recommendations do not automatically impose legal requirements. Instead, the CDC is “utilizing” the group for advice, not delegating final executive power.

The ACIP was not established to be an operational entity. The ACIP was established as an advisory committee under a statute authorizing the creation of advisory committees—42 U.S.C. § 217a. It neither makes nor implements government decisions or policy, nor do its members have any authority to implement any recommendation issued by the committee. Those final agency decisions belong to the Secretary or the CDC Director, while the responsibility to implement those recommendations rests with the CDC. Neither the ACA nor *Braidwood* alter the ACIP’s advisory status.

Even if the Court were to adopt the flawed logic that the ACA mandate is an “operational” function, that single function cannot “de-FACA” the entire ACIP. A committee’s status under FACA is determined by its *primary* function. For the ACIP, that primary function remains

⁵ See, e.g., *Jud. Watch*, 76 F.3d at 1235 (holding that “operational” functions involve “actual management or operation of federal programs” rather than the mere provision of “advice and recommendations”).

providing expert clinical and scientific guidance to the CDC Director. The insurance coverage trigger at issue in *Braidwood* is a closely connected legislative consequence of that advice, not the “operation” of the committee itself.

III. The ACIP Has Continuously Operated as an Advisory Committee Subject to FACA.

The ACIP’s establishment as an advisory committee in 1964 predated the passage of FACA. Since FACA’s enactment in 1972, the ACIP has been chartered accordingly. The ACIP’s formal charter has long explicitly acknowledged its status as a FACA-governed body, stating that “The Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. § 1001 et seq.), as amended.”⁶ Moreover, following *Braidwood*, the Department of Health and Human Services (“HHS”) chose not to reorganize the ACIP as an operational unit, instead maintaining its existing FACA-compliant structure and processes.

The ACIP has continuously operated pursuant to all provisions of FACA, which include conducting meetings that are open to the public, publishing public notice of meetings in the Federal Register, maintaining a functional and regularly renewed charter, providing an opportunity for public comment and public involvement during meetings, and recording detailed minutes of all meetings.⁷

Indeed, the significant good faith efforts of the CDC and the ACIP to comply with FACA provide further proof of the ACIP’s advisory status. Unlike the PSTF, which operates with a degree of statutory independence, the ACIP is inextricably managed by a Designated Federal Officer (“DFO”), a role required by FACA. *See* 5 U.S.C. § 1009. The DFO for the ACIP has consistently and rigorously carried out FACA’s statutory mandates outlined above as well as approving the

⁶ CTRS. FOR DISEASE CONTROL & PREVENTION, *Amendment to the Charter of the Advisory Committee on Immunization Practices* (signed Dec. 1, 2024; filed April 1, 2026), <https://www.cdc.gov/acip/downloads/acip-charter.pdf> [<https://perma.cc/E8LM-QFVT>].

⁷ *See id.*; 5 U.S.C. § 1009.

ACIP's agenda, attending meetings of the ACIP, and ensuring the ACIP's transparency through the publication of meeting agenda, minutes, and other materials.

The CDC's continued employment of a DFO to manage the ACIP is a functional admission that the committee remains advisory. If the ACIP were truly an operational body, the DFO's role would be legally unnecessary and structurally inappropriate.

IV. In Renewing the ACIP's Charter, Secretary Kennedy Explicitly Affirmed FACA's Application to the ACIP.

The most compelling evidence that the ACIP remains subject to FACA is found in Secretary Robert F. Kennedy Jr.'s execution of a recent amendment to the ACIP's charter, which retains the language stating that "[t]he Committee is governed by the provisions of the Federal Advisory Committee Act, Public Law 92-463 (5 U.S.C. § 1001 et seq.), as amended."⁸ If it were the belief of the Secretary that the rules and regulations of FACA do not apply to the ACIP, the Secretary could have removed this description of how the ACIP is governed. In renewing the ACIP's charter, however, and keeping this explicit statutory reference to FACA, the Secretary concedes, explicitly affirms, and legally ratifies the applicability of FACA to the ACIP.

V. BRAIDWOOD DOES NOT EXEMPT THE ACIP FROM FACA.

In *Braidwood*, the Court observed that "the [PSTF] ceased to be an advisory committee in 2010 when Congress enacted the Affordable Care Act and empowered the [PSTF] to issue binding recommendations. [PSTF] members are officers because, by operation of the ACA, their 'A' and 'B' recommendations are not purely advisory." 606 U.S. at 766 n.3 (citation modified).

⁸ CTRS. FOR DISEASE CONTROL & PREVENTION, *Amendment to the Charter of the Advisory Committee on Immunization Practices* (signed Dec. 1, 2024; filed April 1, 2026), <https://www.cdc.gov/acip/downloads/acip-charter.pdf> [<https://perma.cc/E8LM-QFVT>]. This amendment was signed on December 3, 2025 by Secretary Kennedy with April 1, 2026 specified as the filing date, the date on which the former ACIP Charter was set to expire.

The ACIP is different. As the district court noted in rejecting the argument that the ACIP's role violated the Appointments Clause, the ACA "contains no language removing or modifying the Secretary's background authority over ACIP." *Braidwood Mgmt. Inc. v. Becerra*, 627 F.Supp.3d 624, 640 (N.D. Tex. 2022).

The plain language of the ACA statute at issue in *Braidwood* also affirms that the ACIP remains in a purely advisory role by referencing only the PSTF under 42 U.S.C. § 300gg-13(a)(1), but then qualifying the ACIP as "of the Centers for Disease Control and Prevention" in the very next subparagraph. *See* 42 U.S.C. § 300gg-13(a)(2). The ACA's implementing rules are consistent with this distinction. Where 45 CFR § 147.130(a)(1)(i) references only the PSTF, the following subparagraph parrots the statutory "of the CDC" language *and* further states that an ACIP recommendation is "considered in effect after it has been adopted by the Director of the Centers for Disease Control and Prevention." *See* 45 CFR § 147.130(a)(1)(ii). *Braidwood* took specific notice of this rule and stated hypothetically that similar rules could be promulgated and applied to PSTF recommendations.⁹ This, however, does not *de facto* erase the ACIP's advisory status for the foregoing reasons.

a. Braidwood Did Not Consider Whether the ACIP is Exempt from FACA.

The question of whether the ACIP remains an "advisory committee" under FACA was not before the Supreme Court in *Braidwood*. The district court had disposed of the questions concerning the ACIP and its interaction with the Appointments Clause without consideration of FACA. In so doing, it observed differences in the functions and operations of the ACIP and PSTF that led it to differing conclusions under their Appointments Clause analyses. Specifically, the district court observed that features such as the subsequent ratification of the ACIP's

⁹ *See Braidwood*, 606 U.S. at 767 n.4.

recommendations by the CDC Director or by the Secretary avoided the Appointments Clause problem it found with respect to the PSTF.¹⁰

b. *Braidwood* Cannot Be Read to Exempt the ACIP from FACA.

Braidwood's grant of certiorari was limited to the constitutional challenge to the PSTF under the Appointments Clause. Because the ACIP “was not before [the Court], [the Court] did not consider it.” See *United States v. L. A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 38 (1952) (noting that a decision is not a binding precedent on an issue not raised or argued). It would, therefore, be inappropriate to read the *Braidwood* decision so broadly as to implicitly repeal or override the statutory mandates of FACA. It is a settled rule that the Court does not “decide questions of a constitutional nature unless absolutely necessary to a decision of the case.” *Burton v. United States*, 196 U.S. 283, 295 (1905). To interpret a footnote limited to discussing the PSTF as a *sub silentio* reclassification of the ACIP’s statutory status would violate the principle that the Court does not normally decide any issues not presented. See *Izumi Seimitsu Kogyo Kabushiki Kaisha v. U.S. Philips Corp.*, 510 U.S. 27, 34 (1993).

c. *Braidwood*’s Applicability is Confined to PHS § 2713.

Even if this Court were to find that *Braidwood* has implications for FACA’s applicability to the ACIP, such an impact must be strictly confined to the ACIP’s role under the ACA’s preventive services coverage requirement. The *Braidwood* litigation solely concerned that mandate. The Court, therefore, did not address, nor did it have occasion to address, the myriad other roles the ACIP plays within the federal government.

¹⁰ See *Braidwood Mgmt., Inc. v. Becerra*, 627 F.Supp.3d at 639–40. The court observed that ACIP is “under the supervision and direction of the Secretary,” 42 U.S.C. § 202, and its “vaccine recommendation . . . is considered in effect after it has been adopted by the Director of the [CDC],” 45 C.F.R. § 147.130(a)(1)(ii). Because the Secretary maintains the “power to superintend,” which includes the “right to judge and direct” the ACIP’s output, the Secretary’s “ratification of the challenged ACIP provisions remedies any appointment defects.” *Id.* (citation modified).

The ACIP's responsibilities are far broader than simply triggering insurance coverage. It fulfills a broad advisory role by providing clinical guidance on vaccine administration, contraindications, and schedules that are relied upon by medical and public health professionals nationwide—functions that are purely advisory in nature and contemplated by Congress under PHS § 222 (42 U.S.C. § 217a). Beyond this broad role and separate from the role Congress contemplated under the ACA, the ACIP has been prescribed roles under multiple other federal statutes previously brought to this Court's attention, including but not limited to the Vaccine for Children ("VFC") program under Section 1928 of the Social Security Act (42 U.S.C. § 1396s). *Braidwood* did not consider the ACIP's operation under these other statutorily contemplated roles.

The public interest necessitates that the ACIP remain subject to FACA because its recommendations carry immense consequences for the health and economic well-being of every American. Shielding such influential advice from public scrutiny would allow vaccine policy to be formulated in private, resulting in the exact "shadow government" scenario that Congress enacted FACA to prevent and which this very action challenges.

VI. CONCLUSION

For the foregoing reasons, this Court should conclude that *Kennedy v. Braidwood Management, Inc.* does not undermine FACA's applicability to the ACIP. The ACIP performs primarily advisory functions for purposes of FACA. Congress has repeatedly treated the ACIP as an advisory committee across multiple statutory schemes and has never exempted the ACIP from FACA, even while expressly exempting PSTF. The Court therefore should apply FACA's requirements accordingly.

Dated: March 4, 2026

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that this document was filed and served through the ECF system upon the following parties on this 4th day of March 2026:

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