DEMOCRACY FORWARD

NATIONAL HEALTH LAW PROGRAM

Comments to the Advisory Committee on Immunization Practices
December 4-5, 2025 Meeting
Docket No. CDC-2025-0783
Agency: Centers for Disease Control and Prevention, Department of Health and Human Services

Democracy Forward Foundation (DFF) and the National Health Law Program (NHeLP) submit these comments to the Advisory Committee on Immunization Practices (ACIP) in advance of the upcoming ACIP meeting on December 4 and 5, 2025. DFF is a nonprofit national legal organization that advances democracy and social progress through litigation, policy and public education, and regulatory engagement. DFF represents clients, including non-profits, local governments, tribes, small businesses, unions, and individuals, in challenging harmful and unlawful governmental action and in supporting governmental action. NHeLP is a public interest law firm whose mission is to advance access to quality health care and to protect the legal rights of low-income and under-served people, particularly children. NHeLP provides education and consultation support and engages in litigation and policy to further the Program's mission.

DFF and NHeLP strongly support the use of expert, evidence-based guidance to inform public health policy and protect public health. There is strong reason to doubt, however, whether the current membership of ACIP shares this commitment. Membership in the Committee has now skewed toward those with a bias against vaccinations. Perhaps as a result of this bias, ACIP has violated numerous aspects of ACIP's charter, Policies and Procedures, and the Federal Advisory Committee Act. These actions raise serious questions about the integrity of its recommendations, in particular, the forthcoming decisions concerning hepatitis B vaccines and whether these decisions will violate the Administrative Procedure Act (APA).

DFF and NHeLP submit these comments to urge ACIP to take action to restore the integrity of its decision-making process on crucial matters of public health and safety. We ask ACIP to refrain from any revisions to its recommendations concerning vaccination schedules, including hepatitis B vaccines, until that action has been taken.

Until recently, ACIP members were widely respected members of the scientific community who possessed clinical, scientific, and public health expertise in immunization. On June 9, 2025, the Secretary of Health and Human Services, Robert F. Kennedy, Jr., summarily fired all 17

members of ACIP via a newspaper op-ed and replaced them with members who have little-to-no relevant experience, a demonstrated history of vaccine skepticism, and clear conflicts of interest.

The current ACIP membership is in violation of the ACIP charter, which requires that members "shall be selected from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety." U.S. Dep't of Health Hum. Servs., Charter of the Advisory Committee on Immunization Practices 4 (Apr. 1, 2024), https://perma.cc/WVL8-XJWH. Abandoning the rigorous appointment process, Secretary Kennedy quickly appointed new membership that fails to meet the charter's qualifications. Far from having the necessary expertise in the use of vaccines, many of them are avowedly anti-vaccine and anti-science. For example, newly appointed ACIP member Dr. Robert Malone holds fringe anti-science views, including declaring that the COVID-19 vaccines "caus[e] a form of AIDS." David Wallace-Wells, *'I Think He Is About to Destroy Vaccines in This Country,'* The N.Y. Times, (June 18, 2025), https://perma.cc/QU6L-T85E. Dr. Malone has also stated that he considers the "anti-vaxxer" label to be "high praise." *Id*. Another new member, Dr. Evelyn Griffin, is an obstetrician and gynecologist with no apparent experience in childhood vaccines or immunology. Other ACIP members are similarly unqualified and subscribe to fringe anti-science conspiracy theories. Dr. Kirk Milhoan has suggested that the COVID-19 vaccine "may have been deliberately engineered to cause harm," and Dr. Catherine Stein has worked with the anti-vaccine nonprofit Children's Health Defense. Restef Levi, PhD, has even admitted on a podcast that he has little vaccine experience. *See* Lisa Schnirring & Mary Van Beusekom, *RFK announces new ACIP Members, including vaccine critics*, Ctr. for Infectious Disease Rsch. & Pol'y, (June 12, 2025), https://perma.cc/PV3A-K67G. The current ACIP membership, with its strong anti-vaccine bias, has almost certainly prejudged the issue of Hepatitis B vaccination for infants, rendering the forthcoming meeting a mere pretextual formality.

The current composition of the ACIP membership is particularly concerning, as there is significant evidence that the CDC's current approval process of ACIP recommendations is shambolic, merely a rubber stamp with a predetermined outcome. Decisions of ACIP are subject to approval by the director of the CDC. On July 29, 2025, the Senate confirmed Dr. Susan Monarez to be Director of the CDC, and she was sworn in on July 31, 2025. However, on August 27, 2025, less than a month into Dr. Monarez's tenure, Secretary Kennedy fired her without public explanation. Dr. Monarez stated that, on August 25, 2025, Secretary Kennedy personally demanded that she "preapprove the recommendations of a vaccine advisory panel newly filled with people who have publicly expressed anti-vaccine rhetoric." Susan Monarez, *Robert F.*

Kennedy Jr., the CDC and Me, The Wall Street Journal, (Sept. 4, 2025), https://perma.cc/Z9ME-VPMM. In a public statement, Dr. Monarez's lawyers stated that "[w]hen CDC Director Susan Monarez refused to rubber-stamp unscientific, reckless directives and fire dedicated health experts, she chose protecting the public over serving a political agenda." Sophie Gardner, *Monarez would not cross 'red lines' before she was fired, confidant says*, Politico (Aug. 28, 2025) https://perma.cc/T4QQ-85TP. In other words, when Dr. Monarez refused to agree to rubber-stamp ACIP's recommendations, Secretary Kennedy fired her.

This evidence strongly suggests that the CDC's eventual approval of any ACIP vaccine recommendations has been unlawfully prejudiced and predetermined. Secretary Kennedy has essentially imposed a requirement that the Acting CDC Director possess an "unalterably closed mind." *Ass'n of Nat'l Advertisers, Inc. v. FTC*, 627 F.2d 1151, 1170, 1174 (D.C. Cir. 1979). Decisionmakers violate both the Due Process Clause and the Administrative Procedure Act's requirement of reasoned decisionmaking when they act with an "unalterably closed mind and are "unwilling or unable" to rationally consider arguments. *Air Transp. Ass'n of Am., Inc. v. Nat'l Mediation Bd.*, 663 F.3d 476, 487 (D.C. Cir. 2011) (quoting *Ass'n of Nat'l Advertisers, Inc*., 627 F.2d at 1174); *see also McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1323 (D.C. Cir. 1988) (agency violates APA's notice and comment requirements when it acts with "too closed a mind"). Secretary Kennedy's demands that Dr. Monarez commit to rubberstamping ACIP's reckless, unscientific recommendations—and his decision to fire her when she refused to do so—raises serious questions as to the integrity of any federal vaccine policy.

In addition to violating ACIP's own charter, the current composition of the committee violates the Federal Advisory Committee Act (FACA). 5 U.S.C. §§ 1001 *et seq*. The current ACIP membership is not "fairly balanced in terms of the points of view represented," 5 U.S.C. § 1004(b)(2), but instead skews impermissibly towards fringe conspiracy theories and anti-vaccine skepticism. Secretary Kennedy's firing of the entire ACIP membership in June 2025, as well as his firing of Dr. Monarez for refusing to commit to rubber stamping ACIP recommendations, also violates FACA's mandate that the committee not be "inappropriately influenced by the appointing authority." *Id*. § 1004(b)(3).

Several of the new ACIP members also have conflicts of interest that preclude them from serving on the committee. ACIP's Policies and Procedures prohibit any member from serving "as a paid litigation consultant or expert witness in litigation involving a vaccine manufacturer." Advisory Committee on Immunization Practices Policies & Procs. 15, (June 2022), https://perma.cc/M38J-3VQ8 ("ACIP Policies"). However, at least two newly appointed members of ACIP, Dr. Robert Malone and Martin Kulldorff, PhD, previously served as expert witnesses in

cases against vaccine manufacturers. *See* Christina Jewett & Sheryl Gay Stolberg, *Kennedy's New Vaccine Advisers Helped Lawyers Raise Doubts About Their Safety,* The N.Y. Times (June 13, 2025), https://perma.cc/44GV-ZK5G. These conflicts preclude both Dr. Malone and Mr. Kulldorff from participating in any discussions and decision-making of issues related to vaccines. Further, neither Dr. Malone nor Mr. Kulldroff have disclosed these conflicts of interest. *See* Conflicts of Interest Disclosures of ACIP Members, CDC, https://perma.cc/Z5QQ-LAGF (last visited Nov. 24, 2025).

ACIP has also repeatedly failed to follow their own published policies and procedures when it comes to the upcoming December meeting. *See* ACIP Policies at 7. ACIP's Policies and Procedures require that "the meeting date, items to be discussed, and location" be published in the Federal Register "at least 60 days prior to the meeting." *Id*. The December meeting, and the high-level description of the topics that "may" be discussed, was published in the Federal Register on November 13, fewer than 30 days in advance of the meeting.[1] Additionally, the public comment period closes on November 24, 2025. *See* Meeting of the Advisory Committee on Immunization Practices, 90 Fed. Reg. 50945 (Nov. 13, 2025) ("Written comments must be received between November 13-24, 2025"). This is in direct contravention of ACIP's policies and procedures, which provide that "[w]ritten comments will be accepted up to 48 hours following the end of an ACIP meeting." ACIP Policies at 10.

Furthermore, in addition to the artificially, and impermissibly, short time-period for submitting comments on the proposed December meeting topics, ACIP has failed to provide sufficient information to enable the public comment period to be meaningful. ACIP compounded the confusion and error when it published an agenda for its December meeting on its website on November 14, 2025; that publication discloses only that there will be presentations and discussions of hepatitis B vaccines and, at the end of the day, "votes." There is no further disclosure of whether both adult and newborn recommendations will be addressed or any indication of the topics that will be the subject of presentations and discussions. "In order to allow for useful criticism," it is crucial for ACIP to provide more than a bare-bones list of high-level topics for the public to comment on. *Conn. Light & Power Co. v. Nuclear Reg, Comm'n*, 673 F.2d 525, 530 (D.C. Cir. 1982); *see also Am. Pub. Gas Ass'n v. Fed. Power Comm'n*, 498 F.2d 718, 722 (D.C. Cir. 1974) (recognizing that the APA requires that the procedures of the Federal Power Commission "give

[1] Although ACIP's procedures provide that "[i]f the notice cannot be published at least 60 days prior to the meeting, the Federal Register announcement will include the reasons for providing less than 60 days' notice, as provided under GSA regulations at 41 CFR § 102-3.150(b)" ACIP Policies at 7, the Federal Register notice did not acknowledge this requirement or provide any reasons for why notice could not be provided in accordance with the Committee's procedures.

the parties fair notice of exactly what the Commission proposes to do, together with an opportunity to comment, to object, and to make written submissions"). By contrast, the APA requires the "'most critical factual material' used by the agency" to be "subjected to informed comment," thus providing "a procedural device to ensure that agency regulations are tested through exposure to public comment, to afford affected parties an opportunity to present comment and evidence to support their positions, and thereby to enhance the quality of judicial review." *Chamber of Com. v. SEC*, 443 F.3d 890, 908 (D.C. Cir. 2006) (holding that the SEC violated the APA because it "relied on extra-record material . . . without affording an opportunity for comment"). By failing to provide sufficient information, including technical studies, staff reports, and other critical material that ACIP considered, it has denied the public the ability to meaningfully provide comments in advance of the December meeting. Asking the public to provide comments but failing to reveal the most crucial information underlying ACIP's meeting agenda makes the public comment period a sham and violates the Administrative Procedure Act.

In addition to all of these procedural irregularities and numerous violations of law, ACIP's decisions may be arbitrary and capricious. If ACIP votes to change the recommendations for Hepatitis B vaccinations, such a decision will almost certainly fly in the face of the best scientific evidence, fail to take into account reliance interests, and be irreconcilable with how ACIP has approached its public health recommendations in the past.

The Hepatitis B Foundation has submitted multiple comments to ACIP for consideration in this matter, and we incorporate those comments, as well as those submitted by the Foundation in September, by reference here. *See* Hepatitis B Foundation, RE: Comments for the September 2025 Meeting of the Advisory Committee on Immunization Practices (Docket No. CDC-2025-0454), Recommendation of Hepatitis B Universal Birth Dose Vaccination (Sept. 12, 2025), https://perma.cc/4AEL-547Q.

At the September meeting, ACIP heard several presentations and received written briefing materials reviewing four decades of medical evidence on hepatitis B vaccination, including birth dose vaccination. The evidence overwhelmingly supports universal hepatitis B vaccination, including birth dose vaccination, as even ACIP's own briefing materials for that meeting acknowledged:

- "An extensive body of literature resulting from over more than 40 years of use in the United States and other countries demonstrates that the hepatitis B vaccines are safe and effective in protecting infants from hepatitis B." ACIP Meeting Materials for Public Posting: Hepatitis B Birth Dose Briefing Document at 3 (Sept 18, 2025),), https://perma.cc/4795-

WE33 (citing Susan Schillie et al., Prevention of Hepatitis B Virus Infection in the United States: Recommendations of the Advisory Committee on Immunization Practices, 67 MMWR Recommendations & Reps. 1 (Jan. 12, 2018)).

- "Based on the included body of evidence: Hepatitis B birth dose induces high seroprotection and efficacy. Hepatitis B birth dose vaccine is safe. Head-to-head comparisons of various hepatitis B recombinant vaccine products, doses, and schedule show no meaningful differences in reported outcomes in efficacy and safety." CDC, Hepatitis B Birth Dose Vaccination CDC Advisory Committee for Immunization Practices Meeting at 33 (Sept. 18, 2025), https://perma.cc/JR9F-ZV63.

- "Summary of evidence: The safety data available for hepatitis B vaccine administered at birth did not identify an increased risk: -Allergic reaction; All-cause mortality; Expected, or unexpected deaths or deaths due to sudden infant death syndrome (SIDS); Seizures or neurologic disease other than seizures." John Su, Acting Dir., Immunization Safety Off., CDC, A Review of the Safety of Hepatitis B Birth Dose Vaccination 23 (Sept. 18, 2025), https://perma.cc/XNZ3-WARF .

At the September meeting, and on request of the Chair, ACIP heard a presentation on a small 2004 study conducted in Guinea-Bassau. John Su Acting Dir., Immunization Safety Off., CDC, Non-specific Effects Following Hepatitis B Vaccination (Sept. 18, 2025), https://perma.cc/S47T-U8HZ. That study looked at 876 children who received Hepaccine vaccines, which are not licensed in the US, at 7 1/2, 9, and 10 1/2 months of age. The CDC concluded that non-specific effects found in the Guinea-Bassau study are not generalizable across immunization programs. *Id*. at 23. This study, therefore, does not support a change from ACIP's current recommendation for universal hepatitis B dose vaccination based upon the inconclusive findings of a 21 year-old study focusing on a different age cohort receiving a vaccine unavailable in the U.S.

As numerous commenters have explained, hepatitis B vaccination at birth is one of the great public health success stories of the last 50 years. Rolling back that success, at the expense of the most vulnerable members of our society—infants—violates the law and would do immeasurable damage to the country's public health.

Please do not hesitate to contact us if we can provide additional clarification or information.

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