Congress of the United States Washington, DC 20515

March 25, 2025

The Honorable Robert F. Kennedy, Jr.

Secretary

U.S. Department of Health and Human Services

200 Independence Ave SW

Washington, DC 20201

Dear Secretary Kennedy,

We are writing to request information regarding the U.S. Department of Health and Human Services' decision to bypass independent expert input in the flu vaccine strain selection process and how the department plans to ensure transparency and scientific integrity in future vaccine decisions. We, along with our constituents, are concerned that the recent changes to this process jeopardize public health, threaten vaccine access, and undermine the scientific integrity of our nation's immunization program.

The department's decision to postpone the Center for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices (ACIP) meeting in February and cancel the Food and Drug Administration (FDA) Vaccine and Related Biological Products Advisory Committee (VRBPAC) meeting in March has created unnecessary and dangerous uncertainty. These committees play a crucial role in reviewing vaccine safety, effectiveness, and availability – and their exclusion from the decision-making process raises significant concerns.

The ACIP meeting was meant to review the safety and effectiveness of vaccines for flu, meningococcal disease, RSV, chikungunya, and mpox, as well as make key decisions regarding the Vaccines for Children program. The delay of this meeting calls into question the accessibility and availability of these crucial vaccines, particularly for vulnerable populations. The VRBPAC meeting was intended to review and endorse the composition of the 2025-2026 flu vaccine – a process that has historically included input from independent experts. Instead, the FDA issued flu vaccine recommendations without convening this advisory committee. This lack of external expert engagement diminishes transparency and public confidence in the department's decision-making process.

Flu vaccine development requires careful strain selection months in advance to ensure timely production and distribution.² The initial cancellation of the FDA's March 13 meeting left key

¹ Goodman, Brenda, and Katherine Dillinger. "<u>After canceling meeting of independent advisers, FDA issues 2025-26 flu vaccine recommendations.</u>" CNN Health, March 13, 2025.

² "FDA-Approved Flu Vaccines Are Safe and Effective." U.S. Food and Drug Administration, October 23, 2024.

stakeholders – including manufacturers and public health officials – unable to proceed with vaccine production in a timely manner.³ The most recent decision to proceed without advisory committee input could severely undermine the credibility of vaccine production. The public deserves a development process that is transparent, science-based, and inclusive of independent expert opinions.

This troubling development comes amid a severe flu season. The CDC reports 540,000 hospitalizations and 23,000 deaths from flu this year, including 134 pediatric fatalities.⁴ In late January into February 2025, flu hospitalizations were higher than any week since before 2009.⁵ Meanwhile, vaccine hesitancy is surging, fueled by misinformation and a lack of trust in public health institutions. It is imperative that the department does not act to fuel this crisis. By excluding independent expert advisory committees, confidence in vaccines is eroded and public safety is threatened.

Given these concerns, we respectfully request answers to the following questions:

- 1. What was the rationale behind postponing the ACIP February meeting and cancelling the VRBPAC March meeting, and why was input from independent advisors excluded from this year's flu vaccine recommendation process?
- 2. Will advisory committees be reinstated in future discussions on flu vaccine strain selection, or does this reflect a permanent procedural change?
- 3. How will the FDA ensure transparency and scientific rigor in future vaccine-related decisions, if external advocates are no longer included?
- 4. What steps is HHS taking to coordinate with other major public health bodies to ensure alignment on vaccine strain selection?

Americans cannot afford uncertainty when it comes to life-saving vaccines. It is imperative that in matters of public health, the federal government follows science, rather than opinion or ideology.

We appreciate your attention to this matter and look forward to your swift response.

Sincerely,

³ Goodman, Brenda. "<u>Disrupted US Vaccine Meetings Could Threaten Timelines, Access and Transparency</u> around Shots." CNN, February 28, 2025.

⁴ "Weekly US Influenza Surveillance Report: Key Updates for Week 10, Ending March 8, 2025." Centers for Disease Control and Prevention. Accessed March 3, 2025.

⁵ Regan, Annette. "<u>As Flu Cases Break Records This Year, Vaccine Rates Are Declining, Particularly for Children and 65+ Adults.</u>" Clinical Advisor, March 3, 2025.

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