

United States Senate

WASHINGTON, DC 20510-3205

March 11, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Kennedy,

I am writing to express my profound concern regarding the recent cancellation of the Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting, which was scheduled for March 13, 2025, to determine influenza vaccine strains for the upcoming flu season. Additionally, the Centers for Disease Control and Prevention (CDC) postponed its Advisory Committee on Immunization Practices (ACIP) meeting in February to review, among other vaccines, the safety and effectiveness of the flu vaccine. These cancellations risk delaying the release of an updated influenza vaccine later this year, as New York State is experiencing its worst influenza season in over a decade. Such a delay unacceptably endangers the lives of older adults and the general public in New York, and throughout our nation.

A disruption in the established timeline for selecting influenza strains can directly impact the manufacturing cycle, which typically takes six months, potentially leading to a reduced supply or delayed availability for the 2025-2026 flu season. This is especially concerning for older adults and vulnerable populations in New York who are at the highest risk for severe complications and death from the flu. The CDC estimates that between 50 and 70 percent of seasonal flu-related hospitalizations occurred in people aged 65 and older, and that 70 percent and 85 percent of seasonal flu-related deaths occurred in people aged 65 and older. The CDC and ACIP recommend a higher dose flu vaccine over standard-dose flu vaccines for people aged 65 and older in order to prevent serious flu complications.

Even as older adults are at greater risk from influenza, we have witnessed a concerning trend of increasingly severe flu seasons in recent years. According to CDC estimates, there have been at least 37 million illnesses, 480,000 hospitalizations, and 21,000 deaths from flu so far this season. That makes this year the worst flu outbreak experienced by Americans since 2017. New York State has recorded over 432,000 flu cases so far this season, which already far surpasses the total from last year's flu season. The escalating severity of influenza underscores the critical need for robust and timely vaccine development and deployment. Any slowdown in this process will exacerbate the risks faced by the American public.

Additionally, it is crucial to consider the burden that severe flu seasons place on local New York health systems. Increased hospitalizations due to influenza can overwhelm emergency rooms, intensive care units, and hospital staff, diverting resources from other essential health care needs.

New York State's current flu outbreak is its worst in at least 15 years.¹ At one point in January, only 13 percent of hospital beds in New York were available due to the surge in influenza, along with other seasonal illnesses.² This surge in demand not only jeopardizes the quality of care for influenza patients but also impacts the overall capacity of our health care infrastructure, potentially leading to preventable deaths across various medical conditions.

Given the risk that any delay in the release of an updated flu vaccine creates for older adults and the general public, I request a written response to the following inquiries by March 21st, 2025:

- 1) Please provide any correspondence relating to the cancellation of the VRBPAC and ACIP meetings and whether they will be rescheduled. If they are to be rescheduled, please provide dates and information on how the FDA and CDC will make up for the potential delay in vaccine manufacturing.
- 2) Please provide justifications for the cancellations of the VRBPAC and ACIP meetings.
- 3) Did FDA and CDC consult with the medical community and groups representing older adults before cancelling the VRBPAC and ACIP meetings, including about the impact of cancelling the meetings? If FDA and CDC did not consult with the medical community and groups representing older adults, please explain why.
- 4) If the meetings are not to be rescheduled, please provide a detailed reasoning and correspondence relating to how FDA and CDC are accounting for the potential consequences.
- 5) If the meetings are not to be rescheduled, what alternative process will determine the selection of influenza strains for next fall's vaccines? When will the American public receive notice of this year's recommendations?

Sincerely,



Kirsten Gillibrand
United States Senator

¹ <https://www.timesunion.com/news/article/ny-experiencing-worst-flu-season-least-15-years-20163112.php>

² <https://spectrumlocalnews.com/nys/central-ny/news/2025/01/09/seasonal-illnesses-straining-medical-facilities-across-new-york>