United States Senate
WASHINGTON, DC 20510

June 4, 2025

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

Dear Secretary Kennedy:

We write to express our extreme concern regarding the Department of Health and Human Services' (HHS') recent policy changes to dramatically curtail access to the COVID-19 vaccine for those Americans who would choose to receive it. We are particularly alarmed by your May 27, 2025 announcement on X—along with Drs. Marty Makary and Jay Bhattacharya, Commissioner of the Food and Drug Administration (FDA) and Director of the National Institutes of Health (NIH), respectively—that the COVID-19 vaccine will no longer be included under the Centers for Disease Control and Prevention's (CDC's) recommended routine immunization schedule for healthy pregnant women. We are also concerned that the CDC changed its recommendation for administering the COVID-19 vaccine for healthy children and adolescents from routine to using "shared clinical decision-making" between clinicians and families. As of the writing of this letter, the CDC has updated the immunization schedule for adults, removing the previous recommendation for pregnant women.

The unjustified announcement "blindsided" senior officials at the CDC and were designed to "further erode public trust in the [agency]." By side-stepping the CDC's Advisory Committee on Immunization Practices' (ACIP's) open and transparent deliberation of the evidence, you have thrown into question coverage of vaccines under Medicare, Medicaid and private insurance for millions of Americans. Your politically driven, anti-science decision—made suddenly and behind closed doors, without input from the public or scientific and medical communities—flies in the face of your commitment to "not…take away anybody's vaccines" and will lead to an untold number of preventable illness and death of Americans. We therefore strongly urge you to reverse this position until there is a thorough, transparent consideration of the body of evidence regarding the COVID-19 vaccine's public health benefit.

Political Motivations Threaten COVID-19 Vaccine Access for Millions of Americans

The ACIP's vaccine recommendations, as adopted by the CDC, form the basis of no-cost access to the vaccines for millions of Americans. For example, the Patient Protection and Affordable Care Act, as amended, requires that most commercial health insurance plans and Medicaid Alternative Benefit Plans cover ACIP-recommended vaccines for a given individual with no cost sharing. In addition, for the Vaccines for Children Program, authorized by the Omnibus Budget Reconciliation Act, ACIP determines which vaccines are provided at no cost to children who are uninsured, underinsured, Medicaid-eligible, Medicaid-enrolled or American Indian or Alaska Native. States must also cover ACIP-recommended vaccines and their administration for

children enrolled in separate State Children's Health Insurance Program (CHIP) programs without enrollee cost-sharing.

More recently, the Inflation Reduction Act expanded no-cost coverage of ACIP-recommended vaccines and vaccine administration without cost-sharing to adults under Medicare Part D, Medicaid and CHIP. The uncertainty and confusion caused by your politically driven actions may lead to many insurers deciding to drop coverage of the COVID-19 vaccine for millions of people. Without insurance coverage, individuals who wish to receive the COVID-19 vaccine will be forced to pay up to $200 or more out-of-pocket—an insurmountable cost for many families, especially amid cost-of-living crisis exacerbated by the current administration's policies.

Politically Driven, Anti-Vaccination Decision-Making Circumvents Scientific Input

You appeared to make this policy change without consulting the FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) and prior to the next scheduled public meeting of the ACIP, the members of which are leading vaccine experts tasked with developing vaccine recommendations. You did so even though the ACIP had independently been considering updating COVID-19 vaccine recommendations to take into account the risk levels of different populations and was expected to vote on those recommendations when it was next scheduled to meet on June 25-27, 2025.

Your announcement is a striking departure from the transparent and evidence-informed manner by which vaccine approvals and recommendations are formulated by HHS. For decades, scientists have weighed in on vaccine recommendations through a strenuous process. Following a decision from FDA experts about whether to approve a new vaccine based on clinical trial evidence and other data, ACIP "weighs extensive evidence about safety, effectiveness and other data to determine the best recommendation for who should receive the vaccine, when and how often." The CDC director may choose to adopt, reject or modify these recommendations, though rejection or modification of such recommendations is rare. In the past quarter century, the CDC director has acted only twice to expand access beyond the ACIP's recommendation, both times in response to extraordinary circumstances—in 2002 for the smallpox vaccine in connection with a vaccination campaign to address potential bioterrorism attacks, and in 2021 for the COVID-19 vaccine for front-line workers during the early phase of the COVID-19 pandemic. However, in an unprecedented and deeply troubling abuse of your authority, you did not wait to hear ACIP's expertise, and you exploited a key vacancy at CDC to set these recommendations yourself. According to the *Washington Post*, this is "the first time an HHS secretary has unilaterally altered an existing recommendation from the advisory committee and the CDC."

Your decision represents a significant public health threat that will endanger millions of Americans. Pregnant women are at higher risk of serious illness and hospitalization if infected with COVID-19, and the virus raises the risk of having a cesarean birth, preeclampsia or eclampsia and blood clots. COVID-19 infection during pregnancy has also been shown to result in higher risk of lower birthweight babies, preterm birth and stillbirth. Babies born to women who were not vaccinated against COVID-19 are at higher risk of needing intensive care. That is why the American College of Obstetricians and Gynecologists (ACOG), and the Society for Maternal-Fetal Medicine (SMFM) strongly recommend women who are pregnant, breastfeeding

or planning to get pregnant get the COVID-19 vaccine. According to ACOG and SMFM, the COVID-19 vaccine has been demonstrated repeatedly to be safe and protective for such individuals. Because this vaccine is so protective and safe for this population, ACOG further recommends eliminating barriers to receiving the COVID-19 vaccine. This is likely why the CDC stated in its "Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States," updated on May 12, 2025:

> "COVID-19 vaccination is *recommended for everyone ages 6 months and older in the United States*…Vaccination is especially important for people at highest risk of severe COVID-19, including people ages 65 years and older; people with underlying medical conditions, including immune compromise; people living in long-term care facilities; *and pregnant women to protect themselves and their infants*." (emphasis added)

After birth, infants under 6 months of age are at the same high level of risk of hospitalization due to COVID-19 as adults ages 65 to 74, and the only means of protecting these infants from COVID-19 is through maternal vaccination. An analysis of HHS data by the American Academy of Pediatrics found that 11,199 children were admitted to the hospital with COVID-19 during the 2024-2025 respiratory virus season, 7,746 of whom were younger than 5 years old. And 41 percent of children ages 6 months to 17 years old hospitalized with COVID-19 from October 2022 to April 2024 did not have a known underlying condition, meaning that "healthy" children are also at risk of severe disease.

Establishing an Anti-Vaccination Policy Roadmap

Enabled by President Trump and fueled by decades of anti-vaccine skepticism, you appear to be establishing a roadmap by which the United States' government can implement unscientific, anti-vaccination policies. By sowing distrust, creating chaos and justifying your actions with misinformation, you are laying the groundwork to undermine access to other safe, effective vaccines, including for those that prevent diseases, such as pertussis (whooping cough), measles, respiratory syncytial virus (RSV), chickenpox, shingles, hepatitis A, as well as cancer caused by hepatitis B and human papilloma virus.

The May 27, 2025 video announcement is just one action in a series of anti-vaccination, anti-science efforts you have led since becoming HHS Secretary. For example, while the ACIP made recommendations for meningococcal and RSV vaccines months ago, you have failed to adopt the recommendations. Further, even though the United States is experiencing the worst outbreak of measles in 25 years, you have downplayed the harm of one of the world's most contagious diseases and made false claims that the measles, mumps and rubella vaccine has not been "safety tested." This undermining of trust in vaccines has led to multiple preventable hospitalizations and deaths. Indeed, President Trump's nominee to serve as your deputy at HHS expressed unqualified support for your recommendation "encourag[ing] parents to take the measles vaccine," while saying nothing about vaccinating children against the disease. And the Trump administration clawed back over $11 billion in pandemic-era funding, which has hampered the ability of public health departments across the country to contain the measles outbreak.

Moreover, on May 20, 2025, Dr. Vinay Prasad, Director of the FDA Center for Biologics Evaluation and Research and Commissioner Makary published an opinion piece in the *New England Journal of Medicine* (NEJM), outlining a new FDA approval framework that creates significant barriers for approval of annual COVID-19 vaccines for millions of Americans. This announcement indicated that the annual COVID-19 vaccine will generally be approved without a randomized, placebo-controlled clinical trial (RCT) *only* for people ages 65 and older and for those who have medical conditions that leave them at higher risk for severe COVID-19. The framework says nothing about the eligibly of healthy people at higher risk of being infected with COVID-19, such as healthcare professionals. This means that, unlike in most other countries, the annual vaccine will *not* be available to healthy individuals older than 6 months of age and under the age of 65 *without* an RCT. This change in the approval process will take away Americans' freedom to choose to get the annual vaccine and put them and their loved ones at risk.

Further, placebo-controlled trials for vaccines when a proven intervention exists are widely considered by the medical and research community to be unethical. Ethical guidance advises, "Extreme care must be taken to avoid abuse of [the option to conduct placebo-controlled trials when a proven intervention exists]"; the FDA and HHS have guidance accordingly restricting placebo-controlled trials to certain situations. There is no question that the existing safe and effective COVID-19 vaccines are such "proven interventions," and withholding their use in new placebo-controlled trials would constitute a grave ethical violation.

Your new approval process for the annual COVID-19 vaccine will significantly delay access to updated FDA-approved vaccines, jeopardizing the health and lives of the American people. Typically, vaccines, such as the annually updated flu shot, are approved after exhibiting immunogenicity data or other laboratory testing data comparable to previous vaccine versions, which themselves have provided robust safety and efficacy data. A multi-year study and lengthy approval process, which is generally considered by experts to be unnecessary, particularly for annually updated vaccines. The significant hurdles associated with FDA's new RCT requirement could discourage vaccine manufacturers and researchers from developing new, innovative products that could prevent cancer, HIV and other diseases and ultimately save lives. Dr. Peter Hotez from the Baylor College of Medicine in Houston stated requiring RCTs for future vaccine development "would basically be a recipe for paralysis."

Indeed, the day after your announcement, Moderna withdrew an application for its new combined flu and COVID-19 vaccine, despite the new vaccine outperforming existing COVID-19 and flu vaccines. It also comes on the heels of the FDA delaying its approval of Novavax's protein-based COVID-19 vaccine, missing its own April 1, 2025 deadline. When the FDA finally approved the vaccine, it did so for only a narrow population (adults 65 and older and those between ages 21-64 with an underlying medical condition). In a highly unusual step, FDA is also requiring that Novavax conduct a placebo-controlled RCT for less vulnerable populations.

Questions

Given the suddenness of your May 27, 2025 announcement and its lack of detail or scientific justification, we respectfully request you provide written responses to the following questions no later than June 18, 2025:

1. Despite "a commitment to gold-standard science," you failed to provide an appropriate, detailed explanation for your change in the COVID-19 vaccination recommendations.
    a. What specific studies, scientific or clinical data did you consult as the basis for removing the COVID-19 vaccine from the CDC's recommended vaccine schedule for pregnant women and children? Please provide citations for the research articles or publications you considered.
    b. Did you consult with any scientific or professional organizations, such as those representing obstetricians, pediatricians, family physicians, virologists, immunologists, epidemiologists or other relevant experts, in developing this new policy? Please provide the names of such stakeholders.
    c. Did you decide *not* to follow any recommendations from the scientific and medical communities? Why not?
    d. Did you submit a memo that explains the rationale and scientific justification for your decision? Please provide a copy of such memo, along with any attachments and communications related to it.

2. Your directive implementing the new CDC recommendations suggests that the decision was made "[b]ased on a review of the recommendation of the FDA and the NIH."
    a. Please list all individuals who carried out this review and their qualifications to weigh in on such decisions, such as their formal scientific and/or medical training, previously held professional positions or appointments, etc.
    b. Please provide a copy of the recommendation made by the NIH.
    c. Why were the CDC and ACIP apparently excluded from the process through which you imposed the new CDC recommendations?
    d. Given the former acting CDC director's nomination to be CDC director, who is currently responsible for finalizing CDC recommendations?

3. Why did you fail to consult the ACIP before changing the CDC's COVID-19 vaccine recommendation for children and pregnant women, particularly before the ACIP's next public meeting?

4. The ACIP is scheduled to meet in June 2025 to discuss COVID-19 vaccine recommendations.
    a. Do you commit to allowing the ACIP to move forward with its meeting in June 2025? If so, when will the meeting be publicly noticed in the Federal Register?
    b. Do you commit to *not* altering the anticipated agenda that includes the discussion of the COVID-19 vaccine?
    c. Do you expect the ACIP's future COVID-19 vaccine recommendations to be influenced by your decision to publish the new vaccine approval framework?
    d. If the ACIP issues a COVID-19 vaccine recommendation that differs from your May 27 announcement, will you commit to listening to the experts and consider adopting that recommendation?

5. Why did you fail to consult the VRBPAC before granting a narrow approval for the Novavax COVID-19 vaccine?

6. What role did you play in the decision to publish the new FDA framework outlined in the May 20, 2025 NEJM opinion piece, and in determining its content?

7. Why did the FDA release this framework in an opinion piece, rather than formally publishing a regulation or guideline written by career vaccine experts?

8. Does FDA plan to release a regulation, rule or formal guidance that formalizes the framework described in the NEJM article?
    a. If so, when will this policy be released?
    b. Will this policy be developed with the input of vaccine experts, providers, pharmacies, patient advocacy groups and/or other stakeholders?
    c. How will you and Commissioner Makary ensure vaccine experts, providers, pharmacies, patient advocacy groups and/or other stakeholders may provide input or feedback on the framework?

9. Does the FDA's new framework apply to initial doses (i.e., primary series) of new formulations of COVID-19 vaccines?
    a. Will this impact parents' choices to vaccinate their children against COVID-19?
    b. Will you commit to preserving the current COVID-19 vaccine approval standards for the primary vaccine series?

10. Given the ethical and recruitment challenges clinical trial sponsors may face because of new RCT requirements, how will FDA ensure the public has access to safe and effective vaccines if companies are unable to complete these trials in a timely manner?

11. Figure 2 of the May 20, 2025 NEJM opinion piece listed pregnancy and recent pregnancy as underlying medical conditions that put an individual at risk of severe COVID-19.
    a. If the CDC is no longer recommending pregnant women get the COVID-19 vaccine, will such individuals still be eligible for the vaccine?
    b. If so, will they be able to get the vaccine at no cost?
    c. If there will be cost-sharing, what will be the cost-sharing policy for the vaccine, and who will make such decisions?

12. Is the list in Figure 2 of the NEJM piece an exhaustive list for what medical conditions will be considered putting an individual at risk for severe COVID-19 disease?

13. How do the conditions in the list align with the fact that the only high-risk condition now stated on the CDC immunization schedule for COVID-19 is "moderately or severely immunocompromised"?

14. Do you believe that parents should have the right to vaccinate their children against COVID-19? If not, why not?

15. Do you expect the current version of the COVID-19 vaccine to remain available in the primary vaccine series for individuals under 65 without underlying medical conditions?

16. Will healthcare workers under age 65 who do not have a condition that predisposes them to severe COVID-19 and hospitalization be able to obtain a COVID-19 vaccine?

17. Do you believe that young, healthy adults should be able to receive a COVID-19 vaccine to reduce the risk of getting Long COVID or of transmitting the virus to individuals with a higher risk of severe infection?
    a. If so, how will the FDA's new framework preserve this choice?
    b. Why does the FDA's new vaccine approval framework fail to consider a broad range of potential benefits of booster shots, such as reduced risk of Long COVID-19 and a shorter duration of illness?

18. Has the FDA communicated with pharmacies about whether they plan to restrict COVID-19 vaccine access in response to the new vaccine approval framework?
    a. If so, will pharmacies require patients to verify they have health conditions putting them at a higher risk of severe COVID-19 to receive the vaccine?
    b. What will be an acceptable means of verification?

19. What information did you provide health insurers (including Medicaid and Medicare) regarding their requirements for coverage of the COVID-19 vaccine going forward?
    a. Do you expect insurers to drop or alter coverage of the COVID-19 vaccine for children and pregnant women due to the altered CDC recommendation?
    b. If so, was that taken into consideration when formulating the recommendation?

20. Have you communicated with the vaccine manufacturers to ensure there will be enough supply of the vaccine for the upcoming respiratory illness season? What steps are you taking to ensure supply chains will not be disrupted?

21. Do you have any plans to change FDA approval frameworks or the CDC immunization schedule for any other vaccines? If so, which ones?

Your anti-vaccine, anti-science stance has taken priority over the public health and well-being of the American people. We urge you to save lives by reversing course and making evidence-based policy in an open, transparent and clear manner.

Sincerely,

Tammy Duckworth	Elizabeth Warren	Lisa Blunt Rochester
United States Senator	United States Senator	United States Senator