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July 29, 2025

Martin Makary, M.D., M.P.H.
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Makary:

We write to express our alarm at the role you are playing in your position as the Commissioner of the Food and Drug Administration (FDA) to threaten the availability of safe and effective vaccines for millions of Americans. We are requesting more information and an explanation regarding recent developments and announcements in FDA's vaccine approval policy, which seem to be happening largely outside of the usual agency practices and without sufficient transparency to Congress or the public.

We are deeply troubled by the latest series of FDA actions that are likely to interfere with the ability of Americans to receive a COVID-19 vaccine this year and in the future. Unquestionably, the development and administration of the COVID-19 vaccines changed the course of our nation's response to the COVID-19 pandemic and enabled the recovery from the global public health crisis, resulting in millions of lives saved. Additionally, annually updated vaccines and boosters remain the best defense against severe illness, hospitalization, and death from the virus. Instead of acknowledging this historic public health achievement, the changes you have announced to FDA's COVID-19 vaccine approval process threaten to disrupt the country's vaccine infrastructure, not just for COVID-19, but for all vaccines.

Since March, FDA has engaged in several unprecedented and questionable policy decisions that undermine the availability and accessibility of vaccines in the United States. First, FDA canceled its March 13, 2025, Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting, which was intended to make recommendations for the flu strains to be included in the 2025-2026 flu vaccine for the Northern Hemisphere. The VRBPAC typically meets in spring to make those recommendations, so manufacturers have enough time to produce the vaccine for patients. The VRBPAC meeting on flu strains was never rescheduled, and FDA only issued recommendations after meeting behind closed doors without input from

independent vaccine advisors.[1] Instead of committing to rescheduling to uphold the transparent process, you fostered distrust by claiming FDA simply "rubber stamps" international recommendations on flu vaccine strain selection every year.

Then, FDA missed the April 1, 2025, goal date for communication on a decision for the Novavax Biologics License Application (BLA) for its COVID-19 vaccine—a goal date mandated by the Prescription Drug User Fee Act (PDUFA) — even though the vaccine was reportedly ready for full approval.[2] Reporting also indicated FDA political appointees inserted themselves into the approval process by abruptly halting release of the approval decision.[3] When the BLA was finally approved on May 16, 2025, the evidence of this unprecedented intervention was clear in that the approval of the vaccine was conditional on the company conducting a new randomized clinical trial of its vaccine, despite it having been available under an emergency use authorization (EUA) since 2022. Further, the final approval was restricted to only people over 65 years of age and people older than 12 who have underlying health conditions that put them at higher risk from COVID-19 infection.[4] This effectively limits options for Americans considered to be at lower risk, eliminating their ability to choose to receive the vaccine and potentially exposing them to greater risk if a more virulent strain of COVID-19 emerges.[5] Both the initial delay approving Novavax's BLA and the narrowed scope of final approval are unusual and indicate FDA is altering its policies in a manner that will curtail access to COVID-19 and other vaccines based on political considerations, not scientific evidence.

On May 20, 2025, you and Dr. Vinayak Prasad, the Director FDA's Center for Biologics Evaluation and Research (CBER) published an article in the New England Journal of Medicine (NEJM) stating all manufacturers of COVID-19 vaccines — currently Moderna, Pfizer/BioNTech, and Novavax — will need to conduct annual randomized clinical placebo-controlled trials to earn approval for use in people 65 and older, or people between 6 months and 65 years who have one or more risk factors.[6] Again, this decision, which represents a significant change in FDA's process for approving vaccines, was announced with no apparent opportunity for stakeholders or the public to provide input and no transparency into the process the agency undertook to arrive at this decision.

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[1] *After canceling meeting of independent advisers, FDA issues 2025-26 flu vaccine recommendations*, CNN (Mar. 13, 2025).

[2] *FDA Punts on Major Covid-19 Vaccine Decision After Ouster of Top Official*, The Wall Street Journal (Apr. 2, 2025).

[3] *Top Trump FDA official Brenner hits pause on Novavax Covid-19 vaccine decision*, Politico (Apr. 2, 2025).

[4] *F.D.A. Approves Novavax Covid Vaccine With Stricter New Conditions*, The New York Times (May 17, 2025).

[5] *Id*.

[6] Vinay Prasad, M.D., M.P.H., and Martin A. Makary, M.D., M.P.H., *An Evidence-Based Approach to Covid-19 Vaccination*, New England Journal of Medicine (May 20, 2025); *FDA unveils new COVID-19 framework, restricting shots to elderly and high-risk people,* Regulatory Affairs Professionals Society (May 20, 2025).

Requiring placebo-controlled trials for vaccines undergoing an annual update is both impractical and unethical. As has been practice for decades with the influenza vaccine, COVID-19 vaccines must be updated to target dominant strains. This is by nature a time-bound exercise, and requiring lengthy clinical trials on a product that has undergone no fundamental change to its recipe unnecessarily withholds protection from disease. Furthermore, withholding a proven intervention when one exists goes contrary to medical ethics. It is standard practice to evaluate new interventions against the standard of care. Requiring a placebo control for seasonal vaccine updates does not add to the knowledge base and puts clinical trial volunteers at risk.[7]

The safety profiles of these vaccines have been demonstrated, and the vaccines have been in circulation either under permanent approval or EUA, yet you are requiring additional data and effectively limiting access to these vaccines. Ironically, the same day the NEJM article was released, Secretary Kennedy testified that observational data could provide the necessary data rather than requiring placebo-controlled studies or "unethical experiments"; yet the opposite approach is suggested here, only creating greater confusion.

You have argued Americans are not getting the booster vaccines as one reason to limit their approval. However, the standard for a vaccine BLA is the product is "safe, pure and potent" and does not provide the agency with discretion to consider public uptake of therapies or other unrelated rationale as a reason to restrict or limit approval. This approach is a blatant disregard for the role of Congress in the authority it has granted the agency. The journal article refers to this approach as "FDA's new Covid-19 philosophy" and the agency's "Covid-19 vaccination regulatory framework." Instead of following the congressionally mandated process required of FDA, you are instead attempting to regulate vaccines through publications and the media instead of through data and scientific evidence. As a result, you are undermining FDA's role and obligation to the American people and the regulatory process as intended by Congress under the Administrative Procedure Act.[8] Congressional intent provides the opportunity for public comment and true transparency, such as by issuing draft guidance and proposed regulation for changes in standards—not a livestreamed, scripted conversation between two senior FDA officials that was not open to outside questions.

Most recently, on July 16, 2025, Dr. Prasad overruled agency scientific experts in his decision to narrow the approval for the Moderna COVID-19 vaccine. This is the third time in less than three months as your CBER Director that he has overridden the expertise of agency career staff and threatened access to vaccines. Not only does this decision apply the questionable "new Covid-19 philosophy" but also includes new hurdles in yet another unexplained policy shift. The data submitted to the agency showed the vaccine produces antibodies against COVID-19, but Dr. Prasad said this is a "surrogate endpoint" that is not "gold standard science." His definition of "gold standard science" flies in the face of recommendations by career scientists, expert opinion, and the well-established public health standard. He has been unclear how his opinion will be applied to other vaccine approvals moving forward, or what he expects

[7] *I'm a Republican former congressman and doctor. A placebo-controlled vaccine trial mandate is dangerous*, STAT News (May 22, 2025).

[8] Pub. L. 79–404, 60 Stat. 237.

companies to demonstrate, introducing significant uncertainty into the market for vaccines and undermining future vaccine development.

These actions are far from the promise of "radical transparency" so frequently cited by the Trump Administration. Congress and the public deserve more information about the rationale behind FDA's decisions that will likely have harmful effects on the health and safety of the American people. It is a particularly critical time to prepare for the upcoming respiratory illness season, including COVID-19, influenza, and respiratory syncytial virus (RSV), and we are requesting further information on the status of those preparations as soon as possible. Please provide responses to the questions below by August 12, 2025.

1. In the Town Hall, Dr. Prasad stated the NEJM article was "developed by [Secretary Kennedy] and you and the only authors on the paper are the people who wrote the paper,"[9] Is that accurate? Did you consult with CBER prior to publication of the policy? If so, were the views of career officials at FDA incorporated?

    a. Who at FDA, the Department of Health and Human Services (HHS), or any other federal department, agency or division advised on or reviewed the article before it was published? Provide names and titles for each individual listed.

    b. As the Centers for Disease Control and Prevention (CDC) typically makes recommendations with input from the Advisory Committee on Immunization Practices on vaccine schedules and the types of individuals for whom a vaccine is recommended, did FDA consult with CDC in the approval process of the Novavax COVID-19 vaccine? If not, why not?

    c. What authority is the agency relying on in releasing and enforcing this framework?

2. Does FDA expect there will be COVID-19 vaccines approved for individuals between the ages of 6 months and 65 years with no known underlying health conditions during 2025-2026?

    a. Do the Moderna and Pfizer/BioNTech COVID-19 vaccines that have full FDA approval maintain approved status for the 2025-2026 season? If so, has FDA instituted new limitations to their approved use? If not, provide the current approval status of these products.

    b. Are manufacturers of COVID-19, influenza, and other seasonal vaccines required to complete clinical trials this year?

    c. When does FDA intend for these vaccines to be available this year?

[9] U.S. Food and Drug Administration, *An evidence based approach to COVID vaccination* (May 20, 2025).

d. Does FDA expect there will be multiple COVID-19 vaccines available for 2025-2026, as during prior years?

e. Does FDA expect there will be COVID-19 vaccines approved for children under 12 years old for the 2025-2026 season?

f. Despite the administration of the Novavax vaccine in individuals 6 months old and older under its EUA, the age range for which FDA has approved the Novavax vaccine excludes very young children, many of whom are unvaccinated. Will the FDA approve a COVID-19 vaccine for 2025-2026 from one or more manufacturers for young children who have not previously received a vaccine?

g. What was the specific scientific justification for requiring the change in indication?

3. What additional data is FDA seeking to consider approval of vaccines for healthy, young individuals who wish to receive the vaccine to protect themselves and their loved ones from severe illness?

    a. Is FDA independently conducting analysis or is it relying on data from trials conducted by a manufacturer? If FDA is requiring that trials be conducted by manufacturers, will that be an annual requirement?

    b. Has FDA assessed whether its new framework, over time, will discourage manufacturing of COVID-19 vaccines or decrease rates of uptake among the general public? If so, provide all documentation that shows FDA's analysis of the public health impact of its new COVID-19 vaccine framework, including effect on rates of serious illness, hospitalization, and death from COVID-19.

4. In the Town Hall, you said FDA will require new randomized placebo-controlled clinical trials on COVID-19 vaccines as a prerequisite for approval each year.

    a. What are the specific aspects the new clinical trial must include to satisfy this requirement? Have manufacturers received detailed guidance on this requirement?

    b. The NEJM article you authored provides some description of how clinical studies of COVID-19 vaccine efficacy should be designed under this new framework, including "the control group could receive a saline placebo, to permit documentation of the full adverse-event profile."[10] When there are vaccines with proven efficacy available, why does FDA propose the dramatic and – in the

[10] Vinay Prasad, M.D., M.P.H., and Martin A. Makary, M.D., M.P.H., *An Evidence-Based Approach to Covid-19 Vaccination*, New England Journal of Medicine (May 20, 2025).

opinion of experts – unethical step of requiring manufacturers conduct trials that administer a control group with a placebo?[11]

5. FDA made its final determination regarding the Novavax BLA for its COVID-19 vaccine several weeks after the PDUFA action date of April 1, 2025.

    a. What was the cause for the delay? Who was involved in the decision to delay a final determination?

    b. Did an internal FDA policy change or presentation of new scientific evidence contribute to the decision to delay the final determination? If so, please provide details of the policy change or evidence.

    c. Is there a Center Director Decisional Memorandum for this approval? If yes, will it be made public?

6. Have any of the FDA employees who were responsible for reviewing the Novavax BLA received termination notices during HHS's reduction in force (RIF) implemented on April 1, 2025? If so, indicate how many of the reviewers have been terminated.

7. Will the Novavax vaccine still be available under EUA to individuals younger than 65 without an underlying condition during the 2025-2026 season?

8. Has FDA been presented with or independently collected any scientific evidence indicating reduced efficacy of the Novavax, Moderna, or Pfizer COVID-19 vaccines? If so, provide documentation of the evidence and indicate the source of the information.

9. In comments made shortly before the three-page NEJM article was published, you said FDA planned to "unleash a massive framework" for a new approach to vaccine approval.[12]

    a. Is there additional guidance from FDA forthcoming? If so, when will FDA issue the guidance and will there be opportunity for public comment?

    b. Is FDA making more policy changes concerning approval and review of COVID-19 or other vaccines? Provide details of any changes.

    c. As FDA is developing new policy, how is it weighing its approach to approving seasonal vaccines such as ones against COVID-19 and influenza with the need to have those vaccines available to patients at the appropriate time each year when rates of respiratory illness are highest?

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[11] *When a Vaccine Safety Trial Becomes Unethical*, The New York Times (May 16, 2025).

[12] *FDA commissioner says new vaccine 'framework' for industry is coming within weeks,* STAT News (May 15, 2025).

If you have any questions about this request, please contact the Committee Democratic staff at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Ranking Member

Diana DeGette
Ranking Member, Subcommittee on Health

Yvette Clarke
Ranking Member, Subcommittee on Oversight and Investigations