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ONE HUNDRED NINETEENTH CONGRESS
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December 5, 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 continued concern over the growing role of the Food and Drug Administration (FDA) in undermining our nation's vaccine infrastructure—limiting access to safe and effective vaccines that protect patients. In the agency's latest attack, Dr. Vinay Prasad, Director of the Center for Biologics Evaluation and Research (CBER) and Chief Medical and Scientific Officer, sent an email to career scientists and other civil servants containing inaccuracies, misinformation, and unsupported claims regarding the agency's regulation of vaccines, and asserting an unproven link between COVID-19 vaccines and pediatric deaths. Dr. Prasad's factually unsupported statements continue a troubling trend under your leadership—of the agency making policy announcements with zero transparency regarding its decision-making process, zero public access to the "evidence" it is relying on, and zero opportunity for the public to provide input. Twelve former Commissioners from both Democratic and Republican administrations wrote regarding their concern that FDA is upending core policies of vaccine development in a way that undermines the public interest.[1]

Dr. Prasad's has offered no credible scientific basis for his claims linking COVID-19 vaccines to children's deaths, which you yourself parroted the day after his memo became public in an interview.[2] The "findings" Dr. Prasad references in the letter were not published in a peer reviewed journal or otherwise made public. Its first sentence, stating that children died "after and because of receiving COVID-19 vaccination," implies causality between receiving the COVID-19 vaccine and pediatric deaths—an unsupported assertion that is not grounded in meaningful scientific analysis. In fact, Dr. Prasad concedes as much in the next sentence, by saying the relation of these deaths to vaccination is only "possible." It is appalling that your

[1] Robert Califf et al., *A Threat to Evidence-Based Vaccine Policy and Public Health Security at the FDA*, New England Journal of Medicine (Dec. 3, 2025).

[2] NPR, *FDA to Raise Hurdles for Vaccines, Faulting COVID Shots for 10 Kids' Deaths*, (Nov. 29, 2025).

leadership would circulate misleading statements which are known to be scientifically overstated and yet they demand they be treated as truth.

FDA has also made the deeply irresponsible decision to withhold the data that supposedly supports these latest claims. Dr. Prasad claims these statements are a "profound revelation," but has yet to provide evidence to substantiate his claims. He also claimed "many more deaths may be unreported," but provided no epidemiologic evidence from experts to suggest there was underreporting for pediatric deaths. He also ignored these vaccines were evaluated at previous FDA advisory committee and ACIP meetings, during which scientific experts examined the benefit-risk profile and determined these vaccines met the threshold to be administered. Meanwhile, you and Dr. Prasad have treated the fact that 183 children died of COVID-19 in the United States from 2020 to 2022 as, in effect, irrelevant.[3]

Further, Dr. Prasad used reports from the Vaccine Adverse Event Reporting System (VAERS) to make his claims. However, the VAERS database allows anyone to submit entries, which is why the Department of Health and Human Services (HHS) disclaims that it may "contain information that is incomplete, inaccurate, coincidental, or unverifiable" on the database's website.[4] Though this publicly-sourced data is helpful in identifying early safety signals for new vaccines, Dr. Prasad is now reevaluating old data instead of examining new safety reports or data, which would provide updated signals for any such side effects.[5] As experts note, reports of such cases are often complex and require careful scrutiny to determine true cause of death.[6] They also note it would not be surprising if these blunt claims, which do not appear to be coupled with required medical verification, are debatable.[7]

The email also proposes several new changes for oversight and approval of vaccines, such as stricter requirements for authorizing vaccines for use by pregnant women, unspecified revisions to seasonal flu vaccine approval, requiring studies for co-administration of vaccines (which is already standard practice), and requiring large, randomized studies of pneumonia vaccines to prove reduction of disease rather than show the creation of antibodies. FDA has yet to provide meaningful data to prove these changes are necessary. It is clear that these changes will certainly make it more difficult to get approval of vaccines through the process which experts say has "helped provide children and adults with timely access to safe and effective vaccines, saving many lives."[8] As experts have also noted, establishing FDA regulations via internal agency email is legally questionable, eliminates the opportunity for public comment, and

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[3] Heather K. Dykstra et al., *Characteristics of Children Ages 1–17 Who Died of COVID-19 in 2020–2022 in the United States,* Pediatrics (Nov. 2024).

[4] Vaccine Adverse Event Reporting System, *VAERS Data* (https://vaers.hhs.gov/data.html) (accessed Dec. 3. 2025).

[5] NBC, *FDA Claims Covid Shots Killed 10 Children and Vows New Vaccine Rule*s (Nov. 29, 2025).

[6] The New York Times, *F.D.A. Seeks More Oversight of Vaccine Trials and Approvals* (Nov. 28, 2025).

[7] The Guardian, *Experts Say Strict New FDA Protocol for Vaccine Approval is 'Dangerous and Irresponsible'* (Nov. 29, 2025).

[8] *See* note 1.

creates regulatory uncertainty for the companies looking to bring potentially beneficial products to market.[9]

While this email is vague regarding what the changes in policy will be, it is crystal clear that you and Dr. Prasad have preconceived notions of supposed harms that justify policies to limit American's access to these safe and proven vaccines. Experts have already said the standards you and Dr. Prasad appear to be setting are "impossible," and in many cases "unethical," to meet.[10] Others have noted your actions amount to an unprecedented "science by press release" and an undercutting of scientifically supported methods. [11] This could also chill development of new vaccines.[12]

Dr. Prasad's memo represents a dangerous trend in the agency's politicization of science under your leadership. His email makes clear that Dr. Prasad has aligned himself with an extreme, anti-vaccine, partisan agenda that puts the lives of the American at risk. Meanwhile, claiming you alone found the deaths in children disregards the work of FDA civil servants who have continually monitored the safety of the vaccines and examined the issues that you are now manipulating to retrofit an anti-vaccine agenda. Indeed, individuals inside FDA have indicated that Dr. Prasad's analysis is "a huge exaggeration."[13]

In our July 29, 2025, letter to you, to which you have still not responded, we requested information and an explanation regarding announcements in FDA's vaccine approval policy. We noted those announcements are happening outside of the usual agency practices and without transparency to Congress or the public. Your recent actions are continuing this trend of poor leadership, lack of transparency, and policymaking unsupported by evidence. This is far from the professionalism and scientific rigor we expect our federal health agencies to abide by and it represents an obstruction of legitimate congressional oversight.

To enable some transparency into your dangerous actions and rhetoric, please provide responses to the questions below by December 19, 2025.

1. Dr. Prasad claimed "at least 10 children have died after and because of receiving COVID-19 vaccination," without providing the data to support this. He stated the findings are based on "detailed analysis of deaths voluntarily reported to the VAERS system" between 2021 and 2024.

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[9] Liz Szabo, *FDA Official Proposes 'Impossible' Standards for Vaccine Testing That Could Curtail Access to Immunizations*, University of Minnesota (Dec. 1, 2025).

[10] *Id.*

[11] *See* note 3.

[12] The Washington Post, *Blaming Some Child Deaths on Covid Shots, FDA Vows Stricter Vaccine R*ules (Nov. 28, 2025).

[13] Zachary Brennan and Max Bayer, *Prasad's claim of 10 Covid vaccine deaths may be an overcount, FDA sources say,* Endpoints News (Dec. 4, 2025).

a. Please provide the deidentified data upon which you are drawing your conclusions, including:

   i. Ages and gender of the children at time of vaccine administration and at time of death;

   ii. Any underlying health conditions of the children;

   iii. Vaccine and dosage the children received and dates they were received;

   iv. Date of death; and

   v. Whether COVID-19 or another cause is listed as a cause of death on the corresponding death certificate.

b. For each of these 10 cases, please explain how FDA's reviewers confirmed the accuracy of information reported in VAERS. If there were any internal discrepancies in the VAERS reports, how did FDA resolve them?

2. Dr. Prasad's email references a small meeting with OVRR and OBPV stakeholders at which Dr. Tracy Beth Hoeg presented slides on COVID-19 vaccine related deaths. Please produce those slides.

3. Please describe how FDA weighed the COVID-19 vaccine's proven effectiveness in preventing illness, hospitalization, long COVID, or death in children against its claims of COVID-19 vaccine related deaths. Specifically:

   a. A 2024 National Academies of Sciences, Engineering, and Medicine report suggested that during a 2022 survey, 1.3 percent of children who had previously been infected with COVID-19 reported experiencing long-COVID symptoms at the time of the survey. Did FDA's analysis look at COVID-19 vaccine effectiveness at preventing long-COVID in children?

   b. An April 8, 2022, Morbidity and Mortality Weekly Report looked at data from 40 health care systems to evaluate cardiac complications after COVID-19 infection and COVID-19 vaccination. After evaluating this data, the authors concluded the risk for cardiac complications was significantly higher after COVID-19 infections than after COVID-19 vaccinations for males and females in all age groups.[14] Did FDA's analysis look at the risk of long-term health complications from COVID-19 infection in children relative to the risk of side effects from the vaccine?

[14] Centers for Disease Control and Prevention, *Cardiac Complications After SARS-CoV-2 Infection and mRNA COVID-19 Vaccination — PCORnet, United States, January 2021–January 2022* (April 8, 2022).

4. Despite decades of data showing vaccines are safe and effective in reducing morbidity and mortality for many infectious diseases, Dr. Prasad's email announced a change in FDA's requirements for determining the safety and efficacy of vaccines for approval. Please provide data supporting your determination that the existing requirements are insufficient to prove safety and efficacy of vaccines.

5. What legal authority is the agency relying on to unilaterally release its "path forward" for vaccine regulation via email? Please provide the exact statutory and regulatory citations and explain how those authorities permit FDA to forego formal rulemaking, public comment, and processes outline in statute.

    a. Will you convene a Vaccines and Related Biological Products Advisory Committee (VRBPAC) meeting for any proposed changes to the standards for vaccine policy to enable a transparent discussion among scientific experts?

    b. Will you convene a VRBPAC meeting for any other proposed changes to the standards for vaccine approval? Specifically, will you provide transparency and participation by experts in any decision making surrounding aluminum in vaccines?

6. In Dr. Prasad's email, he made several claims about the risk of COVID-19 vaccines compared to the risk of COVID-19 on young, healthy boys and men. He claims a "widely discussed, peer reviewed paper in 2022" found that COVID-19 boosters were harmful to young men. However, he did not provide citations or even the name of the paper, though used it to substantiate a claim that FDA's vaccine policy has "harmed more than [it] saved."

    a. Please produce the referenced paper.

    b. What criteria has FDA analyzed to support the claim that vaccines may have "harmed more children than we saved?"

7. What data and adverse event reports support your statements and possible label changes regarding the safety of COVID-19, influenza, or pneumococcal vaccines for pregnant women? Please provide this data.

8. Provide the names and titles of all HHS personnel who were involved in proposing the policy changes outlined in the November 28, 2025, staff email.

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