

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

May 12, 2026

VIA EMAIL

The Honorable Dr. Martin Makary
Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993

Dear Commissioner Makary:

I write regarding the latest incident in a disturbing pattern for Trump Administration health agencies: political interference in the publication of scientific research about vaccines. Over the last several months, scientists at the Food and Drug Administration (FDA) have reportedly been ordered to withdraw from publication or refrain from submitting studies regarding the safety of vaccines against COVID-19 and shingles (“the studies”). The studies, which apparently bolstered widely accepted scientific conclusions about the safety of approved vaccines, should be read and assessed by the research community, and the censorship that has blocked them from broader access should trouble anyone concerned about the fate of American science. Accordingly, I write to request that you immediately allow the FDA-employee authors to resubmit the studies and desist from further censorship of agency scientists.

Recent reporting indicates that, beginning last October, FDA officials ordered scientists to withdraw two studies about the benefits of COVID-19 vaccines that had already been accepted by prestigious medical journals. One of these, which had been accepted by the journal *Drug Safety*, looked at health outcomes for Medicare beneficiaries receiving COVID-19 vaccines in 2023 and 2024, and found that for people 65 and older there were “no new safety signals.”¹ The other COVID-19 vaccine study, which had been accepted by the journal *Vaccine*, examined people with private insurance between the ages of six months and 64 years of age who received COVID-19 vaccines during the same time period, found no safety concerns that had not already been acknowledged by health officials, and concluded that for people in this age group “the benefits of vaccination outweigh the risks.”² Then, in February, FDA officials declined to sign off on the submission of abstracts of two studies about a shingles vaccine for a scientific conference, one describing the safety of the shingles and the other its efficacy; the agency is apparently not permitting the studies to go forward.³

¹ Christina Jewett, *F.D.A. Blocked Publication of Research Finding Covid and Shingles Vaccines Were Safe*, N.Y. TIMES (May 5, 2026), <https://www.nytimes.com/2026/05/05/us/politics/fda-covid-vaccine-studies.html>.

² Lizzy Lawrence, *How two top FDA officials are quietly upending vaccine regulations*, Stat (Nov. 12, 2025), <https://www.statnews.com/2025/11/12/fda-vaccine-policy-controlled-by-vinay-prasad-tracy-beth-hoeg/>.

³ Christina Jewett, *F.D.A. Blocked Publication of Research Finding Covid and Shingles Vaccines Were Safe*, N.Y. TIMES (May 5, 2026), <https://www.nytimes.com/2026/05/05/us/politics/fda-covid-vaccine-studies.html>.

Confronted with these blatant acts of meddling in scientific research, the Department of Health and Human Services (HHS) has said the COVID-19 studies' "broad conclusions" were not supported by the gathered data.⁴ This vague critique is strikingly similar to the concerns about "appropriate methodology" invoked when Dr. Jay Bhattacharya, acting director of the Centers for Disease Control & Prevention, recently blocked from publication in the CDC's in-house journal a study demonstrating significant protection against hospitalization that COVID-19 vaccines provided last winter.⁵ Former FDA officials have reacted to this latest example of politicization at HHS by noting "a pattern here for not letting information out that might support the general safety of vaccines, with methodological rationales given by non-scientist spokespersons."⁶

I am deeply concerned that under the Trump Administration the FDA is no longer concerned with ensuring that vaccines are safe and effective and is instead focused on presenting a distorted vision of vaccine science to the public. Just weeks into his tenure, HHS Secretary Robert F. Kennedy, Jr. cancelled the public meeting of the FDA advisory body responsible for selecting the strain for flu the vaccine.⁷ Kennedy subsequently fired Dr. Peter Marks, the head of the FDA division responsible for regulating vaccines, because Marks refused to allow Kennedy to "edit" entries in a database for reporting vaccine side effects.⁸ Several months later, you and Dr. Vinay Prasad, who at the time was FDA's top vaccine official, announced a new "approach" to evaluating COVID-19 vaccines but, as a former FDA advisory committee member pointed out, you failed to follow agency practice for such a change, and gave the scientific community no opportunity for public comment before announcing it.⁹

In perhaps the most overt example of politicization at FDA, late last year Dr. Prasad issued a memo to agency staff—which was quickly leaked and widely reported on—calling for an overhaul of regulatory requirements for approval of vaccines based on an agency finding that at least 10 children had died "because of" COVID-19 vaccines, a finding scientists received with skepticism because it was accompanied by no supporting data.¹⁰ In that memo Prasad wrote, of you, "There is no doubt that without this FDA commissioner, we would not have performed this

⁴ Padmanabhan Ananthan, *US FDA blocked publication of COVID, shingles vaccine safety studies*, REUTERS (May 5, 2026), <https://www.reuters.com/legal/litigation/us-fda-blocked-research-publication-that-covid-shingles-vaccines-are-safe-nyt-2026-05-05/>.

⁵ Lena Sun, *CDC delays publishing report showing covid vaccine benefits*, WASH. POST (Apr. 9, 2026), <https://www.washingtonpost.com/health/2026/04/09/covid-vaccine-report-delayed/>.

⁶ Maya Yang, *FDA blocked studies finding Covid and shingles vaccines safe, HHS official says*, THE GUARDIAN (May 5, 2026), <https://www.theguardian.com/us-news/2026/may/05/covid-shingles-vaccines-studies-fda>

⁷ Dan Levine and Michael Erman, *Meeting of US FDA vaccine advisers canceled, committee member says*, REUTERS (Feb. 26, 2025), <https://www.reuters.com/business/healthcare-pharmaceuticals/meeting-us-fda-vaccine-advisors-canceled-committee-member-says-2025-02-26/>.

⁸ Matthew Perrone, *Ex-official says he was forced out of FDA after trying to protect vaccine safety data from RFK Jr.*, ASSOCIATED PRESS (Apr. 7, 2025), <https://www.ap.org/news-highlights/spotlights/2025/ex-official-says-he-was-forced-out-of-fda-after-trying-to-protect-vaccine-safety-data-from-rfk-jr/>

⁹ Kathryn Edwards, *The FDA is circumventing key roles and procedures for licensure and use of Covid vaccines*, STAT (May 22, 2025)

¹⁰ Matthew Herper and Helen Branswell, *Experts say top FDA official's claim that Covid vaccines caused kids' deaths requires more evidence*, STAT (Nov. 29, 2025), <https://www.statnews.com/2025/11/29/covid-vaccine-deaths-fda-memo-vinay-prasad/>.

investigation and identified this safety concern.”¹¹ But despite the significant public attention it generated, to date you have provided no data to substantiate the claim of child deaths.

This manipulation of science has only been possible because you and top political appointees have consolidated control while marginalizing FDA staff. Reports indicate that at least seven senior leaders in the agency’s vaccine center were forced out of their positions, and that conditions became so dire many people sought to leave for other parts of the agency.¹² Among those demoted was Dr. Richard Forshee, a former top vaccine safety official who is also a listed author for both of the suppressed COVID-19 studies.¹³ Earlier this year, after he resigned as FDA’s top drug regulator, Dr. Richard Pazdur described a climate of fear and politicized retribution under your leadership, and said that key decisions about approval of pharmaceuticals were being made “in a conference room that is adjacent to the Commissioner’s personal office; there’s not even enough room in that office for the entire review staff that has worked on the application to attend this meeting.”¹⁴

Anti-vaccine activists, including the current HHS Secretary, stake their authority on claims that the country’s scientific agencies are hopelessly corrupt.¹⁵ But the current Trump Administration has overseen an unprecedented campaign of suppression and censorship of vaccine science, and wasted tens of millions of taxpayer dollars in the process by hiding the results of studies that had already been paid for. In order for the Permanent Subcommittee on Investigations to understand the Trump Administration’s efforts to interfere in the publication of scientific reports, please provide the following information and records by May 26, 2026:¹⁶

1. All communications between your office and the FDA staff listed as authors of the studies between September 2025 and the present;

¹¹ Email from Dr. Vinay Prasad, Director, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, to CBER staff, Nov. 28, 2025, <https://www.fda.gov/media/191442/download?attachment>.

¹² Lizzy Lawrence, *Under Vinay Prasad, employees at a key FDA center fear speaking out, look for the exits*, STAT (Oct. 31, 2025), <https://www.statnews.com/2025/10/31/vinay-prasad-fda-cber-management-issues-insiders-say/>.

¹³ Joann F. Gruber et al, *Safety Monitoring of Multiple Health Outcomes Following 2023-2024 COVID-19 Vaccination among Medicare Beneficiaries Aged 65 Years and Older in the United States*, MEDRXIV (Jan. 5, 2025), <https://www.medrxiv.org/content/10.1101/2025.01.03.25319975v1.full-text>; Abstract for Carla E. Zelaya et al, *Safety Monitoring of Multiple Health Outcomes following 2023-2024 COVID-19 Vaccination among Commercial Health Plan Enrollees Aged 6 Month-64 Years in the United States*, Annual Meeting of the International Society for Pharmacoepidemiology (Aug. 24, 2025), <https://2025ispe.eventscribe.net/fsPopup.asp?PosterID=744059&mode=posterInfo>.

¹⁴ STAT, *Former FDA official has grave concerns about the agency*, YOUTUBE (Jan. 13, 2026), <https://www.youtube.com/watch?v=BkE1YgH9uyM&t=1587s>.

¹⁵ Robert King, *RFK Jr. said CDC employees were ‘killing children,’ former director says*, POLITICO (Sept. 17, 2025), <https://www.politico.com/live-updates/2025/09/17/congress/rfk-jr-said-cdc-employees-were-killing-children-former-director-says-00568626>.

¹⁶ “Records” include written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (emails, email attachments, Signal, WhatsApp, or other encrypted messages, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

2. All projections, budgets, or other documents related to money the agency had already expended on the studies at the time they were pulled from publication or submission;
3. All records reflecting policies currently in force related to publication in medical journals by agency staff, including requirements for review or clearance of studies by political appointees;
4. All records reflecting policies currently in force related to communication of scientific findings with the public, including the authority of political appointees to edit or modify work product of agency scientists;
5. A list of all studies or abstracts since January 20, 2025, on which agency employees are included as co-authors that, have been accepted for publication by a scientific journal or presentation at a scientific conference but have been otherwise blocked from public view, including:
 - a. The names of the study's authors;
 - b. A description of the study's subject matter;
 - c. The names of the official or officials who ordered the study held back;
 - d. A detailed description of the reason the study was held back from publication or submission.

Please contact the Subcommittee if you have questions about the procedures for transmitting documents. Thank you for your attention to this request.

Sincerely,



Richard Blumenthal
Ranking Member
Permanent Subcommittee on Investigations

cc: The Honorable Ron Johnson
Chairman
Permanent Subcommittee on Investigations