United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

December 15, 2025

The Honorable Robert F. Kennedy, Jr.
Secretary
Department of Health and Human Services

Dear Secretary Kennedy:

On November 28, 2025, Dr. Vinay Prasad, the Chief Medical Officer and Center for Biologics Evaluation and Research (CBER) Director at the Food and Drug Administration (FDA), reportedly emailed a memo to CBER staff "to report that [Office of Biostatistics and Pharmacovigilance (OBPV)] career staff have found that at least 10 children have died after and because of receiving COVID-19 vaccination."[1] Further, the memo outlined the Biden Administration's failure to fully investigate the safety of the vaccines, including the risks of myocarditis.[2] For nearly five years, I have attempted to obtain full and complete transparency from our federal health agencies about the same vaccine safety and efficacy concerns raised in Dr. Prasad's memo—including through the issuance of a subpoena to the Department of Health and Human Services (HHS) in January 2025.[3] I write to request that HHS immediately produce records and information related to the claims in Dr. Prasad's memo.

According to Dr. Prasad's memo, in the summer of 2025, Dr. Tracy Hoeg, an FDA official, reviewed reports of death in children following receipt of a COVID-19 vaccine.[4] Based on a subsequent review, OBPV determined that at least 10 of these deaths were "related" to the

[1] Emily Kopp, FDA Chief Medical Officer Demands 'Introspection' By Staff After Report Tracing 10 Children's Deaths to COVID Vaccine, Daily Caller, Nov. 29, 2025, available at https://dailycaller.com/2025/11/29/food-drug-administration-vinay-prasad-demands-introspection-staff-email-report-10-children-deaths-covid-vaccine/; Memorandum from Dr. Vinay Prasad, Chief Medical Officer and Center For Biologics Evaluation and Research, Food and Drug Administration, at 1 available at https://cdn01.dailycaller.com/wp-content/uploads/2025/11/CBER-Email.pdf. On Nov. 28, 2025, the *New York Times* reported that it had obtained the memo, and it was "not publicly released." See Christina Jewett, F.D.A. Seeks More Oversight of Vaccine Trials and Approvals, N.Y. Times, Nov. 28, 2025, https://www.nytimes.com/2025/11/28/health/fda-children-deaths-covid-vaccines.html.

[2] Emily Kopp, FDA Chief Medical Officer Demands 'Introspection' By Staff After Report Tracing 10 Children's Deaths to COVID Vaccine, Daily Caller, Nov. 29, 2025, available at https://dailycaller.com/2025/11/29/food-drug-administration-vinay-prasad-demands-introspection-staff-email-report-10-children-deaths-covid-vaccine/; Memorandum from Dr. Vinay Prasad, Chief Medical Officer and Center For Biologics Evaluation and Research, Food and Drug Administration, available at https://cdn01.dailycaller.com/wp-content/uploads/2025/11/CBER-Email.pdf.

[3] Subpoena from Ron Johnson, Chairman, Permanent Subcommittee on Investigations, to Dorothy Fink, Acting Secretary, Department of Health and Human Services, Jan. 28, 2025, on file with Subcommittee.

[4] Memorandum from Dr. Vinay Prasad, Chief Medical Officer and Center For Biologics Evaluation and Research, Food and Drug Administration, at 2 available at https://cdn01.dailycaller.com/wp-content/uploads/2025/11/CBER-Email.pdf.

vaccines.[5] According to Dr. Prasad, this is a conservative assessment and represents "where vaccines are exculpated rather than indicted in cases of ambiguity," and that the true number of deaths is likely higher.[6] Dr. Marty Makary, the Commissioner of the FDA, recently stated that the work reviewing reports of death in children linked to the COVID-19 vaccines remains ongoing.[7] Unfortunately, autopsies were strongly discouraged and often impossible to obtain during the pandemic, resulting in a dramatic understatement of the true number of COVID-19 vaccine-caused deaths.[8] As you are also well aware, the Centers for Disease Control and Prevention's (CDC) Vaccine Adverse Event Reporting System (VAERS) also dramatically understates the number of adverse events, which makes the adverse events that have been reported even more alarming.[9] As of November 28, 2025, VAERS has reported 38,913 deaths worldwide associated with the COVID-19 vaccines, with 9,299 (23.9%) of those deaths occurring within 2 days of vaccination.[10] CDC and FDA have consistently ignored their very own safety surveillance system since the first COVID-19 vaccines received emergency use authorization on December 11, 2020.[11]

The failure of the Biden Administration to thoroughly review safety reports connected to COVID-19 vaccines is despicable, though not surprising given what my own investigations have uncovered. In May 2025, I released a report entitled "Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination."[12] This report, which was based on limited records produced in response to my January 2025 subpoena to HHS, showed how Biden Administration health officials at the CDC and FDA downplayed the risks of myocarditis in young people caused by COVID-19 vaccines.[13] As is detailed in that report, in February 2021, health officials were aware of cases of myocarditis in young people following COVID-19 vaccination, and yet, CDC and FDA officials appeared to dismiss and downplay the seriousness of this potential connection.[14]

---

[5] *Id.* at 1.
[6] *Id.* at 2.
[7] Berkley Lovelace, Jr. and Anne Thompson, FDA Chief says Biden administration withheld data on heart risk from Covid vaccines, NBC News, December 4, 2025, available at https://www.nbcnews.com/health/health-news/fda-chief-biden-administration-covid-vaccine-heart-risk-data-rcna247440.
[8] James Lyons-Weiler, The Autopsy Data Are In: What They Reveal About COVId-19 Vaccines and Public Health Oversight, Science, Public Health Policy and The Law, Feb. 6, 2025, available at https://publichealthpolicyjournal.com/the-autopsy-data-are-in-what-they-reveal-about-covid-19-vaccines-and-public-health-oversight/.
[9] Permanent Subcommittee on Investigations Majority Staff Report, Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination, at 12-13, May 21, 2025; Tom Shimabukuro, et al., Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS), Vaccine, Jul. 22, 2015, https://pmc.ncbi.nlm.nih.gov/articles/PMC4632204/.
[10] FDA FAERS system, CDC VAERS system. Reports from all locations worldwide. Data as of November 28, 2025; downloaded December 15, 2025.
[11] Press Release: FDA Takes Key Action in Fight Against COVID-19 By Issuing emergency Use Authorization for First COVID-19 Vaccine, Dec. 11, 2020 (archived version Jan. 1, 2025), archived available at https://web.archive.org/web/20250101104106/https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.
[12] Permanent Subcommittee on Investigations Majority Staff Report, Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination, May 21, 2025.
[13] *Id.*
[14] *Id.*

Dr. Prasad's memo also highlights several other important findings and assertions regarding the failures of Biden Administration health officials, including:

- "This is a profound revelation. For the first time, the US FDA will acknowledge that COVID-19 vaccines have killed American children. Healthy young children who faced tremendously low risk of death were coerced, at the behest of the Biden administration, via school and work mandates, to receive a vaccine that could result in death. In many cases, such mandates were harmful. It is difficult to read cases where kids aged 7 to 16 may be dead as a result of covid vaccines"[15]

- "Putting these facts together, it is horrifying to consider that the US vaccine regulation, including our actions, may have harmed more children than we saved. This requires humility and introspection."[16]

- "There is no doubt that without this FDA commissioner, we would not have performed this investigation and identified this safety concern. This fact also demands serious introspection and reform. Why were these deaths not actively reviewed in real time? Why did it take until 2025 to perform this analysis, and take necessary further actions? Deaths were reported between 2021 and 2024, and ignored for years. I suspect the answer is cultural and systemic."[17]

Dr. Prasad's memo, as well as recent revelations by Commissioner Makary, provide further evidence that FDA officials under the Biden Administration failed to take seriously the threat posed by myocarditis following receipt of a COVID-19 vaccine. It appears, based on the memo, that even after FDA finally acknowledged that myocarditis was a serious adverse event associated with the mRNA COVID-19 vaccines, it continued to neglect its responsibility to oversee the vaccines' safety.[18] According to the memo, "the FDA has failed to properly enforce many required post market commitments for COVID-19 vaccines, including for pregnant woman and to document subclinical myocarditis."[19]

Further, according to Commissioner Makary, "the Biden Administration was sitting on data on myocarditis in young people, and it was not made public."[20] As I noted in my May 2025 report, Biden Administration health officials' primary concern did not appear to be the safety of these vaccines, but "vaccine hesitancy and mandating the injection for virtually every

---

[15] Memorandum from Dr. Vinay Prasad, Chief Medical Officer and Center For Biologics Evaluation and Research, Food and Drug Administration, at 2 available at https://cdn01.dailycaller.com/wp-content/uploads/2025/11/CBER-Email.pdf.
[16] *Id.*
[17] *Id.* at 3.
[18] *Id.* at 3.
[19] *Id.* at 2.
[20] Berkley Lovelace, Jr. and Anne Thompson, FDA Chief says Biden administration withheld data on heart risk from Covid vaccines, NBC News, December 4, 2025, available at https://www.nbcnews.com/health/health-news/fda-chief-biden-administration-covid-vaccine-heart-risk-data-rcna247440.

American."[21] I am grateful that we now have individuals at our federal health agencies who care about vaccine safety and efficacy. I am, however, disappointed that despite having subpoenaed HHS for the type of data and information described in Dr. Prasad's memo, it does not appear to have been provided to my office.

Unfortunately, this is not the only instance of HHS failing to fully and completely respond to my oversight requests. For nearly a year, I have been attempting to get information on the Biden Administration's last-minute four-year extension of liability protections for COVID-19 vaccines, which went into effect in December 2024.[22] To date, HHS has failed to provide a single responsive record to this request. This liability shield prevents those harmed by the COVID-19 vaccines from being able to sue the manufacturers directly and hold them accountable. As Dr. Prasad noted in his memo, vaccine manufacturers have "unique financial incentives," which includes a lack of true liability when their vaccines cause harm.[23] In order to address these "unique financial incentives," as well as provide relief for the harms recently brought to light by the FDA, it is crucial to get answers on why the Biden Administration extended the liability protections for the entirety of President Trump's second term.

I wholeheartedly agree with Commissioner Makary's recent assertion that federal health officials have a "moral duty" to fully inform the public about the harms caused by the COVID-19 vaccines.[24] As part of its efforts to fulfill this "moral duty," I expect HHS to fully respond to my previous requests on the COVID-19 vaccine liability extension and provide the following information by no later than January 5, 2026:[25]

1. Please explain how FDA determined that the 10 deaths were "related" to the COVID-19 vaccine.

2. All records referring or relating to the review of the 96 reports of death following a COVID-19 vaccine, including the 10 deaths determined to be "related," referenced in the November 28, 2025 memo, including but not limited to, any memorandum or report created following that review and the data underlying the reports.

---

[21] Permanent Subcommittee on Investigations Majority Staff Report, Failure to Warn: How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination, at 50-51, May 21, 2025.
[22] Letter from Ron Johnson, Chairman, Permanent Subcommittee on Investigations, to Xavier Becerra, Secretary, Department of Health and Human Services, Dec. 18, 2024. In June 2025, as an accommodation to HHS, I sent a second letter reiterating my request for this information. Letter from Ron Johnson, Chairman, Permanent Subcommittee on Investigations, to Robert F. Kennedy, Jr., Secretary, Department of Health and Human Services, June 26, 2025.
[23] Memorandum from Dr. Vinay Prasad, Chief Medical Officer and Center For Biologics Evaluation and Research, Food and Drug Administration, at 4-5, available at https://cdn01.dailycaller.com/wp-content/uploads/2025/11/CBER-Email.pdf.
[24] Elizabeth Troutman Mitchell, Exclusive: FDA Chief Says He Has 'Moral Duty' to Expose COVID-19 Vaccine Deaths, The Daily Signal, Dec. 10, 2025, available at https://www.dailysignal.com/2025/12/10/exclusive-fda-chief-says-he-has-moral-duty-to-expose-covid-19-vaccine-deaths/.
[25] *Id.*

3. With VAERS reporting 38,913 worldwide deaths as of November 28, 2025 associated with the COVID-19 vaccines, why did FDA limit its review to only 96 (.25%) of the reported deaths?[26]

4. All records referring or relating to the small meeting with Office of Vaccines Research and Review and Office of Biostatistics and Pharmacovigilance staff referenced in the November 28, 2025 memo, including but not limited to:
    a. All communications, presentations, or reports created or received by Dr. Tracy Beth Hoeg and OBPV's subsequent review; and
    b. A list of all attendees at the meeting.

5. Dr. Prasad's memo notes that FDA does not know whether the COVID-19 vaccines harmed more children than were saved.[27] What steps is FDA taking to determine whether the COVID-19 vaccines harmed more children than were saved?

6. Dr. Prasad's memo states that he is not aware of any analysis that properly reviews whether COVID-19 causes more cases of myocarditis than the COVID-19 vaccines.[28] What steps is FDA taking to conduct a proper assessment of whether COVID-19 causes more cases of myocarditis than the COVID-19 vaccines?

7. Dr. Prasad's memo states, "I have seen no evidence that COVID-19 vaccines, which do not halt transmission, benefit third parties."[29] Please explain what evidence FDA has reviewed and/or what analysis FDA has conducted on the benefit of COVID-19 vaccines for third parties.

8. Please explain what steps HHS has taken to examine whether the existing liability shield for COVID-19 vaccines should remain in place?

9. Since December 11, 2020, what steps has HHS, including any sub-components, taken to analyze the 1,671,991 adverse events and 38,913 deaths worldwide associated with the COVID-19 vaccines reported on VAERS? Please provide all documents and communications regarding the discussion and analysis of these adverse events and deaths, and a complete list of names of department and agency personnel who are responsible for the analysis and the review of it.

10. All HHS documents and communications regarding and reacting to the December 2022 Rasmussen polling results showing 28% of the American public believe they personally know someone whose death "may have been caused by side effects of COVID-19

---

[26] FDA FAERS system, CDC VAERS system. Reports from all locations worldwide. Data as of November 28, 2025; downloaded December 15, 2025.
[27] Memorandum from Dr. Vinay Prasad, Chief Medical Officer and Center For Biologics Evaluation and Research, Food and Drug Administration, at 2-3, available at https://cdn01.dailycaller.com/wp-content/uploads/2025/11/CBER-Email.pdf
[28] *Id.* at 3.
[29] *Id.* at 5.

vaccines," and 48% of American's agree "that there are legitimate reasons to be concerned about the safety of COVID-19 vaccines[.]"[30]

Although Dr. Prasad's leaked memo did receive some limited media coverage, it did not receive anywhere near the attention it should have. As a result, the American public remains largely unaware of what should be a blockbuster revelation. Hopefully, the documents HHS will provide in response to this oversight request will garner the public attention they deserve. After receiving and reviewing these documents, I will also request that HHS make relevant personnel available to testify at a hearing of the Permanent Subcommittee on Investigations.

Sincerely,

Ron Johnson
Chairman
Permanent Subcommittee on Investigations

cc: The Honorable Richard Blumenthal
Ranking Member
Permanent Subcommittee on Investigations

The Honorable Dr. Marty Makary
Commissioner
Food and Drug Administration

Dr. Vinay Prasad
Director
Center for Biologics Evaluation and Research

Dr. Tracey Beth Hoeg
Acting Director
Center for Drug Evaluation and Research

[30] Rasmussen Reports, Poll, 'Died Suddenly'? More than 1-in-4 think Someone They Know Died From COVID-19 Vaccines, Jan. 2, 2023, available at https://www.rasmussenreports.com/public_content/politics/public_surveys/died_suddenly_more_than_1_in_4_think_someone_they_know_died_from_covid_19_vaccines.