

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS
WASHINGTON, DC 20510-6250

June 16, 2026

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

The Honorable Jay Bhattacharya
Acting Director
Centers for Disease Control and Prevention

Kyle Diamantas
Acting Commissioner
Food and Drug Administration

Dear Secretary Kennedy, Acting Director Bhattacharya, and Acting Commissioner Diamantas:

Since assuming the chairmanship of the Permanent Subcommittee on Investigations (“PSI” or “the Subcommittee”) in January 2025, I have released multiple reports and thousands of pages of records detailing the harms caused by the COVID-19 injections, including most recently a report showing how federal health agencies willfully ignored problems with a vaccine safety monitoring system leading to missed safety signals.¹

Recently, records produced in response to my request for documents and communications connected to the Food and Drug Administration’s (“FDA”) finding of pediatric deaths linked to the COVID-19 injections, revealed that as early as December 5, 2025, federal health officials recommended updating the vaccines’ safety labels to include a warning of “**myocarditis with fatal outcomes.**”² Press reports suggest that instead of taking steps to address safety issues, federal health officials are doubling down on the mRNA COVID-19 vaccines. According to reports, on June 1, 2026, the Centers for Disease Control and Prevention (“CDC”) awarded Pfizer two contracts for COVID-19 mRNA vaccines worth approximately \$1.24 billion.³ The decision to award these contracts raises questions about CDC’s commitment to vaccine safety.

¹ See 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; and Permanent Subcommittee on Investigations Majority Staff Report, Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals, Apr. 29, 2026.

² PSI_COVID-19_Vaccine_000395-96 (see Enclosure) (emphasis in original).

³ TrialSite Staff, CDC Awards Pfizer \$1.24 Billion for COVID-19 Vaccines Despite Falling Demand and Ongoing Safety Debate, TrialSiteNews, June 11, 2026, available at <https://www.trialsitenews.com/a/cdc-awards-pfizer-1.24-billion-for-covid-19-vaccines-despite-falling-demand-and-ongoing-safety-debate-e3060951>.

Since 2021, I have sent more than 78 letters on the COVID-19 pandemic, including more than 23 letters focused specifically on safety concerns about the COVID-19 injections. In January 2025, I issued a subpoena to the Department of Health and Human Services (“HHS”) to finally get the American public the transparency that the Biden administration had refused to provide.⁴ As a result of my efforts, and thanks to Secretary Kennedy’s commitment to radical transparency, HHS produced millions of pages of records that had been withheld by the Biden administration.

Based on those records, the Subcommittee has uncovered a number of serious failures by federal health agencies under the Biden administration in monitoring the safety of the COVID-19 injections. On May 21, 2025, PSI released a report and thousands of pages of records in conjunction with a hearing revealing the extent to which Biden health officials downplayed the risk of myocarditis caused by the mRNA COVID-19 injections.⁵ That report found that despite being aware of the risk of myocarditis in young people after receiving an mRNA COVID-19 injection, Biden health officials dismissed the seriousness of the threat and ultimately failed to immediately alert the public and health care professionals.⁶

The failures surrounding myocarditis proved to be only the tip of the iceberg in how federal health agencies mishandled vaccine safety monitoring. On April 29, 2026, PSI released a report and records in conjunction with a hearing that detailed how Biden health officials ignored a known flaw in their COVID-19 vaccine safety monitoring system that resulted in safety signals for serious adverse events being missed.⁷ The Subcommittee’s report, entitled “Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals,” revealed that on March 1, 2021, senior officials responsible for monitoring the safety of the COVID-19 injections, including Dr. Peter Marks, were warned by an expert in FDA’s data mining system, Dr. Ana Szarfman, that the algorithm the system used was failing to identify potential safety signals as a result of a statistical limitation called masking.⁸ At the same meeting, Dr. Szarfman presented these same senior health officials with a newer algorithm that would address the masking problem and identify otherwise hidden safety signals.⁹ However, it appears no action was taken to address the flaws Dr. Szarfman identified.¹⁰

On March 26, 2021, roughly three weeks after first warning of the failures of the current safety monitoring method, Dr. Szarfman shared a data analysis using the newer method that identified signals for serious adverse events that were previously hidden.¹¹ The new methodology identified 49 examples of extreme masking and over twenty statistically significant

⁴ 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.

⁵ 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.

⁶ *Id.*

⁷ Permanent Subcommittee on Investigations Majority Staff Report, Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals, Apr. 29, 2026.

⁸ *Id.* at 16-17.

⁹ *Id.*

¹⁰ *See generally* Permanent Subcommittee on Investigations Majority Staff Report, Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals, Apr. 29, 2026.

¹¹ *Id.* at 18-19.

safety signals for adverse events—highlighted in the image below—that were previously undetected including sudden cardiac death.¹²

March 26, 2021: COVID-19 Vaccine Safety Signal Analysis Shared by Dr. Szarfman¹³

Vaccine Type + Manufacturer	Event: PT plus SMQ	ER05	EB05
COVID19 (Custom Term)	Bell's palsy	3.66	0.537
COVID19 (Custom Term)	Paraesthesia ear	2.84	0.624
COVID19 (Custom Term)	Bradykinesia	3.079	0.507
COVID19 (Custom Term)	Product substitution	2.295	0.482
COVID19 (Custom Term)	Sinus rhythm	2.984	0.586
COVID19 (Custom Term)	COVID-19 immunisation	2.65	0.531
COVID19 (Custom Term)	Cardiac telemetry abnormal	1.728	0.454
COVID19 (Custom Term)	AST/ALT ratio abnormal	1.728	0.45
COVID19 (Custom Term)	Diaphragmatic spasm	1.728	0.449
COVID19 (Custom Term)	Mastoid disorder	1.728	0.449
COVID19 (Custom Term)	Cholecystitis acute	2.144	0.481
COVID19 (Custom Term)	Blood pressure systolic	2.949	0.658
COVID19 (Custom Term)	Ejection fraction	2.963	0.575
COVID19 (Custom Term)	SARS-CoV-1 test	2.068	0.491
COVID19 (Custom Term)	Cardiac failure chronic	2.068	0.486
COVID19 (Custom Term)	Acute left ventricular failure	2.278	0.506
COVID19 (Custom Term)	Agonal rhythm	2.032	0.482
COVID19 (Custom Term)	Hypomagnesaemia	2.469	0.528
COVID19 (Custom Term)	Pulmonary infarction	2.593	0.551
COVID19 (Custom Term)	Cerebral artery occlusion	2.227	0.509
COVID19 (Custom Term)	Diastolic dysfunction	2.126	0.509
COVID19 (Custom Term)	Cardiac telemetry normal	2.504	0.624
COVID19 (Custom Term)	Aortic stenosis	2.141	0.509
COVID19 (Custom Term)	Sudden cardiac death	2.258	0.536
COVID19 (Custom Term)	Hypertensive emergency	2.168	0.592
COVID19 (Custom Term)	May-Thurner syndrome	1.974	0.508
COVID19 (Custom Term)	Infusion	1.774	0.486
COVID19 (Custom Term)	Aortic aneurysm rupture	1.76	0.482
COVID19 (Custom Term)	Thalamic infarction	1.756	0.482
COVID19 (Custom Term)	Drainage	2.263	0.686
COVID19 (Custom Term)	Percutaneous coronary intervention	1.722	0.481
COVID19 (Custom Term)	Basal ganglia stroke	2.061	0.525
COVID19 (Custom Term)	Embolic stroke	1.881	0.532
COVID19 (Custom Term)	Cardiac assistance device user	1.861	0.56
COVID19 (Custom Term)	Magnetic resonance imaging heart	1.573	0.627
COVID19 (Custom Term)	Brain natriuretic peptide increased	1.671	0.809
COVID19 (Custom Term)	Ischaemic stroke	1.496	0.696
COVID19 (Custom Term)	COVID-19 pneumonia	1.73	0.855
COVID19 (Custom Term)	Dementia	1.414	0.676
COVID19 (Custom Term)	Acute myocardial infarction	1.639	0.816
COVID19 (Custom Term)	Pneumonia aspiration	1.33	0.629
COVID19_MODERNA	Electrocardiogram ST segment elevation	1.808	0.859
COVID19_MODERNA	Product administered to patient of inappropriate age	1.704	0.994
COVID19_PFIZER/BIONTECH	Asymptomatic COVID-19	5.584	0.911
COVID19_PFIZER/BIONTECH	Cardiac telemetry abnormal	2.186	0.565
COVID19_PFIZER/BIONTECH	Blood pressure systolic	2.649	0.859
COVID19_PFIZER/BIONTECH	Brain natriuretic peptide increased	1.891	0.924
COVID19_PFIZER/BIONTECH	Acute myocardial infarction	1.844	0.927
COVID19_PFIZER/BIONTECH	COVID-19 pneumonia	1.731	0.831

¹² PSI-HHS-000008257443 (attachment entitled COVIDWeek9MaskExamples.xls), available here: <https://www.ronjohnson.senate.gov/wp-content/uploads/2026/05/Masking-Report-Documents-Pt.-2.pdf> at 166.

¹³ *Id.* (the Subcommittee created the image which is a simplified version of the spreadsheet Dr. Szarfman shared).

The complete spreadsheet of the analysis is available here:

<https://ciosensus.box.com/s/zjksa9wbcetwo3ca3yjcbz2wrjvbp4i>, See file “PSI-HHS-000008257443-45 attachment - 49 examples of extreme masking.xls.”

As PSI's April 2026 report revealed, rather than take Dr. Szarfman's warnings seriously and update their safety monitoring system, senior FDA officials told her to cease and desist while they continued to use the flawed system for monitoring COVID-19 vaccine safety.¹⁴ Federal health officials were more worried about "anti-vaccination rhetoric" than truly monitoring the safety of the vaccines.¹⁵

Under Secretary Kennedy's leadership, it appeared that federal health officials were taking steps to address the failure of the Biden administration to take COVID-19 vaccine safety issues seriously. In November 2025, it was reported that the FDA's Center for Biologics Evaluation and Research ("CBER"), which is responsible for COVID-19 vaccine safety oversight, had identified "at least 10 children [who] died after and because of receiving the COVID-19 vaccination."¹⁶ Following these reports, I wrote to Secretary Kennedy requesting the information and records connected to these deaths.¹⁷

The records produced by Secretary Kennedy and HHS to date, confirmed that in November 2025, CBER officials initially identified 10 pediatric deaths as probably or possibly connected to the COVID-19 injections.¹⁸ These same records show, however, that by December 5, 2025 CBER officials had changed their findings on three pediatric deaths from probably or possibly caused by the COVID-19 injections to un-assessable or unlikely—resulting in what appears to be a final finding of seven pediatric deaths assessed as probably or possibly caused by the COVID-19 injections.¹⁹ Although what drove the decision to change these three cases remains to be seen, what is clear is that these officials appear to have determined that the seven cases warranted warning about the risks.

One such FDA official involved in the analysis wrote in a December 5, 2025 email sharing CBER's findings "[o]ur DPV [(Division of Pharmacovigilance)] recommendation is to trigger **class SLC** [(Safety Labeling Changes)] to include **myocarditis with fatal outcomes** in labeling for mRNA COVID-19 vaccines, and we plan to present the results and recommendation for SLC during 12/11/25 SWG."²⁰ It is unclear whether this presentation occurred and to what

¹⁴ Permanent Subcommittee on Investigations Majority Staff Report, *Unmasked: How Biden Health Officials Purposely Turned a Blind Eye Toward COVID-19 Vaccine Safety Signals*, Apr. 29, 2026, at 26.

¹⁵ *Id.*

¹⁶ Emily Kopp, *FDA Chief Medical Officer Demands 'Introspection' by Staff After Report Tracing 10 Children's Deaths to COVID Vaccine*, DailyCaller, 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/>. *See also* PSI_COVID-19_Vaccine_000001-5 (on file with Subcommittee).

¹⁷ Letter from Ron Johnson, Chairman, Permanent Subcommittee on Investigations, to Robert F. Kennedy, Jr., Secretary, Department of Health and Human Services, Dec. 15, 2025, available at <https://www.ronjohnson.senate.gov/wp-content/uploads/2026/05/2025-12-15-RHJ-to-HHS18.pdf>.

¹⁸ PSI_COVID-19_Vaccine_000395-96.

¹⁹ *See* PSI_COVID-19_Vaccine_000327-94 (on file with Subcommittee). In addition, a February 10, 2026 memorandum on deaths in young adults aged 18-24 after receiving a COVID-19 vaccine identified three cases as possibly caused by the vaccine. PSI_COVID-19_Vaccine_000197-271 (on file with Subcommittee). I am also enclosing drafts of the December 5, 2025 memorandum detailing the changes that were made during the course of assessing pediatric deaths after COVID-19 vaccine. *See* PSI_COVID-19_Vaccine_000397-466 (on file with Subcommittee); PSI_COVID-19_Vaccine_000467-533 (on file with Subcommittee); and PSI_COVID-19_Vaccine_000534-600 (on file with Subcommittee).

²⁰ PSI_COVID-19_Vaccine_000395-96 (emphasis in original).

extent this recommendation to include myocarditis with fatal outcomes on the vaccine warning labels was considered.

The safety issues with the COVID-19 injections that the Subcommittee has uncovered so far should have raised serious concerns at HHS and CDC about the mRNA COVID-19 injections. Instead, CDC's reported awarding of approximately \$1.24 billion in new contracts to Pfizer for a vaccine linked to serious adverse events—including potentially the deaths of children—suggests CDC continues to fail to take its vaccine safety responsibilities seriously.²¹

In order to better understand why CDC is continuing to spend billions of taxpayer dollars on these injections, please provide the following by no later than June 30, 2026:

1. All records referring or relating to the decision to award contracts for FY 2026 through FY 2027 to Pfizer for pediatric COVID-19 vaccines (75D30126D21001)²² and adult COVID-19 vaccines (75D30126D21004),²³ including but not limited to any communications referring or relating to the safety of the Pfizer mRNA COVID-19 vaccine between January 1, 2025 and the present.²⁴
2. All communications between and among employees or contractors at the CDC and FDA referring or relating to pediatric deaths connected to the mRNA COVID-19 vaccine between January 1, 2025 and the present.
3. Please explain whether the December 11, 2025 meeting to discuss the recommendation to change the mRNA COVID-19 vaccine safety labels to include “myocarditis with fatal outcomes” occurred and whether any label changes were agreed upon.
 - a. If the recommendation to change the mRNA COVID-19 vaccine safety label was not agreed to, please explain why not.

Thank you for your attention to this matter.

Sincerely,



Ron Johnson
Chairman
Permanent Subcommittee on Investigations

²¹ TrialSite Staff, CDC Awards Pfizer \$1.24 Billion for COVID-19 Vaccines Despite Falling Demand and Ongoing Safety Debate, TrialSiteNews, June 11, 2026, available at <https://www.trialsitenews.com/a/cdc-awards-pfizer-1.24-billion-for-covid-19-vaccines-despite-falling-demand-and-ongoing-safety-debate-e3060951>.

²² Contract number found here: <https://sam.gov/workspace/contract/opp/ab3b1ada9fc34e05a0720007ff8e6a13/view>.

²³ Contract number found here: <https://sam.gov/workspace/contract/opp/ab3b1ada9fc34e05a0720007ff8e6a13/view>.

²⁴ *Id.*

Enclosure

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

The Honorable T. March Bell
Inspector General
Department of Health and Human Services

Enclosure

From: Alimchandani, Meghna
 To: Prasad, Vinayak
 Cc: Mba-Jonas, Adamma (CBER); Ziderman, Craig
 Subject: DPV/OBPV review memo: U.S. VAERS pediatric deaths following COVID-19 vaccines
 Date: Friday, December 5, 2025 6:15:42 PM
 Attachments: US.VAERS.peds.deaths_final_Dec_5_signed.pdf

Dear Dr. Prasad,

Please find attached our finalized review memorandum from DPV/OBPV.

During this week, as we moved towards finalization of the review and completion of memo, the team met several times and discussed cases as part of our quality control/attempts to reduce subjective variability, and below are the changes from the prior case counts that were shared with you, giving us a total of **7 (2 probable, 5 possible)** deaths. **Five deaths (2 probable, 3 possible)** involved **myocarditis** (including one case that also had a component of cardiomyopathy).

Changes from the table shared with you in prior (11/22/25) email:

- VAERS [redacted]: Changed from *possible* to *un-assessable*. Autopsy report is not available. Available death certificate noted "florid lymphocytic myocarditis" as cause of death, and additionally noted "SARS-CoV-2" as a significant contributing factor to death. No medical records in VAERS describing the evaluation and/or interventions related to event. Death occurred >28d days following vaccination.
- VAERS [redacted]: Downgraded from *probable* to *possible*. Parvovirus presented an alternative etiology that was equally as possible as role of vaccine.
- VAERS [redacted]: Changed from *possible* to *un-assessable* due to contradictory information in death certificate and autopsy report. SARS-CoV-2 and Parvovirus presented alternative etiologies.
- VAERS [redacted]: Downgraded from *probable* to *unlikely* due to pediatric cardiologist comments that likely etiology attributed to HOCM:
 - *The patient's left ventricular dimensions, clinical history (drowning, with no previous symptoms), and genetic testing are all consistent with hypertrophic cardiomyopathy (HOCM). Given the autopsy findings are not typical for myocarditis it seems likely that the cause of death is HOCM and unlikely that it is myocarditis of any etiology.*

Our DPV recommendation is to trigger **class SLC** to include **myocarditis with fatal outcomes** in labeling for mRNA COVID-19 vaccines, and we plan to present the results and recommendations for SLC during 12/11/25 SWG.

A huge thank you to Adamma and the rest of the DPV team for seeing this challenging review through to the end. I passed on your message to the review team earlier this week; thank you. This was a MONUMENTAL effort from all of us, to try to do a diligent thorough review while being bombarded with media articles on the subject.

Best regards,

Meghna

From: Alimchandani, Meghna
 Sent: Saturday, November 22, 2025 12:08 AM
 To: Prasad, Vinayak
 Subject: RE:

Dear Dr. Prasad, please find below table to summarize the 10 cases that were assessed as probably or possibly related. We will prepare a presentation for December 11 SWG with tentative labeling recommendations (and discuss with OVR). I had emailed Sherry earlier this week to request a meeting with you early December, but have not heard back yet. I will be on leave (and traveling overseas to visit family, so will not have access to FDA email) during 11/23 – 30, and will touch base when I return 12/1. Thanks, and wishing you happy Thanksgiving.

VAERS ID	Age	Sex	Dose #	Time to Onset of Sx	Reported Cause of death	Assessment
[redacted]	15	Male	2	2 days	Stress cardiomyopathy with perivascular coronary artery inflammation due to unknown etiology	Possible
[redacted]	16	Male	2	2 days	Stress cardiomyopathy following 2nd dose of the Pfizer-BioNTech COVID-19 vaccine (autopsy), CDC ID Branch Pathology Report indicates heart findings of acute myocarditis and fibrosis	Possible
[redacted]	13	Male	2	3 days	Myocarditis of uncertain etiology (autopsy)	Probable
[redacted]	16	Male	1	1 day	Terminal cardiac arrhythmia caused by areas of acute and ischemic changes with old scarring/fibrosis, caused by abnormal thin, narrow coronary vascular disease	Possible
[redacted]	13	Female	3	2 weeks (14 days)	Complications of probable infectious myocarditis with insulin-dependent diabetes mellitus as a significant contributing condition	Possible
[redacted]	8	Female	1	26 days	Florid lymphocytic myocarditis	Possible
[redacted]	12	Female	2	3 days	Myocarditis (initial death certificate); pancarditis with parvovirus B19 infection (amended certificate)	Possible
[redacted]	13	Female	1	15 days	Fulminant myopericarditis (pancarditis) with extensive myocyte necrosis	Probable
[redacted]	15	Male	2	6 days	Drowning with a contributory condition of myocarditis	Possible
[redacted]		Male	1	12 days	Lymphocytic myocarditis	Probable

Thanks,
 Meghna

From: Alimchandani, Meghna
 Sent: Thursday, November 13, 2025 12:20 AM
 To: Prasad, Vinayak <[redacted]>
 Subject: RE:

We are nearing completion of the review of cases – hope to get a summary of the probable and possible case narratives to you by Friday. Of the 97 unique cases of pediatric death following COVID-19 vaccines, 10 cases were assessed by our team as probable (3 cases) or possible (7 cases).

We will need more time to finish up the memo and add references etc. – targeting Nov 21 for the memo.

Thanks,
 Meghna

From: Prasad, Vinayak <[redacted]>
 Sent: Wednesday, November 12, 2025 4:30 PM
 To: Alimchandani, Meghna <[redacted]>
 Subject:

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COVID-19 vaccine-related deaths
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