AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

[redacted]

From: Prasad, Vinayak
Sent: Wednesday, December 10, 2025 11:33 AM
To: Alimchandani, Meghna; Hoeg, Tracy Beth; Traficant, Jim
Cc: Mba-Jonas, Adamma (CBER); Zinderman, Craig
Subject: RE: VAERS deaths following COVID-19 vaccines - PROJECT

No one will sign any report they do not agree with. If someone agrees with TBH, they are free to sign.

Tracy may require minor help/ request edits. Even David K helps me edit essays he doesn't agree with, and doesn't sign. Hope that is ok. Sometimes a critic can make an essay better even while disagreeing.

-v

From: Alimchandani, Meghna [redacted]
Sent: Wednesday, December 10, 2025 11:30 AM
To: Prasad, Vinayak [redacted] Hoeg, Tracy Beth <[redacted]; Traficant, Jim [redacted]
Cc: Mba-Jonas, Adamma (CBER) [redacted] Zinderman, Craig [redacted]
Subject: RE: VAERS deaths following COVID-19 vaccines - PROJECT

Thanks, and just wanted to reiterate that the separate report from Dr. Hoeg's assessment of cases (#5) would not include DPV reviewers. You have our peds memo, and you will have our memo for adults, and you will have the info needed to generate that table of disagreements.

DPV's memo will be signed and finalized at DPV level. I am not trying to be difficult but this is critical so that we can have an independent review by career scientists – if that is your goal. We have language in our memo acknowledging the subjective nature of causal assessment and are fully aware that others may draw different conclusions re causality.

Best regards,
Meghna

From: Prasad, Vinayak [redacted]
Sent: Wednesday, December 10, 2025 11:22 AM
To: Hoeg, Tracy Beth [redacted]; Alimchandani, Meghna [redacted] Traficant, Jim
[redacted]

committee on Investigations
rtment of Health and Human Services
Produced to Permane
ithout Permission from
Not

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Cc: Mba-Jonas, Adamma (CBER) [redacted]; Zinderman, Craig [redacted]
Subject: RE: VAERS deaths following COVID-19 vaccines - PROJECT

Tracy makes good points, as always.

Tracy should include these differences of opinion cases in her report item #5 below. I think it is important to get that on the record.
I personally think Tracy is correct and such cases should be called "possible"

Include me on the invite to your meeting and I will try to drop in if free.

-v

From: Hoeg, Tracy Beth [redacted]
Sent: Wednesday, December 10, 2025 10:36 AM
To: Alimchandani, Meghna [redacted] Prasad, Vinayak <[redacted]; Traficant, Jim [redacted]
Cc: Mba-Jonas, Adamma (CBER) [redacted]; Zinderman, Craig <[redacted]
Subject: RE: VAERS deaths following COVID-19 vaccines - PROJECT

Hi Meghna and Vinay

Thank you so much for outlining this plan.
This is a very important project and I will support it in every way I can.
I think it can set a precedent for how we analyze and publish VAERS and FAERS reports moving forward.
Meghna and Adamma, I look forward to having you both in CDER.
I wonder if we could set up a meeting relatively soon to discuss how we can make this a successful cross center project.
Ideally we will be able to identify reviewers to detail who are really interested in supporting and working on this investigation.
I would love it if we could set up larger group discussions on more difficult reports/cases. Agree with involving cardiologists.

One comment regarding Vinay's mention of parvovirus

Here is a study where 67% of autopsies of adults *without* myocarditis or cardiomyopathy had parvovirus incidentally found in the myocardium
https://pmc.ncbi.nlm.nih.gov/articles/PMC2620852/.
>95% of parvovirus infections remain in the myocardium for life !
About 1/3 of teenagers will have had parvovirus
https://pmc.ncbi.nlm.nih.gov/articles/PMC3327426/#:~:text=Age%2Dspecific%20seroprevalence:,group%20where%20it%20reached%2066.7%25;
finding it on autopsy in the heart is common
When we have the autopsy the stress response/catecholamine induced myocarditis can be distinguished from that seen after parvovirus.
This is something we can discuss in more detail.

Not Disclosed to Permanent Subcommittee on Investigations
Produced to Permanent Subcommittee on Investigations
Without Permission from Department of Health and Human Services

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Tracy Beth Høeg, MD, PhD
Incoming Acting Director
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration
Tel: [redacted]

From: Alimchandani, Meghna [redacted]
Sent: Tuesday, December 9, 2025 4:52 PM
To: Prasad, Vinayak <[redacted]; Hoeg, Tracy Beth [redacted]>; Traficant, Jim [redacted]
Cc: Mba-Jonas, Adamma (CBER) <[redacted] Zinderman, Craig [redacted]
Subject: RE: VAERS deaths following COVID-19 vaccines - PROJECT

Dear Dr. Prasad,

For approx. 625 cases of US VAERS deaths in 18-40y following COVID-19 vaccines, we propose:

1. Dividing the case review between 4 teams; each team will review approx. 156 cases:
   a) OBPV/DPV will review the first 156 cases; of note this batch will include all US deaths in 18 – 24y (there are approx. 118 cases in 18 – 24y). Of note, we have already assembled our team since our meeting with you yesterday, and are planning to meet daily with the reviewers starting next Monday. We will be ready to start the review asap; however there are folks (including me, Adamma and Craig) who will be on holiday leave…so the pace of the review will likely slow down in the last week of December and pick up again in January.
   b) CDER/OSE will stand up **three teams**, with **10 reviewers** in each team, each team will review 156 cases. We defer to you and Dr. Hoeg on detailing 30 reviewers from OSE for this project. We will provide them with an overview of the methodology we used and share our peds deaths memo with them. We will also provide them with the forms needed to obtain access to VAERS.
2. Each team will generate their own final memo on how they categorized the cases with respect to causality categories. We will share a template with the OSE teams.
3. DPV/OBPV will generate an additional overarching memo, to provide an exec summary and recommendations based on the totality of the review by DPV and OSE teams.
4. We propose assigning cardiologists as consults from CDER OND (1 cardiologist for each team) who would help us review the cardiac AE related deaths. We defer to you and Dr. Hoeg on detailing 4 cardiologists for this project (1 for each team).
5. Personnel issues/pending transfers
   a. Meghna will request to delay CDER transfer from Jan 25 to Feb 8, 2025.
   b. Adamma will transfer to CDER effective Jan 6, 2025, but continue to work on this review.
6. Additionally, to manage workload for this high priority review:

Not Disclose Without Permission from Department o
Produced to Permanent Subcommitte
nvestigations
ealth and Human Services

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

a. We would like to request Jane Gwira to help with DPV reviews; do you concur with this approach? She was a DPV medical officer and then team lead previously and is well versed with our review processes.
b. Typically, CBER takes 3 – 4 products to pediatric advisory committee meetings. We propose taking only one CBER product (Epicel annual update) for Spring 2026 pediatric advisory committee (PAC); do you concur?

Craig and Adamma, please chime in as needed. Thanks.

Best regards,
Meghna

From: Alimchandani, Meghna
Sent: Tuesday, December 9, 2025 8:52 AM
To: Prasad, Vinayak <[redacted]>; Hoeg, Tracy Beth [redacted] Traficant, Jim <[redacted]
Cc: Mba-Jonas, Adamma (CBER) [redacted]; Zinderman, Craig <[redacted]
Subject: RE: VAERS deaths following COVID-19 vaccines - PROJECT

Dear Dr. Prasad,

Acknowledging receipt and the discussion we had yesterday afternoon. We are putting together a proposal for next steps and what we would need and will send that by email.

Best regards,
Meghna

From: Prasad, Vinayak [redacted]
Sent: Monday, December 8, 2025 11:27 AM
To: Alimchandani, Meghna <[redacted]>; Hoeg, Tracy Beth <[redacted]; Traficant, Jim [redacted]
Cc: Mba-Jonas, Adamma (CBER) <[redacted]>; Zinderman, Craig [redacted]
Subject: VAERS deaths following COVID-19 vaccines - PROJECT

This is very helpful

I have been talking to Jim and Tracy, and let me fill you all (CZ,AMJ,MA) in on the plan.

As you know, we examined 96 VAERS reports <18— 53 did not have autopsy results available (unclear if some of these have autopsy results but we do not have them)—you all felt 7 were possible/probable/likely

Not Disclose Without Production from Department of Health and Human Services Permanent Subcommittee on Investigations

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

There are ~600 VAERS deaths 18-40, which have never been investigated.

We want to do 2 things

1. For all kid's deaths where we do not have autopsy results, we must make effort to obtain those results. I prefer we directly obtain this information through FDA authorities. If this cannot be done at the FDA, prepare a list of VAERS numbers and we will get it done with the Secretary and Dep Sec/ CDC Director using CDC authority.
2. We want to review all 600 deaths with the *exact same* procedure as the review you have already done—no modifications to the causal assessment framework.
3. For the 600 deaths, there may also be missing autopsy results in our data- we will make efforts to obtain these as per #1

We want this done in 6 weeks.

Obviously it took ~10 people 2 months to do 96, which is roughly 50 a month per 10 people

Meghna will either be in CDER or CBER, but, either way, we want you to lead the project; Craig and Adamma can co-lead.
You will get 10 CBER staff—the folks who already worked with you
And you will be able to detail 30 CDER staff (probably from OSE)

Divide and conquer. Probable wise to make 3 teams of 10 and have each operate independently, rather than a massive team of 30, and divide and conquer, but that is ultimately up to you MA.

Jim will see you get all the resources you need.

I agree with the FDA team that black box is indicated for all products and ages, but this needs more documentation, and there is tremendous public service and interest in this project.

It is also worth discussing, that I want the review to be independent from us, but I want Tracy and Meghna to prepare a second document detailing cases that the team did not conclude were possible/probable/likely/certain, but for which Tracy believes it is—and an explanation from both sides as to why. In one case parvo was used to exculpate a death, though this is incidental in a large number of child autopsies—is one example. It will be for the reader to decide in these cases. This will be a second report.

Then, I will write a cover memo for this entire project. But the teams report will be a separate locked document, of which Meghna is the overseer.

So 6 documents

Produced to Permanent Subcommittee on Investigations
Not Disclose Without Permission from Department of Health and Human Services

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

1. VPs introduction
2. The teams original locked analysis with 7 deaths
3. The teams new analysis with additional autopsy data located
4. The teams analysis of 600 cases
5. Tracy and teams table of persistent disagreements with argument from both sides in table format
6. VPs conclusion

Let us implement this plan ASAP.

I already told David K last night.
-v

From: Alimchandani, Meghna [redacted]
Sent: Saturday, December 6, 2025 11:26 AM
To: Prasad, Vinayak <[redacted]
Cc: Mba-Jonas, Adamma (CBER) [redacted] Zinderman, Craig <[redacted]
Subject: RE: DPV/OBPV review memo: U.S. VAERS pediatric deaths following COVID-19 vaccines

Please see responses below in blue font; thanks.

From: Prasad, Vinayak [redacted]
Sent: Friday, December 5, 2025 11:09 PM
To: Alimchandani, Meghna [redacted]>
Cc: Mba-Jonas, Adamma (CBER) <[redacted]>; Zinderman, Craig <[redacted]
Subject: RE: DPV/OBPV review memo: U.S. VAERS pediatric deaths following COVID-19 vaccines

Great thank you

IT would be helpful to me to know a few more things

1. Among 96 cases how many did contractors request chart data?

   The VAERS program contractor routinely conducts follow-up to further investigate domestic reports of deaths. This follow-up includes contacting reporters and/or the health care provider named in the report to collect vaccination records and clinical records including: death certificates,

Not Disclosed Without Permission from Permanent Subcommittee on Investigations Produced by Department of Health and Human Services

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

autopsy reports, hospital admission/discharge records, and, if applicable, clinician visit notes, ED records, etc. As part of their ongoing review of new and incoming VAERS records for their assigned products, FDA medical officers in OBPV individually examine death reports for COVID vaccines on a continuous basis.

So, as per above usual process, it is our understanding that the contractor had requested medical records for all of these cases, but to confirm this and answer your question, we would need to send this list of VAERS IDs to the contractor and ask them to confirm that they had followed usual process for follow-up for every case on this list. Would you like us to do so?

2. How many patients had autopsy?

   Of the 7 possible/probable cases, *full autopsy* reports were available for six cases, and a *limited autopsy* was available for one case (for this case, it was noted that the family expressed "strong opposition to the performance of an autopsy").

   Please find attached the U.S. VAERS pediatric death reports that did not have autopsy reports (n = 53). Of note, this does not mean that the contractor did not make attempt(s) to obtain the autopsy report, and in some cases an autopsy may not have been performed.

3. Is it possible that there is additional clinical data for some of these patients we do not have?

   Yes, that is possible. Missing and incomplete data is one of the inherent limitations of a passive surveillance system like VAERS. Our review is based on available information in VAERS report and follow up information in VAERS VPN.

   For some of these cases, it is my understanding that CDC CISA had discussed the cases…CDC could provide more information on their processes (https://www.cdc.gov/vaccine-safety-systems/hcp/cisa/index.html). CISA will usually have physicians of medical specialties relevant to the AE in question and do a detailed case discussion, that may include reaching out to the patient's treating physician etc.

Best
v

From: Alimchandani, Meghna [redacted]>
Sent: Friday, December 5, 2025 6:16 PM
To: Prasad, Vinayak [redacted]>
Cc: Mba-Jonas, Adamma (CBER) [redacted]; Zinderman, Craig <[redacted]
Subject: DPV/OBPV review memo: U.S. VAERS pediatric deaths following COVID-19 vaccines

Dear Dr. Prasad,

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

Not Disclose Without Permission from Department of Health and Human Services to Permanent Subcommittee on Investigations

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

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 [redacted]>
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 OVRR). 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.

Not Disclosed Without Permission from Department of Health and Human Services
Produced to Permanent Subcommittee on Investigations

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

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]	7	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.

Not Disclosed to Permanent Subcommittee on Investigations
Without Permission from Department of Health and Human Services

AUTHORIZED FOR PUBLIC RELEASE BY CHAIRMAN JOHNSON

Thanks,
Meghna

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

COVID-19 vaccine-related deaths

how is the vaers review going?

Get Outlook for Mac

Produced to Permanent Subcommittee on Investigations
Not Disclose Without Permission from Department of Health and Human Services