Failure to Warn:
How Federal Health Agencies Downplayed the Risk of Myocarditis and Other Adverse Events Following COVID-19 Vaccination

U.S. Senate Permanent Subcommittee on Investigations
Chairman Ron Johnson
Majority Staff Interim Report

Released in Conjunction with the
Permanent Subcommittee on Investigations'
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I. Executive Summary

On January 28, 2025, Senator Ron Johnson, chairman of the Permanent Subcommittee on Investigations ("PSI" or "the Subcommittee"), subpoenaed the Department of Health and Human Services ("HHS") for records relating to COVID-19 vaccine safety data and communications about the COVID-19 pandemic.[1] Chairman Johnson's subpoena to HHS was a culmination of a multi-year fight to overcome the obstruction of the Biden administration to get unredacted records and data about the COVID-19 pandemic and the safety and efficacy of the COVID-19 vaccines.

For years, Biden officials at HHS and its subcomponent agencies withheld crucial health information from the Subcommittee and the public. Many of Chairman Johnson's more than 70 oversight letters to the Biden administration were either completely ignored or inadequately addressed.[2] Now, under a new administration and a new HHS secretary, HHS is beginning to produce records, pursuant to the chairman's subpoena, that should have been provided years ago, without redactions, to Congress and the public.

This interim report highlights records the Subcommittee has reviewed regarding HHS's awareness of and response to cases of myocarditis—a type of heart inflammation—following COVID-19 vaccination. Portions of these documents have already been made public over the years with various redactions through the tireless efforts of individuals who filed Freedom of Information Act ("FOIA") requests and published the records they obtained.[3] Other documents, some of which will be discussed below, have remained hidden from the public and Congress for years despite Chairman Johnson's efforts to obtain the information.

In conjunction with this interim report, the chairman is releasing 2,473 pages of records he received pursuant to his subpoena. These records contain evidence of the Biden

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[1] Subpoena from Ron Johnson, Chairman, Permanent Subcomm. on Investigations, to Dorothy Fink, Acting Secretary, Dep't of Health and Human Services, Jan. 28, 2025, https://www.ronjohnson.senate.gov/services/files/8FAB9531-F799-4067-BA1C-AB8CA182D100.

[2] These letters were sent when Senator Johnson served as ranking member of the Subcommittee.

[3] *See, e.g.*, Ed Berkovich and Amy Kelly, FOIA'd CDC Emails Reveal Disturbing Myocarditis Timeline Warranting Investigation: Different Messaging Internally Vs. Publicly About COVID-19 Vaccines and Myocarditis, Daily Clout, Nov. 2, 2023, https://dailyclout.io/foiad-cdc-emails-reveal-disturbing-myocarditis-timeline-warranting-investigation/; Naomi Wolf, Amy Kelly, WarRoom/Daily Clout Pfizer Documents Analysts, The Pfizer Papers (2024); Zachary Stieber, CDC Drafted Alert for Myocarditis and COVID-19 Vaccines but Never Sent It, Epoch Times, Jan. 17, 2024, https://www.theepochtimes.com/health/exclusive-cdc-drafted-alert-for-myocarditis-and-covid-19-vaccines-but-never-sent-it-5560613; Zachary Stieber, FDA Influenced Decision Not to Send Alert on Post vaccination Heart Inflammation: Emails, Epoch Times, Jan. 21, 2024, https://www.theepochtimes.com/health/fda-influenced-decision-not-to-send-alert-on-postvaccination-heart-inflammation-emails-5570033?utm_medium=social&utm_source=twitter&utm_campaign=digitalsub; Zachary Stieber, EXCLUSIVE: Email Reveals Why CDC Didn't Issue Alert on COVID Vaccines and Myocarditis, Epoch Times, Jan. 26, 2024, https://www.theepochtimes.com/article/exclusive-email-reveals-why-cdc-didnt-issue-alert-on-covid-vaccines-and-myocarditis-5571675; Zachary Stieber, Timeline: COVID-19 Vaccines and Myocarditis, Epoch Times, Apr. 22, 2024, https://www.theepochtimes.com/health/timeline-covid-19-vaccines-and-myocarditis-5317985; Brenda Baletti, Mounting Evidence Suggests CDC Hid Data on COVID Vaccines and Myocarditis, The Defender, Nov. 27, 2024, https://childrenshealthdefense.org/defender/mounting-evidence-cdc-hid-data-covid-vaccinesmyocarditis/.

administration's efforts to downplay and delay warning the public about the risks of myocarditis associated with the mRNA COVID-19 vaccines.

Specifically, in May 2021, following months of reports of myocarditis after COVID-19 vaccination, health officials at HHS discussed whether to issue a formal warning about the adverse event.[4] The formal warning about myocarditis was initially going to be distributed nationwide as a Health Alert Network ("HAN") message which, according to the Centers for Disease Control and Prevention's ("CDC") website, is "CDC's primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, tribal, and local public health practitioners; clinicians; and public health laboratories."[5] Health officials at CDC and the Food and Drug Administration ("FDA") ultimately decided against issuing a formal HAN and, instead, posted "clinical considerations" on CDC's website about myocarditis.[6]

Based on the subpoenaed records the Subcommittee has received to date, as well as public FOIA documents, this interim report will highlight records and present a timeline showing:

1. U.S. health officials knew about the risks of myocarditis;

2. Those officials downplayed the health concern; and

3. U.S. health agencies delayed informing the public about the risk of the adverse event.

In support of those findings, the records discussed in this interim report will show, in part:

- The Israeli Ministry of Health notifying officials at the CDC in late February 2021 of "large reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine."[7]

- A Department of Defense ("DoD"), Defense Health Agency ("DHA") consultant's presentation and other discussions by CDC officials about the limitations of vaccine

[4] Zachary Stieber, CDC Drafted Alert for Myocarditis and COVID-19 Vaccines but Never Sent It, Epoch Times, Jan. 17, 2024, https://www.theepochtimes.com/health/exclusive-cdc-drafted-alert-for-myocarditis-and-covid-19-vaccines-but-never-sent-it-5560613; Letter from Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Nov. 19, 2024, https://www.ronjohnson.senate.gov/services/files/00AAFB3D-72EE-475F-94D5-66708B4AA86D.
[5] *Id.*; Health Alert Network (HAN), Centers for Disease Control and Prevention, Last Reviewed: Mar. 12, 2025, https://emergency.cdc.gov/han/.
[6] Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults, Centers for Disease Control and Prevention, May 28, 2021, archived: https://web.archive.org/web/20210528145419/https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.
[7] PSICOVID_0000009-14; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 710-713.

safety surveillance systems to detect reports of myocarditis and cardiac-related adverse events.[8]

- CDC officials discussing safety signals for "myocarditis with mRNA vaccines" in mid-April 2021 based on DoD and Israeli data, but still not taking immediate steps to warn the public.[9]

- Discussions among CDC officials in May 2021 on whether to issue a HAN on myocarditis, noting that health care professionals across the nation may not be aware of the risk because "providers aren't reporting these cases to VAERS [Vaccine Adverse Event Reporting System]."[10]

- A CDC official providing up-to-date information on the status of the HAN to Pfizer Inc. ("Pfizer") and Moderna, Inc. ("Moderna") representatives, indicating CDC's preference to keep the vaccine companies more informed about vaccine adverse events, rather than the American people.[11]

- Draft meeting notes from late May 2021 exchanged between U.S. public health officials which included the question: "Is VAERS signaling for myopericarditis now?"; and the answer: "For the age groups 16-17 years and 18-24 years, yes."[12]

- Then-Acting FDA Commissioner Janet Woodcock emailing then-CDC Director Rochelle Walensky in late May 2021 noting that the "FDA does not concur with the issuance of the myocarditis HAN as written[.]"[13]

- CDC officials editing the drafts of the HAN and, subsequently, a less formal website statement discussing the need to "walk back" a sentence advising doctors to "consider restricting patients with myocarditis from rigorous activity like competitive sports for at least 3 months until cleared by a healthcare professional."[14] This critical piece of information, which was still included, in part, in a May 26, 2021 draft of the HAN, was ultimately omitted from the May 28, 2021 "clinical considerations" posted on CDC's website.[15]

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[8] *See, e.g.*, PSICOVID_00008808, 4651; FOIA production: https://s3.documentcloud.org/documents/23656227/cdc-emails-chat-messages-on-post-vaccination-myocarditis.pdf at 257-258.
[9] FOIA production: https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view at 301-302.
[10] PSICOVID_00004649-4650; FOIA production: https://s3.documentcloud.org/documents/23656227/cdc-emails-chat-messages-on-post-vaccination-myocarditis.pdf at 257-258.
[11] *See, e.g.*, PSICOVID_00004649-4650, PSICOVID_00004808-4809.
[12] PSICOVID_00009452.
[13] PSICOVID_00005565.
[14] PSICOVID_00005566.
[15] Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults, Centers for Disease Control and Prevention, May 28, 2021, archived: https://web.archive.org/web/20210528145419/https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.

- The Biden White House distributing talking points to top U.S. health officials, including then-National Institute of Allergy and Infectious Diseases ("NIAID") Director Anthony Fauci, downplaying the risk of myocarditis.[16]

Rather than provide the public and health care providers with immediate and transparent information regarding the risk of myocarditis following mRNA COVID-19 vaccination, the Biden administration waited until late June 2021 to announce changes to the labels for the Moderna and Pfizer COVID-19 vaccines based on the "suggested increased risks" of myocarditis and pericarditis.[17] Even though CDC and FDA officials were well aware of the risk of myocarditis following COVID-19 vaccination, the Biden administration opted to withhold issuing a formal warning to the public for months about the safety concerns, jeopardizing the health of young Americans.

[16] PSICOVID_00005295-5312.

[17] Coronavirus (COVID-19) Update: June 25, 2021, Food and Drug Administration, Jun. 25, 2021, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021; Jack Phillips, FDA Adds Warning About Heart Inflammation to COVID-19 mRNA Vaccines, Epoch Times, Jun. 27, 2021, https://www.theepochtimes.com/article/fda-adds-warning-about-heart-inflammation-to-covid-19-mrna-vaccines-3876245.

II. Unredacted records reveal more details about health agencies' decision to not issue formal warning about COVID-19 vaccine adverse event

a. Timeline: CDC and FDA fail to issue formal public warning about myocarditis in early 2021

As early as February 2021, officials at the CDC appear to have begun to receive reports regarding myocarditis in young adults following COVID-19 vaccination.[18] By May 2021, health officials at HHS discussed whether to issue a formal warning regarding the risk of myocarditis—a type of heart inflammation.[19] The formal warning about myocarditis would have been distributed nationwide as a Health Alert Network ("HAN") message which, according to the CDC's website, is "CDC's primary method of sharing cleared information about urgent public health incidents with public information officers; federal, state, territorial, tribal, and local public health practitioners; clinicians; and public health laboratories."[20] In late May 2021, draft meeting notes exchanged between U.S. public health officials included the question: "Is VAERS signaling for myopericarditis now?"; and the answer: "For the age groups 16-17 years and 18-24 years, yes."[21]

However, health officials at CDC and the FDA ultimately decided against issuing a formal HAN and, instead, posted "clinical considerations" on CDC's website about myocarditis.[22] The timeline below details the Biden administration's awareness of and response to the risk of myocarditis following COVID-19 vaccination. The records discussed illustrate the Biden administration's efforts to downplay and delay warning the public about the risks of this adverse event.

January 2021

According to a public report, "28 cases of myocarditis, pericarditis, or myopericarditis [were] reported to VAERS."[23]

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[18] PSICOVID_00004602-4603; Zachary Stieber, Timeline: COVID-19 Vaccines and Myocarditis, Epoch Times, Apr. 22, 2024, https://www.theepochtimes.com/health/timeline-covid-19-vaccines-and-myocarditis-5317985.
[19] Zachary Stieber, CDC Drafted Alert for Myocarditis and COVID-19 Vaccines but Never Sent It, Epoch Times, Jan. 17, 2024, https://www.theepochtimes.com/health/exclusive-cdc-drafted-alert-for-myocarditis-and-covid-19-vaccines-but-never-sent-it-5560613; Letter from Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Nov. 19, 2024, https://www.ronjohnson.senate.gov/services/files/00AAFB3D-72EE-475F-94D5-66708B4AA86D.
[20] *Id.*; Health Alert Network (HAN), Centers for Disease Control and Prevention, Last Reviewed: Mar. 12, 2025, https://emergency.cdc.gov/han/.
[21] PSICOVID_00009452.
[22] Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults, Centers for Disease Control and Prevention, May 28, 2021, archived: https://web.archive.org/web/20210528145419/https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.
[23] Zachary Stieber, Timeline: COVID-19 Vaccines and Myocarditis, Epoch Times, Apr. 22, 2024, https://www.theepochtimes.com/health/timeline-covid-19-vaccines-and-myocarditis-5317985.

February 2021

According to a public report, "64 cases of myocarditis, pericarditis, or myopericarditis [were] reported to VAERS, including two deaths."[24]

February 26, 2021

Health officials from CDC, FDA, National Institutes of Health ("NIH") and other entities participated in a group called the Vaccine Safety Technical Work Group ("VaST") that "provided guidance to CDC's COVID-19 vaccine safety monitoring efforts, provided a forum for review of data from several U.S. government vaccine safety systems, and assured that a diverse group of scientists and clinicians, external to the federal government, promptly reviewed vaccine safety data."[25]

Following a February 22, 2021 call, Lauri Markowitz, a CDC official who co-led the VaST, emailed members and attendees of the work group "draft minutes and summary report from the VaST call this week."[26] She reminded her colleagues that "*all VaST documents and communications are confidential.*"[27] The draft meeting notes stated that CDC official, Dr. John Su, "gave an update from VAERS."[28] The meeting notes continued:

> There have been 19536 VAERS reports (Moderna: 7092 PfizerBioNTech: 12444), including 1287 reports of COVID-19 disease after vaccination and 980 death reports to VAERS. Of the death reports, 470 were from long term care facilities. **Where known, the cause of death was often cardiovascular**.[29]

February 28, 2021

CDC, and eventually FDA officials, were notified about a request from an Israeli Ministry of Health official to obtain a CDC and FDA point of contact to discuss reports of myocarditis in young people after receiving the Pfizer COVID-19 vaccine.[30] This was significant because, at the time, Israel was vaccinating much more of its population, including younger people, compared to the U.S.'s vaccine campaign.[31] In Israel, for example, teenagers 16

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[24] *Id.*
[25] Lauri Markowitz, et al., COVID-19 Vaccine Safety Technical (VaST) Work Group: Enhancing vaccine safety monitoring during the pandemic, Vaccine, Sept. 17, 2024, https://pmc.ncbi.nlm.nih.gov/articles/PMC11310362/pdf/nihms-1961946.pdf.
[26] PSICOVID_00010326-10336.
[27] *Id.*
[28] PSICOVID_00010328.
[29] *Id.* (emphasis added).
[30] See PSICOVID_00004720-4724; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 710-713.
[31] See Gretchen Vogel and Jennifer Couzin-Frankel, Israel reports link between rare cases of heart inflammation and COVID-19 vaccination in young men, Science, Jun. 1, 2021, https://www.science.org/content/article/israel-reports-link-between-rare-cases-heart-inflammation-and-covid-19-vaccination. Emily Anthes and Noah Weiland, Heart Problem More Common After Covid-19 Than After Vaccination, Study Finds, N.Y. Times, Sept. 1, 2021, https://www.nytimes.com/2021/08/25/health/covid-myocarditis-vaccine.html.

and older, could receive the vaccine since late January 2021.[32] A description of the Israeli health official's request that was included in an email between CDC officials stated:

> **The Israeli National Focal Point is noticing a large number of reports of myocarditis, particularly in young people, following the administration of the Pfizer vaccine.** The Israeli National Focal Point is requesting a Point of Contact from the CDC and FDA to discuss the issue[.][33]

March 2021

According to a public report, "54 cases of myocarditis, pericarditis, or myopericarditis [were] reported to VAERS."[34]

March 9, 2021 – March 10, 2021

Documents show that FDA and CDC officials began drafting "responses to the Israeli Ministry of Health's inquiry."[35] On March 9, 2021, an FDA official emailed his "draft responses" to CDC's vaccine safety team lead in the COVID-19 Vaccine Task Force, Dr. Tom Shimabukuro.[36]

The next day, Shimabukuro emailed his CDC colleagues a document with the file name, "Myocarditis Response," and wrote, "[t]his is for that joint FDA-CDC to the Israeli [Ministry of Health]. Please let me know if you have any thoughts."[37] The document Shimabukuro shared with his colleagues was titled, "Summary of VAERS Reports of myocarditis, pericarditis and myopericarditis following vaccination with mRNA COVID-19 vaccines."[38] The background section of the two-page document stated that it:

> [R]esponds to questions posed from the Israeli Ministry of Health to the FDA and CDC. They are investigating a safety signal of myocarditis/myopericarditis in a younger population (16-30 years old) following administration of Pfizer-BioNTech Covid-19 vaccine. The [Israeli] Ministry of Health stated they received reports of around 40 cases of this adverse event. They did not provide additional details about these cases.[39]

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[32] *Id.*; Israel expands vaccination campaign to teens aged 16-18, Times of Israel, Jan. 23, 2021, https://www.timesofisrael.com/israel-expands-vaccination-campaign-to-teens-aged-16-18/.
[33] PSICOVID_00004724 (emphasis added).
[34] Zachary Stieber, Timeline: COVID-19 Vaccines and Myocarditis, Epoch Times, Apr. 22, 2024, https://www.theepochtimes.com/health/timeline-covid-19-vaccines-and-myocarditis-5317985.
[35] PSICOVID_ 0000009-14; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 710-715.
[36] *Id.*
[37] *Id*.
[38] PSICOVID_00004602; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 714.
[39] *Id.*

The document included responses to four questions posed by the Israeli Ministry of Health and appears to be based on data obtained from "a search of the U.S. Vaccine Adverse Event Reporting System (VAERS) conducted on February 23, 2021[.]"[40] That search apparently revealed six cases of myocarditis, seven cases of myopericarditis, and 14 cases of pericarditis."[41] The document noted:

> During this analysis period the reporting rate of myopericarditis following administration of the mRNA COVID-19 vaccines was low and estimated to be 0.7 per million doses of vaccine administered. **However, the limitations of passive surveillance such as under-reporting, lack of a control group, missing and incomplete data make it challenging to assess causation. Thus, FDA has not made a final determination regarding the causality between myopericarditis and the mRNA COVID-19 vaccines.** We will continue to monitor this outcome in active and passive surveillance.[42]

It remains unclear whether this document or another version of it was shared with the Israeli Ministry of Health.[43]

March 15, 2021 – April 1, 2021

On March 15, 2021, Markowitz began corresponding with an Israeli Ministry of Health official and asked whether the official would "be able to present data from vaccine safety monitoring in Israel."[44] The CDC official noted that "the VaST meetings are closed, virtual, and all data presented are confidential."[45]

On March 16, 2021, the Ministry official wrote, "[w]e will be happy to share our data" and later that day, the CDC official responded "[t]hank you for this note and for your willingness to present to VaST. We were hoping you could present on Monday, April 5."[46] Records show that the Ministry official did agree to present to the VaST meeting on April 5, 2021.[47] As discussed later in this report, on March 24, 2021, the CDC official requested that the Israeli Ministry official focus her presentation on data from "Israel's post-authorization safety

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[40] PSICOVID_00004602-4603; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 714-715.
[41] PSICOVID_00004602; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 714.
[42] PSICOVID_00004603 (emphasis added); FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 715 (emphasis added).
[43] On December 5, 2024, then-Ranking Member Johnson, wrote to HHS, FDA, and CDC requesting records relating to CDC's interactions with the Israeli Ministry of Health about myocarditis. The requests in that letter were included in the January 28, 2025 subpoena to HHS. As the Subcommittee receives more documents on this matter, it will update the public record.
[44] PSICOVID_00000008; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 726.
[45] *Id.*
[46] PSICOVID_00000007; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 725.
[47] PSICOVID_00000004; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 722.

monitoring systems and specifically any information you have on **deaths reported after vaccination**."[48] By April 1, 2021, the Ministry official requested to have more time to present her data at the April 5, 2021 meeting.[49]

April 2021

According to a public report, "158 cases of myocarditis, pericarditis, or myopericarditis [were] reported to VAERS."[50]

April 2, 2021

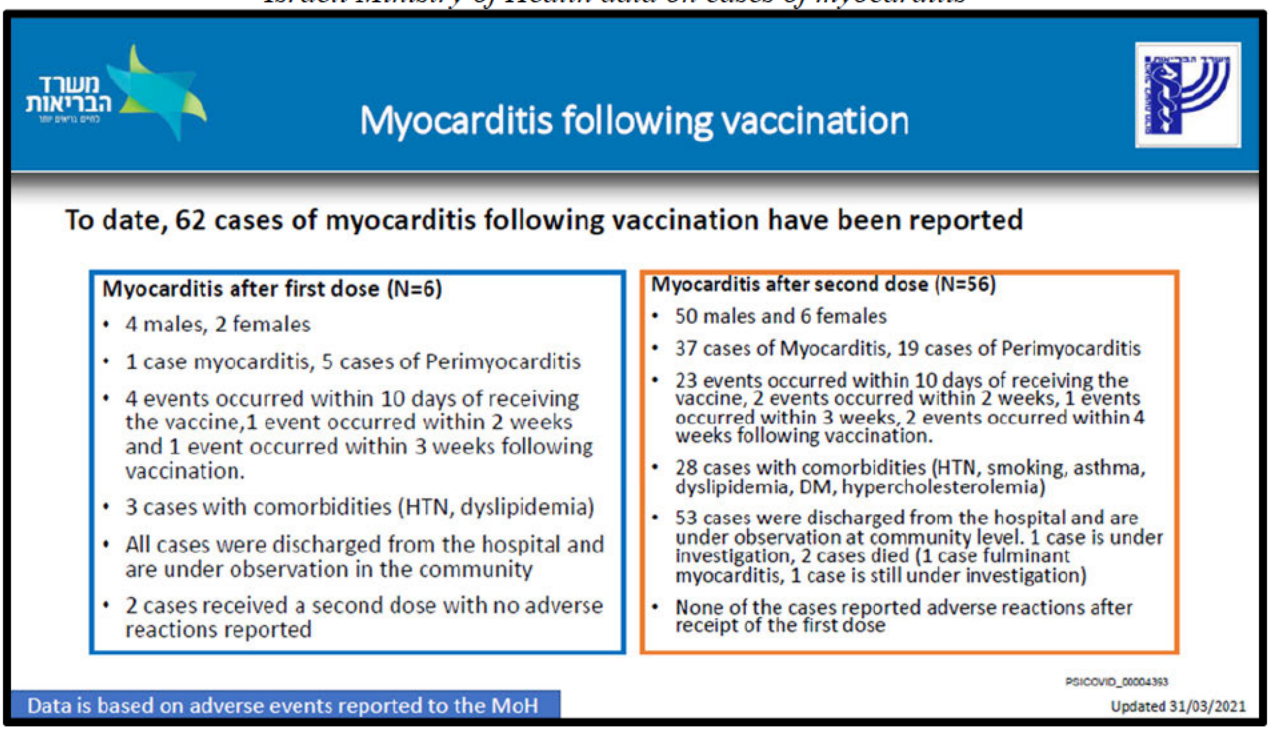
Following a March 29, 2021 VaST meeting, Markowitz emailed VaST group members from HHS, CDC, FDA, NIH, and other entities draft tables that showed adverse events detected by several vaccine safety surveillance systems for the Pfizer, Moderna, and Johnson and Johnson vaccines.[51] According to the draft tables, VAERS contained 931 death reports associated with the Pfizer vaccine, 1,071 pregnancy reports associated with the Moderna vaccines, and 18 death reports associated with the Johnson and Johnson vaccine.[52] The "DoD VAERS" surveillance system contained 7 death reports (227 total adverse event reports) for the Pfizer vaccine, 10 death reports (268 total adverse event reports) for the Moderna vaccine, and 0 death reports (4 total adverse event reports) for the Johnson and Johnson vaccine.[53]

April 5, 2021

Slides created by the Israeli Ministry of Health ahead of the April 5, 2021 CDC's and FDA's VaST meeting, included data on cases of myocarditis and pericarditis following COVID-19 vaccination.[54] A presentation on "Israel's Covid-19 vaccine safety data" by an Israeli Ministry of Health official was included in the April 5, 2021 meeting agenda.[55]

[48] PSICOVID_00000004 (emphasis included in original).
[49] PSICOVID_00000003-4; FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 721-722.
[50] Zachary Stieber, Timeline: COVID-19 Vaccines and Myocarditis, Epoch Times, Apr. 22, 2024, https://www.theepochtimes.com/health/timeline-covid-19-vaccines-and-myocarditis-5317985.
[51] PSICOVID_00008700, 8705-8717.
[52] PSICOVID_00008705, 8708, 8711. It is unclear what the phrase "pregnancy reports" represents. The draft tables indicated that the VAERS data were through March 22, 2021.
[53] *Id.* The draft tables indicated that the DoD VAERS data were through March 19, 2021.
[54] The slides are based on data as of March 31, 2021. See PSICOVID_00004378-4400; FOIA production: https://drive.google.com/file/d/1ywgzcxpfQI86lqslZPpYxylPuVnlgKfw/view at 1-23.
[55] PSICOVID_00004377.

Israeli Ministry of Health data on cases of myocarditis[56]



Following the April 5, 2021 VaST meeting, CDC's draft Combined Systems Safety Monitoring Report summarizing the meeting, labeled as "Confidential," stated that "VaST appreciated the excellent presentation of data from Israel's spontaneous reporting system. **The signal for myocarditis that colleagues from Israel described should be further examined in U.S. safety monitoring systems.**"[57] In the section of the draft report titled "Future analyses requested," the document stated, "Data should be examined in other systems not only for [pulmonary embolus] but also for acute myocardial infraction and for myocarditis (based on data from Israel)."[58]

April 9, 2021

Markowitz emailed VaST group members from HHS, CDC, FDA, NIH, and other entities similar draft tables that she previously shared on April 2, 2021. The data from the categories identified earlier remained unchanged.[59]

April 12, 2021

Dr. Renata Engler, a consultant for the DHA Immunization Healthcare Division office at DoD, presented at the VaST meeting on cases of myocarditis following COVID-19

[56] PSICOVID_00004393; FOIA production: https://drive.google.com/file/d/1ywgzcxpfQI86lqslZPpYxylPuVnlgKfw/view at 16.
[57] PSICOVID_00008783.
[58] *Id.*
[59] PSICOVID_00008782, 8784-8793.

vaccination.[60] As discussed later in the report, Engler's presentation identified limitations with a vaccine safety surveillance system called V-safe and its ability to detect cardiac-related adverse events.[61] CDC's notes on the VaST meeting stated that "**DHA feels there is a high likelihood that cardiac symptoms following COVID-19 vaccination represent a hypersensitivity eosinophilic myocarditis.**"[62]

April 15, 2021

Markowitz emailed VaST group members from HHS, CDC, FDA, NIH, and other entities updated draft tables that showed adverse events detected by several vaccine safety surveillance systems for the Pfizer, Moderna, and Johnson and Johnson vaccines.[63] These versions of the draft tables included specific references to myocarditis and pericarditis. For example, in VAERS, there were 43 myopericarditis reports for the Pfizer vaccine, 54 myopericarditis reports for the Moderna vaccine, and 0 myopericarditis reports for the Johnson and Johnson vaccine.[64] The draft tables noted that none of these cases of myopericardtis were above the background rates. Under the section for the "DoD VAERS" surveillance system, the draft tables noted that "myocarditis case series presented" for the Pfizer and Moderna vaccines.[65] The draft tables indicated for both the Pfizer and Moderna vaccines, "[m]yopericarditis to be further investigated with more robust systems."[66]

April 19, 2021

A CDC official emailed Shimabukuro and others about whether there "has been any signal with pericarditis and mRNA vaccines."[67] Shimabukuro responded, in part:

> DoD and the Israeli MOH [Ministry of Health] think they have a signal for myocarditis with mRNA vaccines, but there is potentially a lot of ascertainment bias in the DoD data. **We don't have any evidence to suggest a signal or safety problem for myocarditis or pericarditis with mRNA vaccines** from VAERS and VSD [Vaccine Safety Datalink] surveillance and FDA and VA [Department of Veterans Affairs] have not detected any signals in their monitoring.[68]

Although Shimabukuro stated that safety surveillance systems like VAERS did not detect a safety signal for myocarditis, this interim report will discuss how other CDC officials acknowledged that reports of myocarditis nationwide may not be reflected in VAERS if

[60] PSICOVID_00008798, 8800-8811.
[61] PSICOVID_00008808.
[62] PSICOVID_00008935. (emphasis added).
[63] PSICOVID_00008933, 8939-8948.
[64] PSICOVID_00008939, 8942, 8945. The draft tables indicated that the VAERS data on myopericarditis were through April 5, 2021.
[65] PSICOVID_00008939, 8942.
[66] *Id.* While the draft table for the Pfizer vaccine specifically noted that no concerns were raised regarding the results of the DoD VAERS data, the draft table for Moderna did not include this language for the same category.
[67] FOIA production: https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view at 301-302.
[68] *Id.*

providers never enter it into the system.[69] This type of underreporting is a known limitation of VAERS that Shimabukuro, himself, identified in a 2015 article he co-authored.[70]

May 2021

According to a public report, "487 cases of myocarditis, pericarditis, or myopericarditis [were] reported to VAERS."[71]

May 10, 2021

Despite increasing awareness of reports of myocarditis post-COVID-19 vaccination, the FDA authorized the Pfizer COVID-19 vaccine for emergency use in adolescents 12 through 15 years of age.[72] FDA's May 10, 2021 public announcement did not mention the risk of myocarditis and broadly stated that "the known and potential benefits of this vaccine in individuals 12 years of age and older outweigh the known and potential risks[.]"[73]

May 14, 2021

On May 14, 2021, CDC officials, including then-CDC Director Rochelle Walensky, received an internal notification that stated, in part:

> In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where EMA [European Medicines Agency] recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination. CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data.[74]

May 17, 2021

The CDC's COVID-19 VaST Work Group noted in their public meeting summary for May 17, 2021, that members "felt that information about reports of myocarditis should be communicated to providers."[75] Similarly, the VaST Work Group's draft meeting report, labeled

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[69] *See, e.g.*, PSICOVID_00004651; FOIA production: https://s3.documentcloud.org/documents/23656227/cdc-emails-chat-messages-on-post-vaccination-myocarditis.pdf at 257-258.
[70] 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/.
[71] Zachary Stieber, Timeline: COVID-19 Vaccines and Myocarditis, Epoch Times, Apr. 22, 2024, https://www.theepochtimes.com/health/timeline-covid-19-vaccines-and-myocarditis-5317985.
[72] Press release, Coronavirus (COVID-19) Update: FDA Authorizes Pfizer-BioNTech COVID-19 Vaccine for Emergency Use in Adolescents in Another Important Action in Fight Against Pandemic, May 10, 2021, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use.
[73] *Id.*
[74] PSICOVID_00004600-4601; FOIA production: https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view at 271-272.
[75] COVID-19 VaST Work Group Report – May 17, 2021, https://archive.cdc.gov/www_cdc_gov/vaccines/acip/work-groups-vast/report-2021-05-17.html.

"Confidential," noted, in part, that "[f]urther information should be collected through medical record review about potential myocarditis cases that were reported into VAERS"; "[t]he lack of a signal in some safety systems could be due to the limited number of second vaccine doses administered in the younger age group to date"; and "some members expressed concern about the updated clinical guidance for simultaneous vaccination of COVID-19 vaccines with other adolescent vaccines."[76]

The draft safety surveillance data tables that were connected with the May 17, 2021 VaST meeting showed that in VAERS, there were 3.1-5.6 myopericarditis reports per 1 million (age-stratified) doses administered across all vaccines[.]"[77] The draft tables showed that in "DoD VAERS," there were "22 cases of myocarditis following mRNA vaccines (16 Moderna, 6 Pfizer)" with a background rate of 2-23 cases, and "19 cases of myocarditis following dose 2 of mRNA vaccines" with a background rate of 1-9 cases.[78]

Public FOIA documents and unredacted records produced to the Subcommittee show that over the following two weeks, CDC officials emailed drafts of the HAN and communicated about the timing of its release.[79]

May 23, 2021

On May 23, 2021, CDC official Dr. Henry Walke, who was at that time the incident manager for CDC's COVID-19 response, emailed Walensky the "latest" draft of the HAN on myocarditis.[80] Walensky then asked Walke whether this will "be a full HAN" and stated, "I'm fine with how this reads . . . grateful."[81] Below are images of the draft HAN Walensky received, which included comments from "DD" who could be CDC official Dr. Demetre Daskalakis—then-Director of the Division of HIV/AIDS Prevention—(who also contributed to the development of the HAN) that stated, "[w]ill need to decide what we are calling this communication: Alert, Advisory, etc and then also decided [sic] what the recommended circulation should be: pediatrics, adolescent medicine, pediatric emergency medicine, pediatric infectious diseases, and pediatric cardiology?"[82]

[76] PSICOVID_00009423.
[77] PSICOVID_00009424, 9427. The draft tables indicated that the VAERS data on myopericarditis were through May 14, 2021.
[78] *Id.* The draft tables indicated that the DoD VAERS population data were through March 19, 2021 and the results data were through April 3, 2021.
[79] FOIA production: https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view at 315; PSICOVID_00004634-4636.
[80] PSICOVID_00005558-5560; Biography, Henry Walke, Centers for Disease Control and Prevention, https://www.cdc.gov/orr/leadership/director.html.
[81] FOIA production: https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view at 315 (ellipsis appear in original email).
[82] PSICOVID_00005558-5560.

May 23, 2021: Then-CDC Director Walensky receives draft HAN[83]

From: Walke, Henry (CDC/OD/ORR/OD)
To: Walensky, Rochelle (CDC/IOD)
Subject: DRAFT_Myocarditis_Advisory_05232021_1109
Date: Sunday, May 23, 2021 1:12:18 PM
Attachments: DRAFT_Myocarditis_Advisory_05232021_1109.docx

Latest HAN.

[83] *Id.*

Clinician Advisory: Cases of Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

Commented [DD(1]: Need to decide what to title this

Summary

In recent weeks, occasional cases of mild myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination, particularly in adolescents and young adults. To date, the number of reports is small given the number of vaccine doses administered; most cases were mild and patients have responded well to conservative treatment (e.g., NSAIDS, rest). CDC and its partners are actively investigating these reports to assess for any relationship to vaccination. CDC recommends that healthcare providers 1) consider myocarditis and pericarditis in adolescents and young adults with acute chest pain, shortness of breath, or palpitations following recent COVID-19 vaccination and consider consultation with cardiology and infectious disease and/or rheumatology for suspected cases of myocarditis and pericarditis, and 2) report any suspected cases to the Vaccine Adverse Event Reporting System (VAERS). The benefit of vaccination in preventing acute and chronic complications of COVID-19 in this population outweighs the risk of occasional and mild myocarditis and pericarditis. CDC continues to recommend COVID-19 vaccination for individuals 12 years or older given the risk of COVID-19 illness and related, potentially severe, complications.

Background

Myocarditis is the inflammation of the heart muscle, and pericarditis is the inflammation of the lining outside of the heart. Common symptoms may include chest pain, shortness of breath, or palpitations. Cases of acute myocarditis include those with symptoms not attributable to another cause and at least one of the following: elevated biomarkers of cardiac injury (e.g. troponin), electrocardiogram (ECG or EKG) or cardiac magnetic resonance imaging (cMRI) findings suggestive of cardiac injury, or abnormal cardiac function on echocardiogram or cMRI.[1,2] Acute pericarditis includes patients with at least two of the following: acute chest pain, pericardial rub on exam, new ST-elevation or PR-depression on ECG, or new or worsening pericardial effusion.[3] When myocarditis and pericarditis are present together, as is often the case, the term myopericarditis is used.

Myocarditis and pericarditis are frequently attributed to seasonal viral infections, although the specific virus is often not identified. For most cases, patients respond to conservative treatment (e.g., NSAIDS, rest), but other treatments may be required for more severe cases. Patients can typically return to normal activity after initial improvement in symptoms; for those with myocarditis or myopericarditis, even if mild, restriction from rigorous athletic activity is recommended for at least 3 months.[4]

CDC is monitoring VAERS for possible cases of myocarditis and pericarditis following vaccination since the initial authorization of COVID-19 vaccines. Based on reports to VAERS, cases have occurred:

- predominantly in adolescents and young adults,
- more often in males than females,
- following both Pfizer-BioNTech and Moderna mRNA COVID-19 vaccines,
- more often following dose 2 than dose 1, and
- typically within a week after vaccination.

May 23, 2021: Then-CDC Director Walensky receives draft HAN (continued)

To date, the number of reports is small given the number of vaccine doses administered, and most cases have been mild and responded quickly with appropriate medical care. Additional follow-up is ongoing to understand the clinical characteristics of these cases and possible risk factors and to assess for any possible relationship to vaccination. CDC will continue to monitor for and evaluate reports of myocarditis and pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available.

Recommendations for Clinicians

- Myocarditis or pericarditis should be considered in adolescents or young adults with acute chest pain, shortness of breath, or palpitations following recent COVID-19 vaccination. In this younger population, coronary events are less likely to be a source of these symptoms.
- For evaluation of patients with suspected myocarditis or pericarditis:
  - For initial evaluation, consider an ECG, troponin level, and inflammatory markers such as C-reactive protein and erythrocyte sedimentation rate. In the setting of normal ECG, troponin, and inflammatory markers, myocarditis or pericarditis are unlikely.
  - Cardiology consultation is strongly encouraged for assistance with evaluation and management and further testing as indicated to assess for evidence of cardiac injury including echocardiogram and, where appropriate, cMRI.
  - For cases of myocarditis, it is important to evaluate for potential etiologies of myocarditis, particularly acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (i.e., SARS-CoV-2 nucleocapsid antibodies), and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing). Consider consultation with infectious disease for complete evaluation of potential etiologies and/or rheumatology.
- For management of patients with myocarditis or pericarditis:
  - To date, there are no indications to alter management as compared to that of classic myocarditis and pericarditis. Most cases of myocarditis and pericarditis improve with conservative management.
  - For patients with myocarditis, restriction from rigorous athletic activity is recommended for at least 3 months pending repeat evaluation by cardiology. .[4]
- CDC continues to recommend COVID-19 vaccination for individuals 12 years and older.
- Healthcare providers should report all cases of myocarditis and pericarditis post COVID-19 vaccination to VAERS.

Recommendations for Public Health

- Encourage healthcare providers and the public to report myocarditis, pericarditis, and other adverse events following receipt of COVID-19 vaccines to VAERS as required under the Emergency Use Authorizations for COVID-19 vaccines.
- Disseminate this advisory to healthcare providers in your jurisdictions.
- CDC continues to recommend COVID-19 vaccination for individuals 12 years and older.

Commented [DD(2]: Will need to decide what we are calling this communication: Alert, Advisory, etc and then also decided what the recommended circulation should be: pediatrics, adolescent medicine, pediatric emergency medicine, pediatric infectious diseases, and pediatric cardiology?

May 23, 2021: Then-CDC Director Walensky receives draft HAN (continued)

Recommendations for the Public

- CDC continues to recommend COVID-19 vaccination for everyone 12 years or older. If you have concerns about vaccination, talk with your or your child's doctor.
- Cases of myocarditis and pericarditis following COVID-19 vaccination are rare and have typically been mild. Also, most patients responded well to everyday treatments, like rest and aspirin or ibuprofen, and quickly felt better. If you or your child received an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) and develops chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after recent vaccination, contact your doctor, or seek medical care. Avoid rigorous physical activity, such as climbing a steep hill or running, until a doctor has examined you, run any necessary tests, and said you may do those activities again.
- Report possible health problems following receipt of any COVID-19 vaccine to VAERS.

For More Information

- NIH materials on myocarditis and pericarditis
- Frequently asked questions about VAERS reporting for COVID-19 vaccines VAERS - FAQs (hhs.gov)
- How to report to VAERS

References

1. Sagar S, Liu PP, Cooper LT, Jr. Myocarditis. Lancet. 2012;379:738-47.

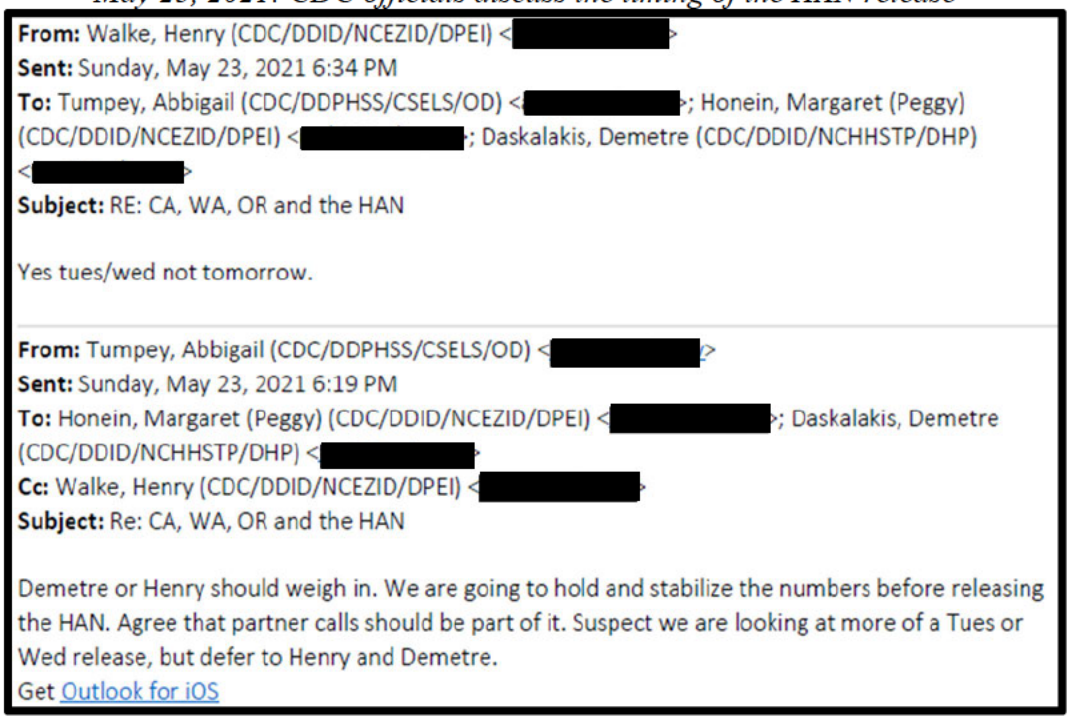
2. Ferreira VM, Schulz-Menger J, Holmvang G, Kramer CM, Carbone I, Sechtem U, et al. Cardiovascular Magnetic Resonance in Nonischemic Myocardial Inflammation: Expert Recommendations. J Am Coll Cardiol. 2018;72:3158-76.

3. Adler Y, Charron P, Imazio M, Badano L, Baron-Esquivias G, Bogaert J, et al. 2015 ESC Guidelines for the diagnosis and management of pericardial diseases: The Task Force for the Diagnosis and Management of Pericardial Diseases of the European Society of Cardiology (ESC)Endorsed by: The European Association for Cardio-Thoracic Surgery (EACTS). Eur Heart J. 2015;36:2921-64.

4. Maron BJ, Udelson JE, Bonow RO, Nishimura RA, Ackerman MJ, Estes NAM, 3rd, et al. Eligibility and Disqualification Recommendations for Competitive Athletes With Cardiovascular Abnormalities: Task Force 3: Hypertrophic Cardiomyopathy, Arrhythmogenic Right Ventricular Cardiomyopathy and Other Cardiomyopathies, and Myocarditis: A Scientific Statement From the American Heart Association and American College of Cardiology. J Am Coll Cardiol. 2015;66:2362-71.

By May 23, 2021, according to an unredacted email chain produced to the Subcommittee, CDC officials believed that the release of the HAN on myocarditis was imminent and wrote that they expected it to be made public by May 25 or May 26, 2021:

May 23, 2021: CDC officials discuss the timing of the HAN release[84]



From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <[redacted]>
Sent: Sunday, May 23, 2021 6:34 PM
To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <[redacted]>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[redacted]>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[redacted]>
Subject: RE: CA, WA, OR and the HAN

Yes tues/wed not tomorrow.

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <[redacted]>
Sent: Sunday, May 23, 2021 6:19 PM
To: Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <[redacted]>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <[redacted]>
Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <[redacted]>
Subject: Re: CA, WA, OR and the HAN

Demetre or Henry should weigh in. We are going to hold and stabilize the numbers before releasing the HAN. Agree that partner calls should be part of it. Suspect we are looking at more of a Tues or Wed release, but defer to Henry and Demetre.
Get Outlook for iOS

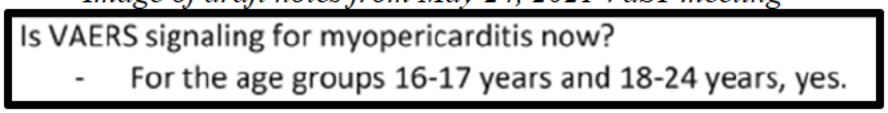
May 24, 2021

A public summary of the CDC's VaST session noted that "[d]ata from VAERS show that in the 30-day window following dose 2 mRNA COVID-19 vaccination, **there was a higher number of observed than expected myocarditis/pericarditis cases in 16–24-year-olds**."[85] The meeting summary also stated, "[d]ata from VSD do not show that rates of myocarditis/pericarditis reports in the window following COVID-19 vaccination differ from expected at this time; however, analyses suggest that **these data need to be carefully followed as more persons in younger age groups are vaccinated**. VSD found no concerns among the over 20 other adverse events of special interest being monitored."[86]

[84] PSICOVID_00004634-4636.
[85] COVID-19 VaST Technical Report May 24, 2021, Centers for Disease Control and Prevention, Last Reviewed: Jun. 1, 2021, https://archive.cdc.gov/www_cdc_gov/vaccines/acip/work-groups-vast/report-2021-05-24.html (emphasis added).
[86] *Id.* (emphasis added).

The non-public, "confidential" draft meeting notes connected to the May 24, 2021 VaST meeting contained the question, "**Is VAERS signaling for myopericarditis?**"[87] The answer unambiguously stated: "**For the age groups 16-17 years and 18-24 years, yes.**"[88]

Image of draft notes from May 24, 2021 VaST meeting[89]



The draft meeting notes further stated that the "VAERS team is also updating the operating case definition, which may have an impact on the number of reports."[90] It is unclear whether this update occurred and what, if any, effect it had on the number of myopericarditis reports. The draft meeting notes did, however, appear to identify an inconsistency between medical terms in VAERS and VSD. The draft notes stated, "VAERS uses MedDRA terms whereas VSD using [sic] ICD-10 codes."[91]

The draft safety surveillance data tables that were connected with the May 24, 2021 VaST meeting showed that in VAERS, there were 255 reports of myopericarditis for the Pfizer vaccine, 156 reports of myopericarditis for the Moderna vaccine, and 22 reports of myopericarditis for the Johnson and Johnson vaccine.[92]

May 25, 2021

Based on records obtained by the Subcommittee and previously made public, on May 25, 2021, CDC official Dr. Sara Oliver communicated with an employee of Moderna regarding the status the HAN.[93] Although the CDC official suggested that the HAN was likely to be released, she did acknowledge there were ongoing discussions on the matter.[94] The CDC official wrote, in part:

> **The pros and cons of an official HAN are what the main discussions are right now.** I think it's likely to be a HAN since that is CDC's primary method of

[87] PSICOVID_00009452 (emphasis added).
[88] *Id.*
[89] *Id.* Based on the documents received to date, the Subcommittee is not aware of other versions of the draft notes about the May 24, 2021 VaST meeting.
[90] *Id.*
[91] PSICOVID_00009453.
[92] PSICOVID_00009438, 9442, 9445. The draft tables indicated that the VAERS data on myopericarditis were through May 20, 2021.
[93] PSICOVID_00004649-4650; Zachary Stieber, EXCLUSIVE: Email Reveals Why CDC Didn't Issue Alert on COVID Vaccines and Myocarditis, Epoch Times, Jan. 26, 2024, https://www.theepochtimes.com/article/exclusive-email-reveals-why-cdc-didnt-issue-alert-on-covid-vaccines-and-myocarditis-5571675. FOIA production included in article at 824-825; Letter from Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Nov. 19, 2024, https://www.ronjohnson.senate.gov/services/files/00AAFB3D-72EE-475F-94D5-66708B4AA86D.
[94] *Id.*

communications to clinicians and public health departments, but **people don't want to appear alarmist either.**[95]

That same day, Benjamin Wakana, the Biden White House's Deputy Director for Strategic Communications and Engagement, emailed Walensky, then-NIAID Director Fauci, and then-NIH Director Francis Collins, among others, a 17-page document of "tough" questions and answers on a variety of topics including myocarditis risks.[96] The section on myocarditis included misleading talking points (which will be discussed later in this interim report) and downplayed the risk of the adverse event.[97]

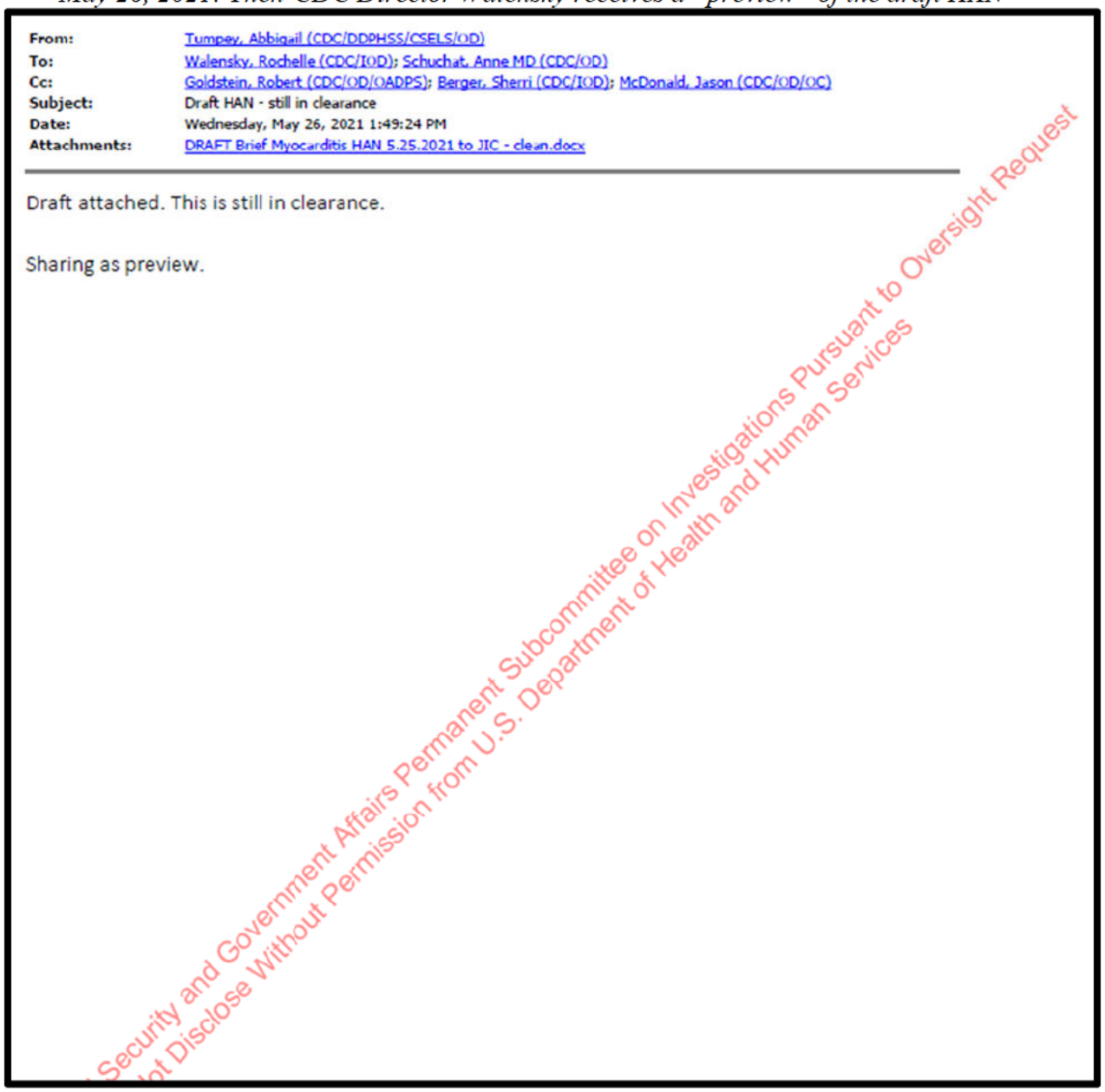
May 26, 2021

On May 26, 2021, CDC official Abbigail Tumpey emailed Walensky and others a "preview" of the HAN on myocarditis that was still in the clearance process.[98] The draft HAN Tumpey attached to her May 26 email, which the Subcommittee obtained, included comments from unnamed reviewers indicating specific language for the HAN that Walensky apparently requested.[99] When compared to the earlier May 23 draft, the May 26 version appears to contain more language emphasizing that benefits of COVID-19 vaccination outweigh the risks.[100]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[95] *Id.;* PSICOVID_00004649-4650 (emphasis added).
[96] PSICOVID_00005295-5312.
[97] PSICOVID_00005297.
[98] PSICOVID_00005562-5564.
[99] *Id.*
[100] *Id.*

May 26, 2021: Then-CDC Director Walensky receives a "preview" of the draft HAN[101]



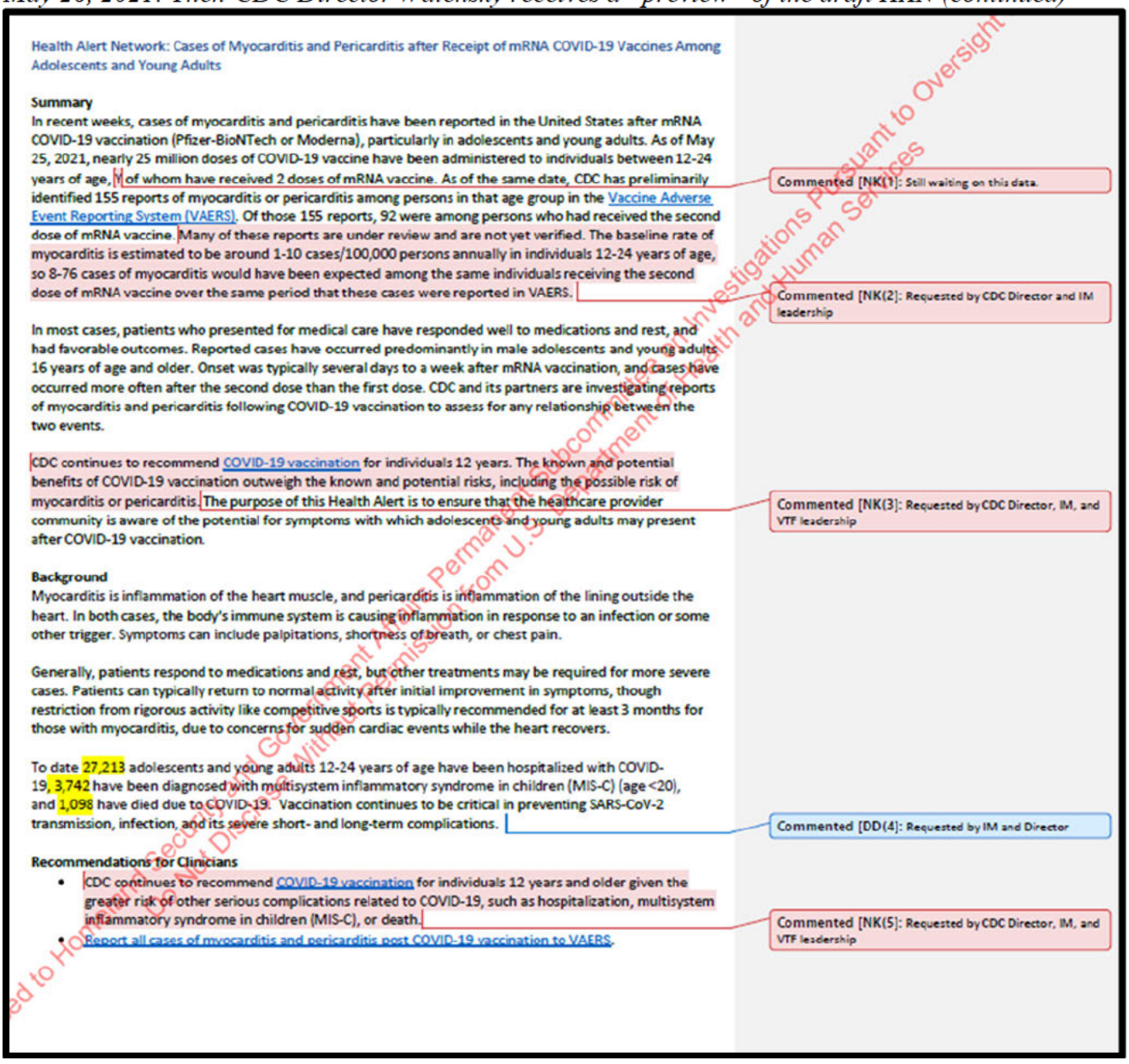
From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)
To: Walensky, Rochelle (CDC/IOD); Schuchat, Anne MD (CDC/OD)
Cc: Goldstein, Robert (CDC/OD/OADPS); Berger, Sherri (CDC/IOD); McDonald, Jason (CDC/OD/OC)
Subject: Draft HAN - still in clearance
Date: Wednesday, May 26, 2021 1:49:24 PM
Attachments: DRAFT Brief Myocarditis HAN 5.25.2021 to JIC - clean.docx

Draft attached. This is still in clearance.

Sharing as preview.

[101] *Id.*

May 26, 2021: Then-CDC Director Walensky receives a "preview" of the draft HAN (continued)



Health Alert Network: Cases of Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults

Summary

In recent weeks, cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in adolescents and young adults. As of May 25, 2021, nearly 25 million doses of COVID-19 vaccine have been administered to individuals between 12-24 years of age, M of whom have received 2 doses of mRNA vaccine. As of the same date, CDC has preliminarily identified 155 reports of myocarditis or pericarditis among persons in that age group in the Vaccine Adverse Event Reporting System (VAERS). Of those 155 reports, 92 were among persons who had received the second dose of mRNA vaccine. Many of these reports are under review and are not yet verified. The baseline rate of myocarditis is estimated to be around 1-10 cases/100,000 persons annually in individuals 12-24 years of age, so 8-76 cases of myocarditis would have been expected among the same individuals receiving the second dose of mRNA vaccine over the same period that these cases were reported in VAERS.

In most cases, patients who presented for medical care have responded well to medications and rest, and had favorable outcomes. Reported cases have occurred predominantly in male adolescents and young adults 16 years of age and older. Onset was typically several days to a week after mRNA vaccination, and cases have occurred more often after the second dose than the first dose. CDC and its partners are investigating reports of myocarditis and pericarditis following COVID-19 vaccination to assess for any relationship between the two events.

CDC continues to recommend COVID-19 vaccination for individuals 12 years. The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis. The purpose of this Health Alert is to ensure that the healthcare provider community is aware of the potential for symptoms with which adolescents and young adults may present after COVID-19 vaccination.

Background

Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an infection or some other trigger. Symptoms can include palpitations, shortness of breath, or chest pain.

Generally, patients respond to medications and rest, but other treatments may be required for more severe cases. Patients can typically return to normal activity after initial improvement in symptoms, though restriction from rigorous activity like competitive sports is typically recommended for at least 3 months for those with myocarditis, due to concerns for sudden cardiac events while the heart recovers.

To date 27,213 adolescents and young adults 12-24 years of age have been hospitalized with COVID-19, 3,742 have been diagnosed with multisystem inflammatory syndrome in children (MIS-C) (age <20), and 1,098 have died due to COVID-19. Vaccination continues to be critical in preventing SARS-CoV-2 transmission, infection, and its severe short- and long-term complications.

Recommendations for Clinicians

- CDC continues to recommend COVID-19 vaccination for individuals 12 years and older given the greater risk of other serious complications related to COVID-19, such as hospitalization, multisystem inflammatory syndrome in children (MIS-C), or death.
- Report all cases of myocarditis and pericarditis post COVID-19 vaccination to VAERS.

Commented [NK(1]: Still waiting on this data.

Commented [NK(2]: Requested by CDC Director and IM leadership

Commented [NK(3]: Requested by CDC Director, IM, and VTF leadership

Commented [DD(4]: Requested by IM and Director

Commented [NK(5]: Requested by CDC Director, IM, and VTF leadership

May 26, 2021: Then-CDC Director Walensky receives a "preview" of the draft HAN (continued)

- Consider myocarditis and pericarditis in adolescents or young adults with acute chest pain, shortness of breath, or palpitations. In this younger population, coronary events are less likely to be a source of these symptoms.
    - For initial evaluation, consider an ECG, troponin level, and inflammatory markers such as C-reactive protein and erythrocyte sedimentation rate. In the setting of normal ECG, troponin, and inflammatory markers, myocarditis or pericarditis are unlikely.
- Obtain history of COVID-19 vaccination if you identify these symptoms.
- Provide routine acute care and aftercare for these patients as clinically indicated. Consider restricting patients with myocarditis from rigorous activity like competitive sports for at least 3 months, due to concerns for sudden cardiac events while the heart recovers.
- Consider consultation with cardiology for assistance with evaluation and management of myocarditis and pericarditis.
- Pursue other etiologies of myocarditis and pericarditis and consider consultation with infectious disease and/or rheumatology to assist in this evaluation.
    - Evaluate for potential etiologies of myocarditis and pericarditis, particularly acute COVID-19 infection (e.g., PCR testing), prior SARS-CoV-2 infection (e.g., detection of SARS-CoV-2 nucleocapsid antibodies), and other viral etiologies (e.g., enterovirus PCR and comprehensive respiratory viral pathogen testing). Consider consultation with infectious disease and rheumatology for complete evaluation of potential etiologies.

Recommendations for Public Health

- CDC continues to recommend COVID-19 vaccination for individuals 12 years and older.
- Encourage healthcare providers and the public to report myocarditis, pericarditis, and other adverse events following receipt of COVID-19 vaccines to VAERS as required under the Emergency Use Authorizations for COVID-19 vaccines.
- Disseminate this alert to healthcare providers in your jurisdictions.

Recommendations for the Public

- CDC continues to recommend COVID-19 vaccination for everyone 12 years and older. If you have concerns about vaccination, talk with your or your child's doctor.
- The known and potential benefits of COVID-19 vaccination outweigh the known and potential risks, including the possible risk of myocarditis or pericarditis.
- Most patients with myocarditis and pericarditis who have presented to medical care have responded well to medication and rest, and quickly felt better.
- If you or your child received an mRNA COVID-19 vaccine (Pfizer-BioNTech or Moderna) and develop chest pain, shortness of breath, or palpitations (feelings of having a fast-beating, fluttering, or pounding heart) contact your doctor, or seek medical care.
- Report possible health problems following receipt of any COVID-19 vaccine to VAERS.

For More Information

- NIH materials on myocarditis and pericarditis
- Frequently asked questions about VAERS reporting for COVID-19 vaccines VAERS – FAQs (hhs.gov)
- How to report to VAERS

Documents show that around the time that Walensky received the updated version of the HAN, then-Acting FDA Commissioner Janet Woodcock, emailed Walensky and appeared to raise concerns about issuing the alert.[102] In the May 26, 2021 email chain that was produced to the Subcommittee without redactions, Woodcock wrote in the subject line, "Rochelle, do you know that FDA does not concur with issuance of the myocarditis HAN as written?"[103] The unredacted email chain is below:

May 26, 2021 email: FDA raises concerns about issuing the HAN[104]

From: Woodcock, Janet
To: Walensky, Rochelle (CDC/OD)
Subject: RE: [EXTERNAL] RE: Rochelle, do you know that FDA does not concur with issuance of the myocarditis HAN as written? jw
Date: Wednesday, May 26, 2021 2:05:22 PM

Thanks so much. I just learned that this was about to go out, despite our concerns. jw

From: Walensky, Rochelle (CDC/OD) <[redacted]>
Sent: Wednesday, May 26, 2021 2:00 PM
To: Woodcock, Janet <[redacted]>
Subject: [EXTERNAL] RE: Rochelle, do you know that FDA does not concur with issuance of the myocarditis HAN as written? jw

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Janet,
Just coming from a hearing and trying to get up to speed. Will hold until we chat.
R

From: Woodcock, Janet <[redacted]>
Sent: Wednesday, May 26, 2021 1:52 PM
To: Walensky, Rochelle (CDC/OD) <[redacted]>
Subject: Rochelle, do you know that FDA does not concur with issuance of the myocarditis HAN as written? jw

[102] PSICOVID_00005565; FOIA emails between Rochelle Walensky, Dir., Centers for Disease Control and Prevention, and Janet Woodcock, Acting Commissioner, Food and Drug Administration, May 26, 2021 (on file with Subcomm.).
[103] *Id.* The version of this email produced under the Biden administration via FOIA almost completely redacted the content of the subject line, concealing Woodcock's statement that "FDA does not concur with the issuance of the myocarditis HAN." Instead, the FOIA version read, "Rochelle, do you know that [Redaction] as written? jw".
[104] PSICOVID_00005565.

Additional emails indicate that on May 26, 2021, CDC and FDA officials were aware that the plan to issue the formal HAN was "nix[ed]" and that the CDC would publish "clinical considerations" on its website instead.[105]

May 27, 2021

Records obtained by the Subcommittee show that Woodcock was not alone in expressing concerns about federal health agencies warning the public about myocarditis. Even after FDA and CDC decided to "nix the HAN," FDA's then-Director of the Center for Biologics Evaluation and Research, Peter Marks, wrote to Walensky, copying Woodcock, and appeared to raise concerns about the plan to post "clinical considerations" on myocarditis and pericarditis on the website.[106] In his email, Marks stated:

> I need to ask for your patience with me. **We still have concerns here if myocarditis and pericarditis have not actually signaled. This is different from the half pager that we spoke about and is pretty close to the original HAN.** Can you help me understand why we are doing this when pediatricians and others in the community already seem to be aware?[107]

Based on the documents produced to date to the Subcommittee and public records, it is unclear what "half pager" Marks referenced in his email. It is also unclear whether Marks was aware of the discussions from the May 24, 2021 VaST meeting that, according to the draft notes from that meeting, included the question the question: "Is VAERS signaling for myopericarditis now?"; and the answer: "For the age groups 16-17 years and 18-24 years, yes."[108]

Following Marks' email, it appears that CDC officials, including Daskalakis, worked on editing the language associated with CDC's website statement about myocarditis. In the afternoon of May 27, 2021, Daskalakis informed his colleagues:

> One language change around management and then we can move it forward. I think we are close… **they want to walk back this sentence:**

[105] PSICOVID_00005569. *See also* Zachary Stieber, EXCLUSIVE: Email Reveals Why CDC Didn't Issue Alert on COVID Vaccines and Myocarditis, Epoch Times, Jan. 26, 2024, https://www.theepochtimes.com/article/exclusive-email-reveals-why-cdc-didnt-issue-alert-on-covid-vaccines-and-myocarditis-5571675. FOIA production included in article at 897-900; PSICOVID_00004808-4809; Zachary Stieber, FDA Influenced Decision Not to Send Alert on Post vaccination Heart Inflammation: Emails, Epoch Times, Jan. 21, 2024, https://www.theepochtimes.com/health/fda-influenced-decision-not-to-send-alert-on-postvaccination-heart-inflammation-emails-5570033?utm_medium=social&utm_source=twitter&utm_campaign=digitalsub.
[106] *Id.*; PSICOVID_00005568.
[107] *Id.* (emphasis added). The bolded sentences above were redacted in the version of this email produced via FOIA. See email between Peter Marks, Food and Drug Administration, and Rochelle Walensky, Dir., et al., May 27, 2021 (on file with Subcomm.).
[108] PSICOVID_00009452.

> Due to concerns for sudden cardiac events while the heart recovers, consider restricting patients with myocarditis from rigorous activity like competitive sports for at least 3 months until cleared by a healthcare professional.[109]

May 28, 2021

On May 28, 2021, CDC posted its "clinical considerations" on its website stating "increased cases of myocarditis and pericarditis have been reported in the United States after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna)," but CDC still "continues to recommend COVID-19 vaccination for everyone 12 years of age and older."[110] The website did not contain the language about reducing rigorous activity that Daskalakis flagged the day prior.

June 2021

According to a public report, "752 cases of myocarditis, pericarditis, or myopericarditis [were] reported to VAERS, including five deaths."[111]

June 21, 2021

Following a June 14, 2021 VaST meeting, Markowitz emailed draft meeting notes and draft safety surveillance data tables that showed in VAERS, "1,029 automated myocarditis and pericarditis reports across all vaccines" including 537 reports for the Pfizer vaccine, 319 reports for the Moderna vaccine, and 27 reports for the Johnson and Johnson vaccine.[112]

June 25, 2021

On June 25, 2021, nearly one month after CDC's decision to effectively downplay the risk of myocarditis by not immediately issuing the HAN, the FDA announced changes to the labels for the Moderna and Pfizer COVID-19 vaccines based on the "suggested increased risks"

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[109] PSICOVID_00005566 (ellipses in original, emphasis added). It is unclear who wanted to "walk back" the sentence and why.

[110] Clinical Considerations: Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults, Centers for Disease Control and Prevention, May 28, 2021, archived: https://web.archive.org/web/20210528145419/https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html. A record produced to the Subcommittee and a FOIA document indicate that the clinical considerations on myocarditis were posted on May 27, 2021 and then were "pulled down" after ten minutes. PSICOVID_00005570; Email from Abbigail Tumpey, Centers for Disease Control and Prevention, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, May 27, 2021 (on file with Subcomm.); Zachary Stieber, FDA Influenced Decision Not to Send Alert on Post vaccination Heart Inflammation: Emails, Epoch Times, Jan. 21, 2024, https://www.theepochtimes.com/health/fda-influenced-decision-not-to-send-alert-on-postvaccination-heart-inflammation-emails-5570033?utm_medium=social&utm_source=twitter&utm_campaign=digitalsub.

[111] Zachary Stieber, Timeline: COVID-19 Vaccines and Myocarditis, Apr. 22, 2024, https://www.theepochtimes.com/health/timeline-covid-19-vaccines-and-myocarditis-5317985.

[112] PSICOVID_00009454-9472, 9461, 9465, 9468. The draft tables indicated that the VAERS data on myocarditis and pericarditis were through June 4, 2021.

of myocarditis and pericarditis.[113] Specifically, the FDA revised the fact sheets for both vaccines "to include a warning about myocarditis and pericarditis."[114]

The same day, Markowitz emailed members of the VaST Work Group draft minutes and draft safety surveillance data tables from the June 21, 2021 VaST meeting.[115] The draft tables indicated 791 myocarditis and pericarditis reports for the Pfizer vaccine, 117-435 myocarditis and pericarditis reports for the Moderna vaccine, and 27 myocarditis and pericarditis reports for the Johnson and Johnson vaccine.[116]

The draft notes for the June 21, 2021 VaST meeting, included a summary of a presentation that was going to be shared with the Advisory Committee on Immunization Practices ("ACIP") on behalf of the VaST Work Group regarding the risk of myocarditis following mRNA vaccination in adolescents and young adults.[117] In reference to this connection between myocarditis and mRNA vaccines, the draft notes stated that the "group felt that the wording [in the presentation] should be changed from 'potential association' to 'likely association[.]'"[118] Indeed, in the public version of the VaST Work Group's slideshow that was presented to ACIP in late June, it stated, "**Data available to date suggest likely association of myocarditis with mRNA vaccination in adolescents and young adults**."[119]

b. Pfizer and Moderna employees are identified in records produced via subpoena

As described above, public reports have revealed that CDC communicated with an unknown employee of Pfizer or Moderna regarding the agency's plans to issue a public warning about myocarditis.[120] Those public reports were based on FOIA documents that contained

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[113] Coronavirus (COVID-19) Update: June 25, 2021, Food and Drug Administration, Jun. 25, 2021, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021; Jack Phillips, FDA Adds Warning About Heart Inflammation to COVID-19 mRNA Vaccines, Epoch Times, https://www.theepochtimes.com/article/fda-adds-warning-about-heart-inflammation-to-covid-19-mrna-vaccines-3876245.

[114] Coronavirus (COVID-19) Update: June 25, 2021, Food and Drug Administration, Jun. 25, 2021, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021.

[115] PSICOVID_00009473-9490.

[116] PSICOVID_00009479, 9483, 9487. The range of reports for the Moderna vaccine is a result of an apparent discrepancy in the draft tables regarding the total number of myocarditis and pericarditis reports associated with the vaccine. The draft tables indicated that the VAERS data on myocarditis and pericarditis were through June 11, 2021 for Pfizer and Moderna, and June 4, 2021 for Johnson and Johnson.

[117] PSICOVID_00009477.

[118] PSICOVID_00009477.

[119] Grace Lee, et al., COVID-19 Vaccine Safety Technical (VaST) Work Group, Jun. 23, 2021, https://stacks.cdc.gov/view/cdc/108330 at 11 (emphasis added); Summary Minutes, MEETING OF THE ADVISORY
COMMITTEE ON IMMUNIZATION PRACTICES (ACIP), Jun. 23, 2021, https://stacks.cdc.gov/view/cdc/157583/cdc_157583_DS1.pdf at 14.

[120] Zachary Stieber, EXCLUSIVE: Email Reveals Why CDC Didn't Issue Alert on COVID Vaccines and Myocarditis, Epoch Times, Jan. 26, 2024, https://www.theepochtimes.com/article/exclusive-email-reveals-why-cdc-didnt-issue-alert-on-covid-vaccines-and-myocarditis-5571675. FOIA production included in article at 824-825; Letter from Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Nov. 19, 2024, https://www.ronjohnson.senate.gov/services/files/00AAFB3D-72EE-475F-94D5-66708B4AA86D.

redactions masking the employee's name and their affiliated company.[121] In response to Chairman Johnson's subpoena, HHS produced unredacted records that identify both Pfizer and Moderna employees communicating with CDC about the development of the HAN and the agency's eventual decision to forgo the formal warning about myocarditis and publish "web content" instead.[122]

For example, when Oliver sent the May 25, 2021 missive described above regarding the CDC's deliberations on the HAN, the unredacted documents confirm that Oliver was in direct communication with Moderna consultant Barbara Kuter.[123]

May 25, 2021 unredacted email shows CDC communicating with Moderna employee about the myocarditis warning[124]

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
To: Barbara Kuter (x)
Subject: RE: Publication - Myocarditis
Date: Tuesday, May 25, 2021 10:29:00 AM

I haven't heard plans for an MMWR yet. There's just not enough data yet so an MMWR wouldn't make sense at this point. I would anticipate as we have additional data and more formal analyses, there may be an MMWR, but not right now.

The pros and cons of an official HAN are what the main discussions are right now. I think it's likely to be a HAN since that is CDC's primary method of communications to clinicians and public health departments, but people don't want to appear alarmist either.

I am not trying to be vague on purpose- I really don't know. If I had to guess, I would think it's likely to be a HAN, but can't say for sure yet. I anticipate there will be firm decisions within the next 24 hours so I'll let you know.

Thanks-
Sara

[121] HHS cited to FOIA exemption (b)(4), which is used to protect trade secrets and other confidential business information, to justify its redactions of the employee's name. *What information is available under the FOIA?*, Dep't of Health and Human Services, https://www.hhs.gov/foia/faqs/what-information-is-available-under-the-foia/index.html (last visited Mar. 24, 2025); *See, e.g.*, Zachary Stieber, EXCLUSIVE: Email Reveals Why CDC Didn't Issue Alert on COVID Vaccines and Myocarditis, Epoch Times, Jan. 26, 2024, https://www.theepochtimes.com/article/exclusive-email-reveals-why-cdc-didnt-issue-alert-on-covid-vaccines-and-myocarditis-5571675. FOIA production included in article at 824-825, 897-900.
[122] *See, e.g.*, PSICOVID_00004649-4650, PSICOVID_00004808-4809.
[123] In addition to using a Moderna email address, several published journal articles have noted that Ms. Kuter is a consultant for Moderna. *See, e.g.*, Shari Pilon-Thomas et al., Neutralizing Antibody Response following a Third Dose of the mRNA-1273 Vaccine among Cancer Patients, Vaccines, Dec. 22, 2023, https://pmc.ncbi.nlm.nih.gov/articles/PMC10818923/pdf/vaccines-12-00013.pdf; Jeffrey Lancet et al., Safety and immunogenicity of a third dose of mRNA-1273 vaccine among cancer patients, Cancer Communications, May 30, 2023, https://pmc.ncbi.nlm.nih.gov/articles/PMC10354405/pdf/CAC2-43-749.pdf.
[124] PSICOVID_00004649.

Other unredacted documents reveal the names of the Pfizer and Moderna employees that were given advance notice on May 27, 2021 regarding CDC's final decision to issue "clinical considerations" about myocarditis rather than a formal HAN message. Below are images of two emails with similar content from Oliver to Pfizer employees Vincenza "Vinnie" Snow and Alejandro "Ale" Cane, as well as Moderna consultant Kuter. In the emails, Oliver provided the Pfizer and Moderna employees draft language for CDC's website on myocarditis:

[REMAINDER OF PAGE INTENTIONALLY BLANK]

May 27, 2021 email: CDC updates Pfizer about its plans to not issue HAN on myocarditis[125]

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
To: Snow, Vincenza T; Cane, Alejandro
Cc: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Mbaeyi, Sarah (CDC/DDID/NCIRD/OD)
Subject: update on myocarditis
Date: Thursday, May 27, 2021 11:16:00 AM

Vinnie and Ale:

Wanted to let you know an update on myocarditis. The (current) plan is to release web content describing the reports of myocarditis/pericarditis and clinical considerations, but not a formal HAN. This will be combined with targeted clinician outreach as well. The goal is to have these web updates posted this afternoon. I'll send them on when they are posted.

The language is still being finalized, but a few highlights are below (language is still draft until it's posted, but wanted you to have an idea of what it may say).

- More than 165 million people have received at least one dose of COVID-19 vaccine in the United States, and CDC continues to monitor the safety of COVID-19 vaccines for any health problems that happen after vaccination.
- In April and May of 2021, there have been increased reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna) in the United States.
- These reports are rare, given the number of vaccine doses administered, and have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults.
- CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination.

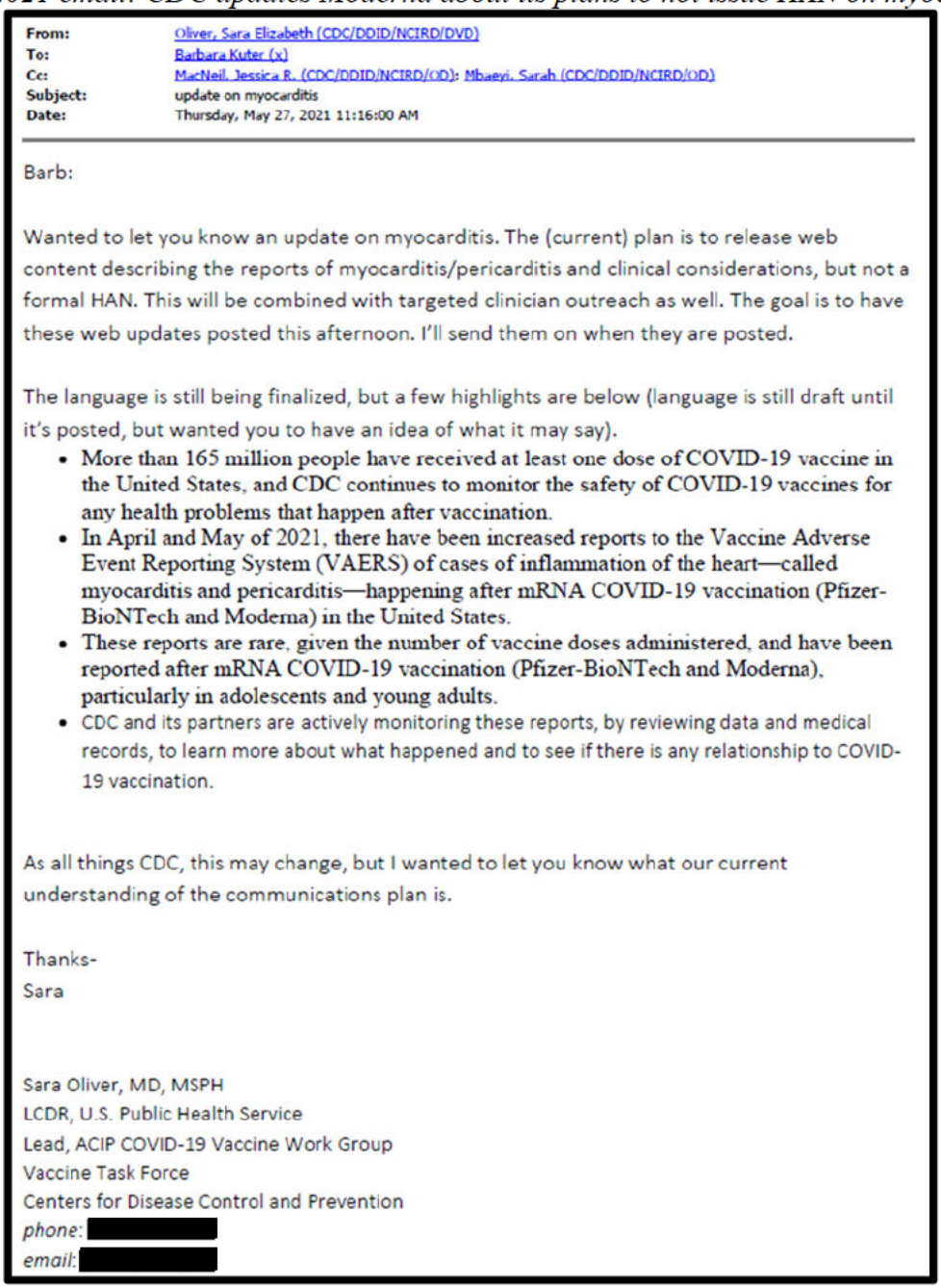
As all things CDC, this may change, but I wanted to let you know what our current understanding of the communications plan is.

Thanks-
Sara

Sara Oliver, MD, MSPH
LCDR, U.S. Public Health Service
Lead, ACIP COVID-19 Vaccine Work Group
Vaccine Task Force
Centers for Disease Control and Prevention
phone: [redacted]
email: [redacted]

[125] PSICOVID_00004808. A similar version of this email was produced via FOIA with redactions. *See* Zachary Stieber, EXCLUSIVE: Email Reveals Why CDC Didn't Issue Alert on COVID Vaccines and Myocarditis, Epoch Times, Jan. 26, 2024, https://www.theepochtimes.com/article/exclusive-email-reveals-why-cdc-didnt-issue-alert-on-covid-vaccines-and-myocarditis-5571675. FOIA production included in article at 899-900.

May 27, 2021 email: CDC updates Moderna about its plans to not issue HAN on myocarditis[126]



From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
To: Barbara Kuter (x)
Cc: MacNeil, Jessica R. (CDC/DDID/NCIRD/OD); Mbaeyi, Sarah (CDC/DDID/NCIRD/OD)
Subject: update on myocarditis
Date: Thursday, May 27, 2021 11:16:00 AM

Barb:

Wanted to let you know an update on myocarditis. The (current) plan is to release web content describing the reports of myocarditis/pericarditis and clinical considerations, but not a formal HAN. This will be combined with targeted clinician outreach as well. The goal is to have these web updates posted this afternoon. I'll send them on when they are posted.

The language is still being finalized, but a few highlights are below (language is still draft until it's posted, but wanted you to have an idea of what it may say).

- More than 165 million people have received at least one dose of COVID-19 vaccine in the United States, and CDC continues to monitor the safety of COVID-19 vaccines for any health problems that happen after vaccination.
- In April and May of 2021, there have been increased reports to the Vaccine Adverse Event Reporting System (VAERS) of cases of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna) in the United States.
- These reports are rare, given the number of vaccine doses administered, and have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech and Moderna), particularly in adolescents and young adults.
- CDC and its partners are actively monitoring these reports, by reviewing data and medical records, to learn more about what happened and to see if there is any relationship to COVID-19 vaccination.

As all things CDC, this may change, but I wanted to let you know what our current understanding of the communications plan is.

Thanks-
Sara

Sara Oliver, MD, MSPH
LCDR, U.S. Public Health Service
Lead, ACIP COVID-19 Vaccine Work Group
Vaccine Task Force
Centers for Disease Control and Prevention
phone: [redacted]
email: [redacted]

The names of the Pfizer and Moderna employees in the emails above should have never been redacted. The public has a right to the unredacted communications between CDC, Pfizer, and Moderna officials, particularly on emails regarding health risks to the public. With the release of these unredacted records, the public can better understand the extent to which CDC

[126] PSICOVID_00004809. A similar version of this email was produced via FOIA with redactions. *See* Zachary Stieber, EXCLUSIVE: Email Reveals Why CDC Didn't Issue Alert on COVID Vaccines and Myocarditis, Epoch Times, Jan. 26, 2024, https://www.theepochtimes.com/article/exclusive-email-reveals-why-cdc-didnt-issue-alert-on-covid-vaccines-and-myocarditis-5571675. FOIA production included in article at 897-898.

opted to keep Pfizer and Moderna employees up-to-date regarding its response to a vaccine adverse event, rather than the American people. The Subcommittee will update the public as it becomes aware of more interactions between CDC, Pfizer, and Moderna.

c. Unredacted records produced via subpoena expose CDC's previously redacted communications about the HAN

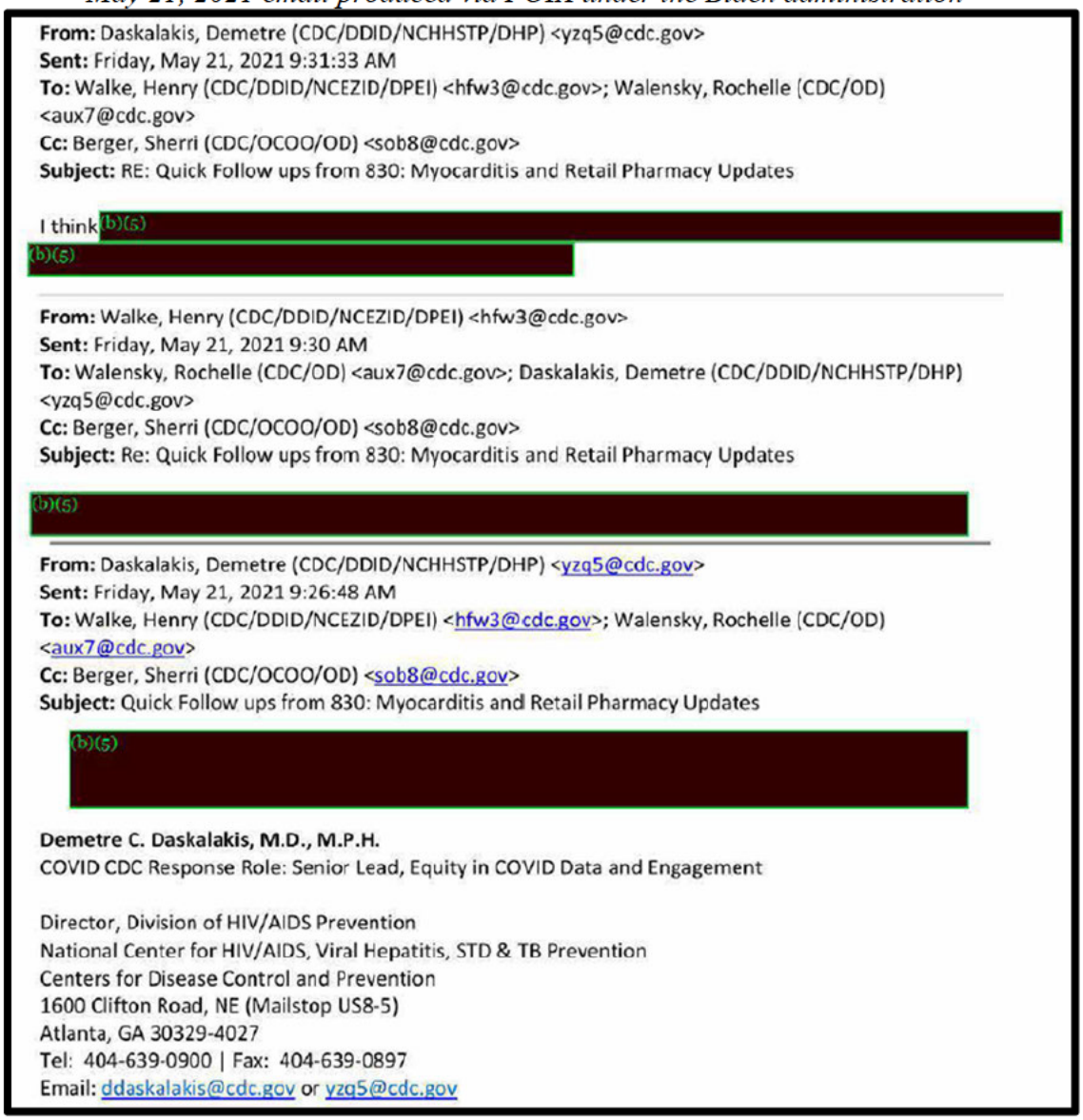
Many of the documents relating to the development of the HAN that HHS produced via subpoena do not contain redactions. As a result, the Subcommittee and the public can finally review previously released, heavily redacted FOIA records with the FOIA redactions completely removed.

For example, the Biden administration publicly produced the May 21, 2021 email chain below through a FOIA request, but it was almost entirely redacted.[127] However, the names of the individuals on the email chain, who were also involved with the development and review of the HAN, including Walensky, were not concealed.[128]

[REMAINDER OF PAGE INTENTIONALLY BLANK]

[127] FOIA production: https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view at 290. HHS justified its redactions on this email chain with FOIA code (b)(5) which is used to protect inter-agency or intra-agency communications that are protected by legal privileges. *What information is available under the FOIA?*, Dep't of Health and Human Services, https://www.hhs.gov/foia/faqs/what-information-is-available-under-the-foia/index.html (last visited Mar. 24, 2025).
[128] *Id.*

May 21, 2021 email produced via FOIA under the Biden administration[129]



From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>
Sent: Friday, May 21, 2021 9:31:33 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Subject: RE: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

I think (b)(5)
(b)(5)

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Friday, May 21, 2021 9:30 AM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>
Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Subject: Re: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

(b)(5)

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>
Sent: Friday, May 21, 2021 9:26:48 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Subject: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

(b)(5)

Demetre C. Daskalakis, M.D., M.P.H.
COVID CDC Response Role: Senior Lead, Equity in COVID Data and Engagement

Director, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road, NE (Mailstop US8-5)
Atlanta, GA 30329-4027
Tel: 404-639-0900 | Fax: 404-639-0897
Email: ddaskalakis@cdc.gov or yzq5@cdc.gov

Following Chairman Johnson's subpoena, HHS, under the current administration, produced an unredacted version of the email chain. With the redactions removed, the public can now see the content of the communications occurring between top CDC officials regarding the HAN.[130]

The unredacted version of the May 21, 2021 email shows Daskalakis informing his CDC colleagues that "[t]here is a HAN in development on Myocarditis."[131] Another CDC official, Dr.

[129] *Id.* This document was part of the same FOIA production then-Ranking Member Johnson cited to on page five in his Nov. 19, 2024 letter to then-HHS Secretary Becerra. *See* Letter from Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Nov. 19, 2024, https://www.ronjohnson.senate.gov/services/files/00AAFB3D-72EE-475F-94D5-66708B4AA86D.
[130] PSICOVID_00004651.
[131] *Id.*

Henry Walke, responded and appear to imply that the HAN would only be created if there was a safety signal associated with the adverse event.[132] A few minutes later, Daskalakis speculated about the need for the HAN.[133] He wrote, "I think the Han in [sic] to alert providers to reporting since **there is concern that the messages have not been trickling from the vaccine programs to providers at large**."[134]

May 21, 2021 email without redactions show CDC's communications about the HAN[135]

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP)
To: Walke, Henry (CDC/DDID/NCEZID/DPEI); Walensky, Rochelle (CDC/OD)
Cc: Berger, Sherri (CDC/OD/OCS)
Subject: RE: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates
Date: Friday, May 21, 2021 9:31:35 AM

I think the HAN in to alert providers to reporting since there is concern that the messages have not been trickling from the vaccine programs to providers at large.

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Friday, May 21, 2021 9:30 AM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>
Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Subject: Re: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

Was there a trigger for starting work on HAN. Didn't think we had a safety signal yet.

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>
Sent: Friday, May 21, 2021 9:26:48 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Subject: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

1. There is a HAN in development on Myocarditis. Haven't seen in yet
2. The Push to Pull/end of Pro-Rata proposal includes the Federal retail pharmacy program

Demetre C. Daskalakis, M.D., M.P.H.
COVID CDC Response Role: Senior Lead, Equity in COVID Data and Engagement

Director, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road, NE (Mailstop US8-5)
Atlanta, GA 30329-4027
Tel: 404-639-0900 | Fax: 404-639-0897
Email: ddaskalakis@cdc.gov or yzq5@cdc.gov

[132] *Id.*
[133] *Id.*
[134] *Id.* (emphasis added).
[135] *Id.*

Other CDC officials appear to have shared Daskalakis' belief about potential underreporting of cases of myocarditis and pericarditis. According to publicly released FOIA documents, a few days before Daskalakis wrote his email, another CDC official, Dr. John Su, informed his colleagues on May 17, 2021 that his team had looked for reports of myocarditis in VAERS, but he wrote: "we're not finding them. Seemingly, providers aren't reporting these cases to VAERS[.]"[136] The notion that health care providers may have not been aware of, or that they were slow to learn about adverse health risks associated with the Pfizer and Moderna COVID-19 vaccines is very troubling.

Given that CDC officials were aware of the growing risk of myocarditis coupled with the lack of nationwide reporting about it, it would make the issuance of the HAN not only useful, but extremely necessary. However, CDC officials ultimately decided against the formal HAN message on myocarditis, potentially leaving the public and health care providers less informed about the cardiac-related risks of the COVID-19 vaccines.

d. HHS has yet to produce remaining communications about the development of the HAN and health officials' response to COVID-19 vaccine adverse events

Chairman Johnson's January 28, 2025 subpoena requires HHS to produce all communications referring or relating to the drafting of the 2021 HAN on myocarditis, the drafting of the clinical considerations on myocarditis and the decision to not release the HAN.[137] HHS continues to produce records responsive to the subpoena.

[136] FOIA production: https://s3.documentcloud.org/documents/23656227/cdc-emails-chat-messages-on-post-vaccination-myocarditis.pdf at 257-258.
[137] Subpoena from Ron Johnson, Chairman, Permanent Subcomm. on Investigations, to Dorothy Fink, Acting Secretary, Dep't of Health and Human Services, Jan. 28, 2025, https://www.ronjohnson.senate.gov/services/files/8FAB9531-F799-4067-BA1C-AB8CA182D100.

II. Unredacted version of FOIA document shows in March 2021 CDC expresses "particular interest in hearing about deaths reported after vaccination"

On December 5, 2024, then-PSI Ranking Member Johnson wrote to HHS, CDC, and FDA requesting documents about the detection of and response to myocarditis and pericarditis in post-vaccinated individuals.[138] In the letter, then-Ranking Member Johnson enclosed five records with heavy FOIA redactions that appeared to show interactions between U.S. public health officials and an Israeli Ministry of Health official regarding reports of myocarditis in young people after receiving the Pfizer COVID-19 vaccine.[139] The Biden administration refused to provide any of the requested records, including the unredacted versions of the documents enclosed with the letter.

In response to Chairman Johnson's January 28, 2025 subpoena, HHS produced unredacted versions of the documents enclosed in the December 5, 2024 letter.[140] Those documents are contained in the records released in conjunction with this interim report. With the redactions removed, it is now clear what information the Biden administration wanted to hide from the public.

For example, on March 15, 2021, Lauri Markowitz, a CDC official who was the co-lead of the Vaccine Safety Technical ("VaST") Work Group, emailed an Israeli Ministry of Health official requesting her to present vaccine safety monitoring data from Israel at a "closed" and "confidential" VaST meeting.[141] The CDC official wrote to the Israeli health official:

> **There is particular interest in hearing about deaths reported after vaccination**. Based on the target population for the initial vaccine roll-out in the United States, the number of deaths is substantially below the number expected. Nevertheless, we would like to hear the experience in other countries.[142]

Once again, on March 24, 2021, after the Israeli health official agreed to present at the VaST meeting, the CDC official reiterated the request for data on deaths after vaccination:

> I want to mention again that we are interested in hearing about Israel's post-authorization safety monitoring systems and specifically any information you have on **deaths reported after vaccination.** We thought that the system there might lend itself to more complete review of deaths reported.[143]

As presented in the images of the FOIA documents below on the left, the Biden administration completely redacted the excerpts above, asserting that they contain deliberative

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[138] Letter from Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Dec. 5, 2024, https://www.ronjohnson.senate.gov/services/files/CCEF4C60-FA50-4A57-804B-D4CA2F835C41.
[139] *Id.*
[140] See PSICOVID_00000001-17.
[141] PSICOVID_00000008.
[142] *Id.* (emphasis added).
[143] PSICOVID_00000004-5 (emphasis included in original).

agency information.[144] Given that, in both instances, these emails were between a CDC official and a non-U.S. government official, the Biden administration's justification for the redaction was not valid.

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[144] Both emails are redacted and marked with the "b(5)" FOIA exemption. This exemption "[p]rotects the integrity of the deliberative or policy-making processes within the agency by exempting from mandatory disclosure opinion, conclusions, and recommendations included within inter-agency or intra-agency memoranda or letters." See FOIA Exemptions & Exclusions, Dep't of Health and Human Services, Aug. 28, 2015, https://www.hhs.gov/foia/exemptions-and-exclusions/index.html.

March 15, 2021 email: CDC expresses interest in post-vaccination deaths[145]

Produced by Biden administration with redactions

From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Monday, March 15, 2021 4:06 PM
To: [redacted] <EMILIA.ANIS@MOH.GOV.IL>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
Subject: Covid-19 vaccine safety data

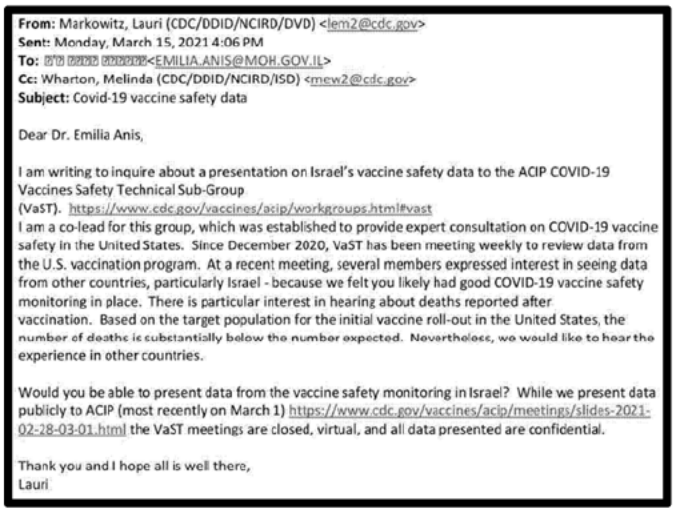
Dear Dr. Emilia Anis,

I am writing to inquire [redacted]

[redacted]

Thank you and I hope all is well there,
Lauri

Produced by Trump administration without redactions



From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>
Sent: Monday, March 15, 2021 4:06 PM
To: [redacted] <EMILIA.ANIS@MOH.GOV.IL>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>
Subject: Covid-19 vaccine safety data

Dear Dr. Emilia Anis,

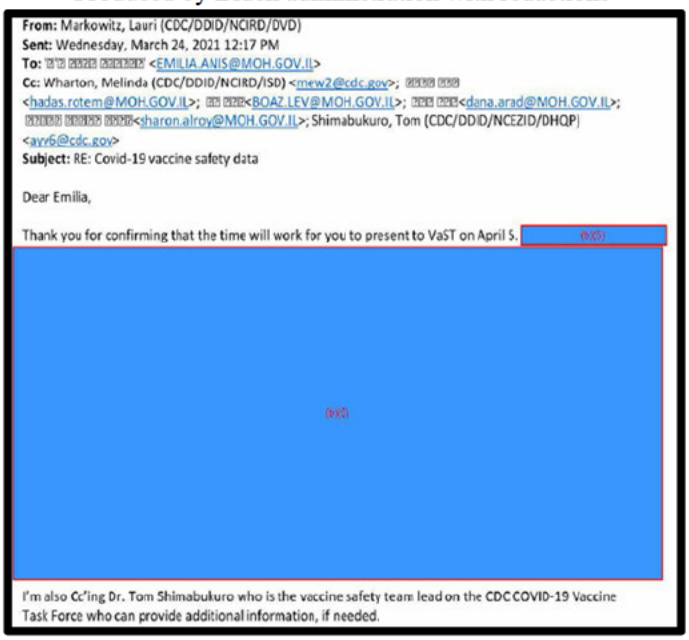
I am writing to inquire about a presentation on Israel's vaccine safety data to the ACIP COVID-19 Vaccines Safety Technical Sub-Group
(VaST). https://www.cdc.gov/vaccines/acip/workgroups.html#vast
I am a co-lead for this group, which was established to provide expert consultation on COVID-19 vaccine safety in the United States. Since December 2020, VaST has been meeting weekly to review data from the U.S. vaccination program. At a recent meeting, several members expressed interest in seeing data from other countries, particularly Israel - because we felt you likely had good COVID-19 vaccine safety monitoring in place. There is particular interest in hearing about deaths reported after vaccination. Based on the target population for the initial vaccine roll-out in the United States, the number of deaths is substantially below the number expected. Nevertheless, we would like to hear the experience in other countries.

Would you be able to present data from the vaccine safety monitoring in Israel? While we present data publicly to ACIP (most recently on March 1) https://www.cdc.gov/vaccines/acip/meetings/slides-2021-02-28-03-01.html the VaST meetings are closed, virtual, and all data presented are confidential.

Thank you and I hope all is well there,
Lauri

March 24, 2021 email: CDC reiterates interest in post-vaccination deaths[146]

Produced by Biden administration with redactions



From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Sent: Wednesday, March 24, 2021 12:17 PM
To: [redacted] <EMILIA.ANIS@MOH.GOV.IL>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; [redacted] <hadas.rotem@MOH.GOV.IL>; [redacted] <BOAZ.LEV@MOH.GOV.IL>; [redacted] <dana.arad@MOH.GOV.IL>; [redacted] <sharon.alroy@MOH.GOV.IL>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: Covid-19 vaccine safety data

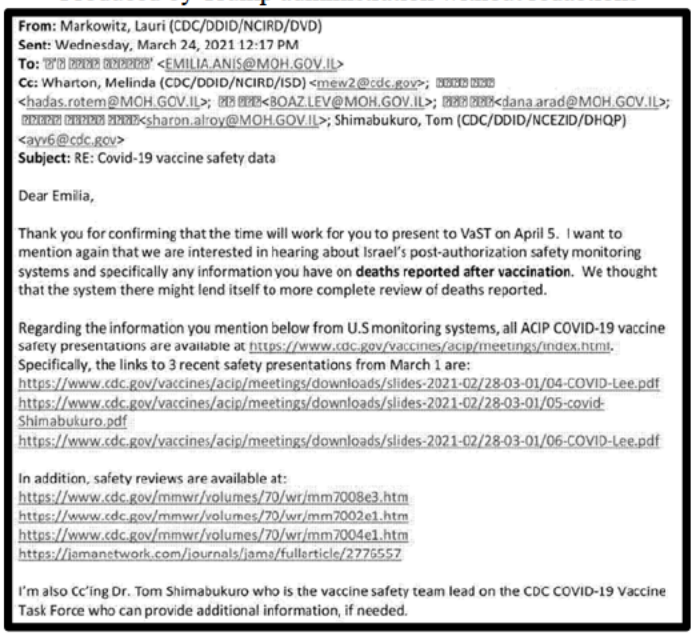
Dear Emilia,

Thank you for confirming that the time will work for you to present to VaST on April 5. [redacted]

[redacted]

I'm also Cc'ing Dr. Tom Shimabukuro who is the vaccine safety team lead on the CDC COVID-19 Vaccine Task Force who can provide additional information, if needed.

Produced by Trump administration without redactions



From: Markowitz, Lauri (CDC/DDID/NCIRD/DVD)
Sent: Wednesday, March 24, 2021 12:17 PM
To: [redacted] <EMILIA.ANIS@MOH.GOV.IL>
Cc: Wharton, Melinda (CDC/DDID/NCIRD/ISD) <mew2@cdc.gov>; [redacted] <hadas.rotem@MOH.GOV.IL>; [redacted] <BOAZ.LEV@MOH.GOV.IL>; [redacted] <dana.arad@MOH.GOV.IL>; [redacted] <sharon.alroy@MOH.GOV.IL>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>
Subject: RE: Covid-19 vaccine safety data

Dear Emilia,

Thank you for confirming that the time will work for you to present to VaST on April 5. I want to mention again that we are interested in hearing about Israel's post-authorization safety monitoring systems and specifically any information you have on **deaths reported after vaccination**. We thought that the system there might lend itself to more complete review of deaths reported.

Regarding the information you mention below from U.S monitoring systems, all ACIP COVID-19 vaccine safety presentations are available at https://www.cdc.gov/vaccines/acip/meetings/index.html. Specifically, the links to 3 recent safety presentations from March 1 are:
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/04-COVID-Lee.pdf
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf
https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/06-COVID-Lee.pdf

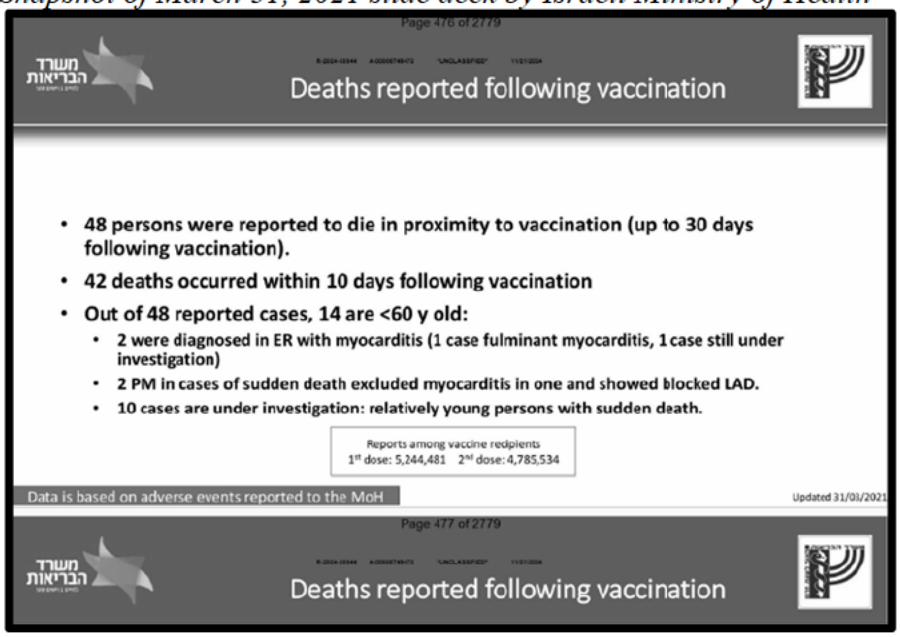
In addition, safety reviews are available at:
https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm
https://www.cdc.gov/mmwr/volumes/70/wr/mm7002e1.htm
https://www.cdc.gov/mmwr/volumes/70/wr/mm7004e1.htm
https://jamanetwork.com/journals/jama/fullarticle/2776557

I'm also Cc'ing Dr. Tom Shimabukuro who is the vaccine safety team lead on the CDC COVID-19 Vaccine Task Force who can provide additional information, if needed.

[145] FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 726; PSICOVID_00000008.
[146] FOIA production: https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf at 722; PSICOVID_00000004.

The slide deck that the Israeli Ministry of Health created for the CDC for its presentation included data on deaths reported after vaccination.[147] According to the slides, which then-Ranking Member Johnson enclosed in his December 5, 2024 letter to HHS, CDC, and FDA, as of March 31, 2021, Israeli health data showed that "48 persons were reported to die in proximity to vaccination (up to 30 days following vaccination)"; "42 deaths occurred within 10 days following vaccination"; "Out of 48 reported cases, 14 are <60 y old[.]"[148]

Snapshot of March 31, 2021 slide deck by Israeli Ministry of Health[149]



The "Confidential" notes on the April 5, 2021 VaST meeting that CDC shared to VaST members indicated that based on the data from Israel, "[t]here is no specific signal associated with all causes of death and specifically sudden death."[150]

To ensure transparency, Chairman Johnson is releasing documents today that are relevant to the December 5, 2024 letter as he awaits further productions from HHS on the Israeli health data.

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[147] Brenda Baletti, Mounting Evidence Suggests CDC Hid Data on COVID Vaccines and Myocarditis, The Defender, Nov. 27, 2024, https://childrenshealthdefense.org/defender/mounting-evidence-cdc-hid-data-covid-vaccines-myocarditis/; FOIA production: https://drive.google.com/file/d/1ywgzcxpfQI86lqslZPpYxylPuVnlgKfw/view at 20-22.
[148] FOIA production: https://drive.google.com/file/d/1ywgzcxpfQI86lqslZPpYxylPuVnlgKfw/view at 20; PSICOVID_00004397.
[149] *Id.*
[150] PSICOVID00008782, 8794-8797 at 8795.

III. In April 2021, a Defense Health Agency consultant warns HHS officials that a vaccine safety monitoring system called V-safe may not detect cardiac adverse events

Dr. Renata Engler, a consultant with the Defense Health Agency ("DHA") Immunization Healthcare Division at the Department of Defense ("DoD"), presented to U.S. public health officials during the April 12, 2021 VaST meeting.[151] Her presentation, which looked at cases of cardiac adverse events following vaccination, was entitled, "Further Considerations Related to Cluster of Cases Consistent with Hypersensitivity Myocarditis in Temporal Association with COVID-19 Vaccines in the Context of Lessons Learned."[152] Engler's presentation offered an apparent warning that CDC's "new individualized app to monitor symptoms and health status," called V-safe, may fall short in its ability to detect cardiac adverse events.[153]

a. Background on V-safe

CDC's January 28, 2021 V-safe protocol document described the safety system as:

> [A]n active surveillance program to monitor the safety of COVID-19 vaccines during the period when the vaccines are authorized for use under Food and Drug Administration (FDA) Emergency Use Authorization (EUA) and possibly early after vaccine licensure. V-safe is a new smartphone-based system that uses text messaging to initiate web-based survey monitoring in the form of periodic health check-ins to assess for potential adverse events following vaccination. CDC will use the follow-up capability of the existing Vaccine Adverse Event Reporting System (VAERS) call center to conduct active telephone follow-up on recipients reporting a significant health impact during v-safe health check-ins. The purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions.[154]

CDC also noted that, "V-safe originally launched in December 2020 to monitor the safety of the COVID-19 vaccines and later expanded to include mpox and RSV vaccines."[155] Since its launch, approximately 10 million people have participated in V-safe.[156]

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[151] It is unclear who attended the April 12, 2021 VaST meeting, but the U.S. public health officials that received DHA's slides and draft after-meeting notes included individuals from CDC, such as Drs. Tom Shimabukuro and John Su (who participated in the meeting), and other HHS, FDA, and NIH officials. *See, e.g.*, PSICOVID_00008798, 8800-8811, 8933-8948.
[152] PSICOVID_00008800.
[153] PSICOVID_00008808.
[154] V-safe active surveillance for COVID-19 vaccine safety, Centers for Disease Control and Prevention, Jan. 28, 2021, https://www.cdc.gov/vaccine-safety-systems/media/pdfs/v-safe-protocol-v2-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-v2-012821.pdf at 1.
[155] About V-safe, Centers for Disease Control and Prevention, last accessed May 6, 2025, https://www.cdc.gov/vaccine-safety-systems/v-safe/.
[156] *Id.*

b. V-safe lacks crucial information in its surveys

Public reports from late 2022 have documented how V-safe surveys—which were meant to allow users to conveniently report vaccine adverse events—were too narrow to properly identify myocarditis because the system lacked distinct categories for users to identify cardiac-related symptoms.[157] Instead, as one report noted, "V-safe users would have to write in cardiac symptoms on the survey form's 'other' field, limited to 250 characters, for them to be counted."[158]

Indeed, V-safe's protocol documents from 2021 do not contain any checkboxes that would clearly represent cardiac adverse events.

Snapshot from Jan. 28, 2021 V-safe protocol document showing available checkboxes for post-vaccination symptoms[159]

Have you experienced any of these symptoms today?
Select all that apply.

- ☐ Chills
- ☐ Headache
- ☐ Joint pain
- ☐ Muscle or body aches
- ☐ Fatigue or tiredness
- ☐ Nausea
- ☐ Vomiting
- ☐ Diarrhea
- ☐ Abdominal pain
- ☐ Rash, not including the immediate area around the injection site
- ☐ None

Any other symptoms or health conditions you want to report_____

As public reports previously noted, V-safe not only omitted cardiac-related symptoms in its checkboxes, it also failed to include the specific "Adverse Events of Special Interest" which CDC identified in its 2021 V-safe protocol document.[160] The complete list of those special

[157] *See, e.g.*, Aaron Siri, V-Safe Part 2: Evidence the CDC Purposely Did Not Include Check-The-Box Selections for Myocarditis, Pericarditis, Seizures, Stroke, and Other Known Potential Serious Harms in V-Safe, Nov. 25, 2022, https://aaronsiri.substack.com/p/v-safe-part-2-what-is-v-safe-what; Greg Piper, CDC knew COVID vax associated with myocarditis but left off post-vax surveys, Just the News, Nov. 28, 2022, https://justthenews.com/government/courts-law/premeditated-cdc-knew-covid-vax-associated-myocarditis-left-post-vax-surveys.

[158] Greg Piper, CDC knew COVID vax associated with myocarditis but left off post-vax surveys, Just the News, Nov. 28, 2022, https://justthenews.com/government/courts-law/premeditated-cdc-knew-covid-vax-associated-myocarditis-left-post-vax-surveys.

[159] V-safe active surveillance for COVID-19 vaccine safety, Centers for Disease Control and Prevention, Jan. 28, 2021, https://www.cdc.gov/vaccine-safety-systems/media/pdfs/v-safe-protocol-v2-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-v2-012821.pdf at 21-22.

[160] Aaron Siri, V-Safe Part 2: Evidence the CDC Purposely Did Not Include Check-The-Box Selections for Myocarditis, Pericarditis, Seizures, Stroke, and Other Known Potential Serious Harms in V-Safe, Nov. 25, 2022, https://aaronsiri.substack.com/p/v-safe-part-2-what-is-v-safe-what; Greg Piper, CDC knew COVID vax associated

interest medical conditions, which included myocarditis and pericarditis, is below:

Snapshot from Jan. 28, 2021 V-safe protocol document listing "Adverse Events of Special Interest"[161]

Attachment 2: Adverse Events of Special Interest

Prespecified Medical Conditions
Acute myocardial infarction
Anaphylaxis
Coagulopathy
COVID-19 Disease
Death*
Guillain-Barré syndrome
Kawasaki disease
Multisystem Inflammatory Syndrome in children[1]
Multisystem Inflammatory Syndrome in adults[2]
Myocarditis/Pericarditis
Narcolepsy/Cataplexy
Pregnancy and Prespecified Conditions
Seizures/Convulsions
Stroke
Transverse Myelitis

* Capture of deaths through v-safe will be limited.

In addition to the point that the specific conditions listed above were reportedly not included in V-safe surveys, the pre-filled symptom checkboxes that were available for users to mark do not appear to have clear associations with many of the "Adverse Events of Special Interest" such as myocarditis and pericarditis.

c. DHA consultant presents concerns about V-safe's limitations during April 12, 2021 VaST meeting

As previously mentioned, Engler, a consultant with DHA's Immunization Healthcare Division, presented to the VaST meeting on April 12, 2021 regarding the association of myocarditis with COVID-19 vaccines.[162] Her presentation appeared to compare historical

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with myocarditis but left off post-vax surveys, Just the News, Nov. 28, 2022, https://justthenews.com/government/courts-law/premeditated-cdc-knew-covid-vax-associated-myocarditis-left-post-vax-surveys.

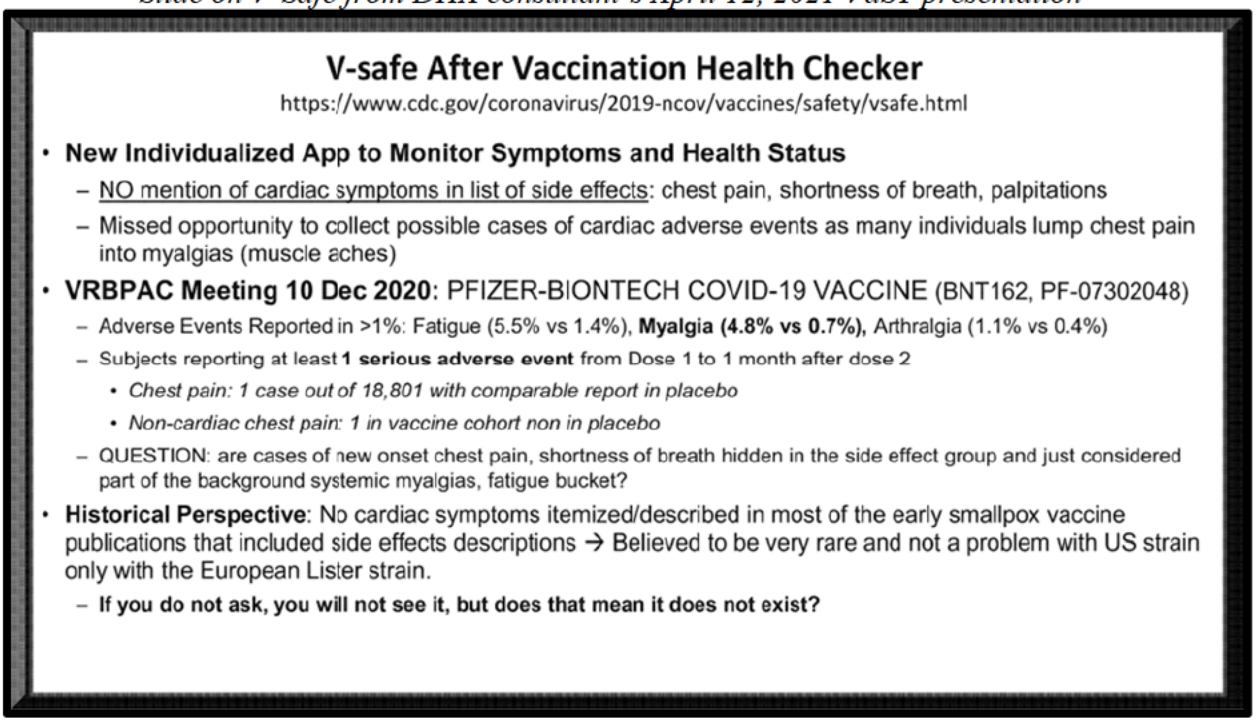
[161] V-safe active surveillance for COVID-19 vaccine safety, Centers for Disease Control and Prevention, Jan. 28, 2021, https://www.cdc.gov/vaccine-safety-systems/media/pdfs/v-safe-protocol-v2-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-v2-012821.pdf at 58.

[162] *See, e.g.*, PSICOVID_00008798, 8800-8811, 8933-8948.

information on the detection of adverse events related to the smallpox vaccine to the current detection of adverse events related to the COVID-19 vaccines.[163]

According to Engler's slides obtained by the Subcommittee, her presentation identified specific limitations with V-safe. Engler's presentation noted that in V-safe there is, "NO mention of cardiac symptoms in the list of side effects: chest pain, shortness of breath, palpitations[.]"[164] The presentation pointed out that this lack of information could result in a "[m]issed opportunity to collect possible cases of cardiac adverse events as many individuals lump chest pains into myalgias (muscle aches)[.]"[165] Engler posed the following question in her slide about V-safe's limitations: "**If you do not ask, you will not see it, but does that mean it does not exist?**"[166]

Slide on V-Safe from DHA consultant's April 12, 2021 VaST presentation[167]



Although public reporting from late 2022 would eventually identify similar limitations with V-safe, Engler's April 12, 2021 presentation is significant because it appears to be one of the earliest internal warnings to U.S. public health officials that V-safe could fail to detect cardiac adverse events, like myocarditis.[168] Given that V-safe was created to "detect and

[163] PSICOVID_00008800-8811.
[164] PSICOVID_00008808 (emphasis in original).
[165] *Id.*
[166] *Id.* (emphasis in original).
[167] *Id.*
[168] *See, e.g.,* Aaron Siri, V-Safe Part 2: Evidence the CDC Purposely Did Not Include Check-The-Box Selections for Myocarditis, Pericarditis, Seizures, Stroke, and Other Known Potential Serious Harms in V-Safe, Nov. 25, 2022, https://aaronsiri.substack.com/p/v-safe-part-2-what-is-v-safe-what; Greg Piper, CDC knew COVID vax associated with myocarditis but left off post-vax surveys, Just the News, Nov. 28, 2022,

evaluate clinically important adverse events and safety issues," it is inexcusable that the system failed to provide users a clear and convenient way to identify cardiac-related symptoms, particularly in early 2021 when U.S. health officials were made aware of increasing reports of myocarditis cases following COVID-19 vaccination.[169]

U.S. public health officials understood that vaccine safety surveillance systems, in general, have limitations.[170] For example, underreporting in VAERS was a known limitation and, by May 2021, CDC officials were discussing how this limitation may explain why there was an apparent lack of myocarditis reports in VAERS.[171] Yet, given the known limitation of underreporting in VAERS, it would seem prudent that V-safe provide users a comprehensive list of symptoms to choose from in the surveys. Instead, according to V-safe's protocol document from 2021 (as presented earlier), the survey narrowly offered users only 10 pre-programed symptoms to consider. V-safe's lack of symptoms for vaccinated users to identify made Engler's question at the end of her slide particularly significant: "If you do not ask, you will not see it, but does that mean it does not exist?"[172]

d. Updated V-safe protocol from May 2021 fails to address DHA consultant's concerns

Following Engler's April 12, 2021 presentation before the VaST working group, CDC updated the V-safe program, but did not address Engler's concerns. On May 20, 2021 CDC published an updated protocol document for V-safe.[173] The document identified four categories of changes to the program including, "[r]evised language to reflect revision of CDC follow-up calls to be specific to medically attended health events[.]"[174]

As a public report previously noted, in V-safe's January 28, 2021 protocol document, a user would receive a follow-up telephone call from VAERS call center staff if "during any v-safe health check-in, a participant reports a significant health impact event, defined as per the survey: a) missed work, and/or b) unable to do normal daily activities, and/or c) got care from a doctor or

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https://justthenews.com/government/courts-law/premeditated-cdc-knew-covid-vax-associated-myocarditis-left-post-vax-surveys.

[169] V-safe active surveillance for COVID-19 vaccine safety, Centers for Disease Control and Prevention, Jan. 28, 2021, https://www.cdc.gov/vaccine-safety-systems/media/pdfs/v-safe-protocol-v2-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-v2-012821.pdf at 1.

[170] *See, e.g.*, Steven Anderson, et al., Overview of U.S. COVID-19 vaccine safety surveillance system, Vaccine, Sept. 17, 2024, https://www.sciencedirect.com/science/article/pii/S0264410X2400224X?via%3Dihub.

[171] *See, e.g.*, PSICOVID_00004651; FOIA production: https://s3.documentcloud.org/documents/23656227/cdc-emails-chat-messages-on-post-vaccination-myocarditis.pdf at 257-258; 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/.

[172] PSICOVID_00008808.

[173] V-safe active surveillance for COVID-19 vaccine safety, Centers for Disease Control and Prevention, May 20, 2021, https://www.cdc.gov/vaccine-safety-systems/media/pdfs/v-safe-protocol-v3-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[174] *Id.* at 2. The three other changes were, "Modified protocol and survey language to reflect enhancement to v-safe that allows registration of dependents and completion of surveys for dependents"; "Additional language to reflect enhancements to the v-safe platform (ability to delete account on participant request, text reminders for 2nd dose)"; and "Minor edits to reflect current survey language and completion messages viewed at end of survey". *Id.*

other healthcare professional[.]"[175] The May 20, 2021 V-safe protocol document revised this practice by narrowing the criteria for initiating a follow-up call.[176] The updated protocol stated, in part, "[i]f, during any v-safe health check-in, a participant reports a significant, medically-attended health impact event for themselves or their dependent, including but not exclusive to requiring care in a hospital or emergency room setting, VAERS call center staff will be informed and active telephone follow-up will be initiated[.]"[177]

No changes were made to the list of symptoms in the V-safe survey in the protocol update.

[175] V-safe active surveillance for COVID-19 vaccine safety, Centers for Disease Control and Prevention, Jan. 28, 2021, https://www.cdc.gov/vaccine-safety-systems/media/pdfs/v-safe-protocol-v2-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-v2-012821.pdf at 5; Aaron Siri, V-Safe Part 3: Who Were the 10 Million V-Safe Users Reporting a 7.7% Rate of Seeking Medical Care After Covid-19-Vaccine? Anti-vaxxers? Pro-vaxxers?, Dec. 12, 2022, https://aaronsiri.substack.com/p/v-safe-part-3-who-were-the-10-million.

[176] V-safe active surveillance for COVID-19 vaccine safety, Centers for Disease Control and Prevention, May 20, 2021, https://www.cdc.gov/vaccine-safety-systems/media/pdfs/v-safe-protocol-v3-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf at 7-8; Aaron Siri, V-Safe Part 3: Who Were the 10 Million V-Safe Users Reporting a 7.7% Rate of Seeking Medical Care After Covid-19-Vaccine? Anti-vaxxers? Pro-vaxxers?, Dec. 12, 2022, https://aaronsiri.substack.com/p/v-safe-part-3-who-were-the-10-million.

[177] V-safe active surveillance for COVID-19 vaccine safety, Centers for Disease Control and Prevention, May 20, 2021, https://www.cdc.gov/vaccine-safety-systems/media/pdfs/v-safe-protocol-v3-508.pdf?CDC_AAref_Val=https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf at 8.

IV. Unredacted version of May 25, 2021 talking points from the Biden White House reveals the absurdity of the redactions made in FOIA documents

On May 25, 2021, Benjamin Wakana, the Biden White House's Deputy Director for Strategic Communications and Engagement, emailed then-CDC Director Rochelle Walensky, then-NIAID Director Anthony Fauci, and then-NIH Director Francis Collins, among others, a document that contained 17 pages of "tough" questions and answers on a variety of topics including myocarditis risks associated with the COVID-19 vaccine, COVID-19 vaccine efficacy, and the Wuhan lab leak.[178] The email and the associated document were released via FOIA with all 17 pages completely redacted.[179]

On November 19, 2024, then-PSI Ranking Member Johnson wrote to then-HHS Secretary Xavier Becerra, then-FDA Commissioner Robert Califf, and then-CDC Director Mandy Cohen requesting, among other items, the completely redacted, 17-page talking points document.[180] The Biden administration ignored the request.

Pursuant to Chairman Johnson's subpoena, HHS, under the current administration, produced the May 2021 talking points to the Subcommittee without any redactions.[181] With the redactions lifted, the public now has the opportunity to see how, contrary to the Biden administration's claims of transparency, federal health officials were anything but transparent.[182]

The 17-page document contains all the talking points the public heard ad nauseam from public health officials throughout the spring and summer of 2021 and into 2022. There is nothing new revealed in the unredacted document that needed to be hidden, which raises the question: why did the Biden administration obstruct the Subcommittee's efforts to obtain it? Perhaps they were embarrassed by how misleading the talking points are in retrospect.

a. Misleading claim: Reports of myocarditis are "rare"

The May 25, 2021 talking points document begins with a section entirely dedicated to information regarding the risk of myocarditis following COVID-19 vaccination. The image below is an excerpt from the section on myocarditis:

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[178] PSICOVID_00005295-5312.
[179] FOIA production: https://drive.google.com/file/d/1wgr-jdUTvvc8MgPnnghjcYLX1uC3L_tJ/view at 28-45; Letter from Ron Johnson, Ranking Member, Permanent Subcomm. on Investigations, to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Nov. 19, 2024, https://www.ronjohnson.senate.gov/services/files/00AAFB3D-72EE-475F-94D5-66708B4AA86D.
[180] *Id.*
[181] PSICOVID_00005295-5312. It is unclear why the Biden administration created this document. Other FOIA records dated May 24, 2021 contain communications among CDC officials regarding edits to a document that may be similar to the 17-page talking points document that the Biden White House eventually sends. Those emails appear to suggest that the document may be for a "Governors Call" scheduled for May 25, 2021. *See* FOIA production: https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view at 242-245.
[182] Biden White House pledges data, transparency, respect for free press, Reuters, Jan. 20, 2021, https://www.reuters.com/article/business/media-telecom/biden-white-house-pledges-data-transparency-respect-for-free-press-idUSKBN29Q08S/.

May 25, 2021: Biden White House circulates "Tough QA" including information on myocarditis[183]

Myocarditis
Toplines

- There have been rare reports of myocarditis and pericarditis occurring after vaccination.
- Reported cases appear to be mild and often go away without requiring treatment.
- These reports are rare given the number of vaccine doses administered, and CDC and FDA will continue to monitor and evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination.
- CDC continues to strongly recommend COVID-19 vaccination for individuals 12 years of age or older given the risk of COVID-19 illness and related, potentially severe, complications.
- Getting vaccinated is the best way to protect you and your family from COVID-19.

The above claim from the talking points that there had been "rare reports of myocarditis" was misleading.[184] As described in the previous section, in May 2021, CDC officials were well-aware of concerns that safety surveillance systems may not be capturing cases of myocarditis because, "providers aren't reporting these cases to VAERS[.]"[185] That was one of the apparent reasons why, according to CDC official Dr. Demetre Daskalakis, CDC was in the process of drafting the HAN in order to "alert providers to reporting since there is concern that the messages have not been trickling from the vaccine programs to providers at large."[186] Therefore, while the actual reports of myocarditis and pericarditis may have been rare at the time, CDC officials knew that the number of reports were likely not representative of the overall amount of cases.

It is important to note that as the Biden White House circulated these talking points to top U.S. public health officials downplaying the risk of myocarditis, CDC was still in the midst of drafting a HAN message on that adverse event. It is unclear, though, whether these talking points, which minimized the risk and harm of myocarditis, had any effect on the decision to not issue the HAN.

b. Misleading claim: CDC is being transparent with the public

Under the same myocarditis section, the talking points document included the question, "Are you afraid these reports [on myocarditis] will impact your vaccination efforts?"[187] The written response was:

> **CDC continues to transparently communicate with the American people.** Our independent vaccine working group published data online about this issue late last

[183] PSICOVID_00005297.
[184] *Id.* (emphasis in original).
[185] FOIA production: https://s3.documentcloud.org/documents/23656227/cdc-emails-chat-messages-on-post-vaccination-myocarditis.pdf at 257-258.
[186] PSICOVID_00004651.
[187] PSICOVID_00005297.

> week. As the CDC has made clear, these occurrences are rare, and the reported cases have been mild and often go away without requiring treatment. CDC does not have cause for concern and strongly recommends that people get vaccinated as soon as possible to protect against COVID-19 and the related, potentially severe, complications that occur.[188]

It is somewhat ironic that in the FOIA version of these talking points, the Biden administration redacted the sentence about CDC's transparent communication with the American people. In reality, CDC and the Biden administration as a whole were anything but transparent with the public regarding COVID-19 vaccine safety and efficacy. By May 2021, the Biden administration was aware of increasing reports of myocarditis following COVID-19 vaccination.[189] Rather than taking the necessary and transparent actions to warn the public about this risk, U.S. public health officials decided against issuing a HAN on myocarditis and waited another month to update the labels on the Pfizer and Moderna COVID-19 vaccines, formally warning the public about myocarditis and pericarditis.[190]

c. Misleading claims: "Getting vaccinated gets us back to normal," "The best way to protect against COVID is to get vaccinated"

The May 2021 talking points included some claims that both at the time, and certainly in retrospect, sound absurd. Under the section titled "confidence," the talking points document included the claims "getting vaccinated gets us back to normal" and "the best way to protect against COVID is to get vaccinated."[191] These statements appeared to falsely imply that in order for the public to resume its pre-pandemic routines, individuals would have to get the COVID-19 vaccine. These were deceptive and dangerous declarations. Not only did the COVID-19 vaccines fail to eliminate breakthrough infections, the extent of both the short and long-term health effects of the vaccines were not fully realized at the time.[192] Therefore, the implication that individuals needed to get vaccinated in order to return to "normalcy" was baseless and created undue pressure on those who had reasonable safety questions and concerns about the vaccines.

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[188] *Id.* (emphasis added).
[189] *See, e.g.*, PSICOVID_00004600-4601; PSICOVID_00004393.
[190] Coronavirus (COVID-19) Update: June 25, 2021, Food and Drug Administration, Jun. 25, 2021, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-june-25-2021.
[191] PSICOVID_00005305; PSICOVID00005309.
[192] Nathan C. Lo et al., Infectiousness of SARS-CoV-2 breakthrough infections and reinfections during the Omicron wave, Nature Medicine, Jan. 2, 2023, https://www.nature.com/articles/s41591-022-02138-x.

V. Conclusion

The Biden administration's decision to downplay the COVID-19 vaccine health risks and delay warning the public about cardiac-related adverse events associated with the mRNA vaccines jeopardized the public's health. Further, based on the records discussed above, it is clear that CDC and FDA officials only relied on the vaccine safety surveillance systems as a means to an end. While some CDC officials recognized that cases of myocarditis may not be captured in VAERS due to underreporting, other U.S. public health officials used the lack of a safety signal in VAERS as justification to forego the issuance of a public health warning.[193]

In addition, in April 2021, a DHA consultant warned top U.S. public health officials at HHS, CDC, FDA, and NIH, that another safety surveillance system, V-safe, could miss "possible cases of cardiac adverse events" because it lacked any mention of cardiac symptoms in its pre-programmed list of vaccine side effects for individuals to check off.[194] Regarding V-safe's omission of inquiries related to cardiac-related symptoms, the DHA consultant questioned her colleagues: "If you do not ask, you will not see it, but does that mean it does not exist?"[195] Rather than updating the V-safe program to include cardiac-related symptoms, or take further steps to account for cases of underreporting in VAERS, CDC and FDA officials appeared to believe—either intentionally or not—that the lack of reports of myocarditis, or other cardiac-related symptoms, in its vaccine safety surveillance systems meant that the health risk was not significant and the need to issue a formal HAN message or the less formal "clinical considerations" was not necessary.[196]

However, when VAERS did apparently signal for a cardiac-related adverse event, U.S. public health officials did not issue the formal HAN message. As discussed in the report, the "confidential" draft notes based on a May 24, 2021 VaST meeting did acknowledge a safety signal for myopericarditis for age groups 16-17 years and 18-24 years.[197] Yet, publicly, health officials continued to downplay the risk of cardiac-related adverse events associated with the COVID-19 vaccine. Indeed, the May 25, 2021 talking points from the Biden White House, underscored the misleading belief that because reports of myocarditis were rare, "CDC does not have cause for concern."[198]

As evidenced by the records presented in the report, including the May 25, 2021 Biden White House "Tough QA" document, federal health officials' primary concern was not cardiac-related adverse events associated with the mRNA vaccines, but instead appears to have been

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[193] *See, e.g.*, FOIA production: https://s3.documentcloud.org/documents/23656227/cdc-emails-chat-messages-on-post-vaccination-myocarditis.pdf at 257-258; PSICOVID_00004651; FOIA production: https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view at 301-302; PSICOVID_00005568.
[194] PSICOVID_00008808.
[195] *Id.*
[196] *See, e.g.*, PSICOVID_00004651; FOIA production: https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view at 301-302; PSICOVID_00005568.
[197] PSICOVID_00009452.
[198] PSICOVID_00005297.

vaccine hesitancy and mandating the injection for virtually every American.[199] It is not surprising then, that they weren't finding what they weren't looking for. The lack of response to Senator Johnson's multiple oversight letters which repeatedly highlighted the safety signals that were obvious to him, confirm the extent to which the agencies turned a blind eye to the COVID-19 vaccine adverse events.

In chronological order, here are excerpts from Senator Johnson's oversight letters from 2021 raising the alarm over COVID-19 vaccine adverse events and injuries:

In a **July 13, 2021** letter to NIH, CDC, and FDA, Senator Johnson wrote, "[w]hen I did specifically raise the alarming safety signals emanating from VAERS . . . with Director Collins in a meeting with other Senate Republicans on April 27, 2021, his dismissive reaction to my concerns was more than troubling. By that date, the number of deaths following COVID-19 vaccination reported to VAERS had already reached 3,411, with 1,349 or 39.5 percent of those deaths occurring on Day 0, 1, or 2 following vaccination."[200] He continued, "[a]s of July 2, 2021, VAERS reported 5,247 domestic deaths with 1,814 or 34.6 percent of those deaths occurring on Day 0, 1, or 2 following receipt of a COVID-19 vaccine."[201]

In an **August 22, 2021** letter to NIH, CDC, and FDA, Senator Johnson wrote, "[a]s of August 20, 2021, VAERS is reporting 12,791 worldwide deaths associated with the three Covid-19 vaccines available under an FDA Emergency Use Authorization (EUA). Of those deaths, 4,632 occurred on Day 0, 1, or 2 following vaccination. As the CDC and the FDA are quick to point out, VAERS reports do not prove causation. But this number of deaths, particularly with 36.2% occurring within 2 days of vaccination, should raise serious concerns."[202] He continued, "[i]t should also be noted that the 12,791 deaths related to Covid-19 vaccines reported on VAERS over the period of 8 months, compares to 8,966 deaths related to all other vaccines reported on VAERS since the inception of VAERS – a period of 31 years. And this does not raise alarm bells within your agencies, or cause you to reconsider assembling an independent safety panel of outside experts?"[203] And further, "[i]n addition to deaths, VAERS is also reporting 16,044 permanent disabilities, 51,242 hospitalizations, and 571,831 total adverse events related to the Covid-19 vaccines. I am receiving a growing number of letters from doctors and nurses detailing the vaccine injuries they are witnessing and treating, together with the suppression and censoring of this information they are experiencing."[204]

In a **September 7, 2021** letter to the FDA, Senator Johnson wrote, "[a]s of August 27, 2021, VAERS is reporting 13,911 deaths and 650,077 total adverse events worldwide following

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[199] PSICOVID_00005305; PSICOVID00005309.
[200] Letter from Sen. Ron Johnson, to Francis Collins, Dir., National Institutes of Health, Rochelle Walensky, Dir., Centers for Disease Control and Prevention, and Janet Woodcock, Acting Commissioner, Food and Drug Admin., July 13, 2021, https://www.ronjohnson.senate.gov/services/files/17788FED-A947-4143-8C1B-95C59E60EE87.
[201] *Id.*
[202] Letter from Sen. Ron Johnson, to Francis Collins, Dir., National Institutes of Health, and Rochelle Walensky, Dir., Centers for Disease Control and Prevention, and Janet Woodcock, Acting Commissioner, Food and Drug Admin., Aug. 22, 2021, https://www.ronjohnson.senate.gov/services/files/10CC4263-0337-453F-B9E5-1E5BA0FDFD10.
[203] *Id.*
[204] *Id.*

receipt of a COVID-19 vaccine. Of the 13,911 deaths, 4,909 (35.3%) have occurred on Day 0, 1, or 2 following vaccination. I fully understand that VAERS does not prove causation, but 35.3% of deaths occurring so soon after vaccination should cause serious concern. Furthermore, VAERS is known to significantly underreport adverse events, raising concerns that the 13,911 deaths and 650,077 adverse events does not provide the full picture. To give perspective, since VAERS's inception, there have been a total of 1,838 deaths reports for flu vaccines over a period of 31 years, or an average of 59 vaccine death reports per year."[205]

In an **October 5, 2021** letter to HHS, NIAID, CDC, and FDA Senator Johnson wrote, "[i]t is beyond puzzling that the federal government continues to ignore foundational medical principles like early treatment or natural immunity, that federal agencies lack basic data regarding vaccine immunity and durability, and that agencies will highlight the relatively few adverse events for one treatment—ivermectin—but largely ignore hundreds of thousands of adverse events and over 15,000 deaths reported on VAERS for COVID-19 vaccines."[206] He continued, "[s]ince 1996, the combined number of reported deaths associated with ivermectin on both VAERS and FAERS totals 379, with 3,680 adverse events. In contrast, since December, 2020, the worldwide total number of deaths associated with COVID-19 vaccines reported on VAERS is 15,386 and the worldwide total number of adverse events exceed 725,000."[207]

In an **October 14, 2021** letter to NIH, CDC, and FDA, Senator Johnson wrote, "[y]ou have failed to take your own safety surveillance systems seriously, even though the latest figures for COVID-19 vaccines from the Vaccine Adverse Event Reporting System includes 16,310 deaths (with 5,326 of those deaths occurring on Day 0, 1 or 2 following vaccination) and 778,685 total adverse events."[208]

And finally, in a **December 29, 2021** letter to CDC, Senator Johnson wrote, "[t]hrough December 17, 2021, there have been 983,758 total adverse events and 20,622 deaths reported worldwide associated with the COVID-19 vaccines. Of the 20,622 deaths, 6,232 (30%) have occurred on day 0,1, or 2 following vaccination. In contrast, over 30 years of reporting on seasonal flu vaccines, there have been a total of 200,264 adverse events and 2,078 deaths."[209]

As evidenced above, despite instances of underreporting, the data contained in VAERS throughout 2021 was highly concerning. In October 2020, Dr. Tom Shimabukuro, one of CDC's top vaccine safety surveillance officials, touted that "VAERS can rapidly detect safety signals and can detect rare adverse events."[210] Although Senator Johnson repeatedly sounded the alarm

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[205] Letter from Sen. Ron Johnson, to Janet Woodcock, Acting Commissioner, Food and Drug Admin., et al., Sept. 7, 2021 (on file with Subcomm.).
[206] Letter from Sen. Ron Johnson, et al., to Xavier Becerra, Secretary, Dep't of Health and Human Services, et al., Oct. 5, 2021, https://www.ronjohnson.senate.gov/services/files/3F84D215-46DE-4FD4-A317-A110D1EF1468.
[207] *Id.*
[208] Letter from Sen. Ron Johnson, to Francis Collins, Dir., National Institutes of Health, et al., Oct. 14, 2021, https://www.ronjohnson.senate.gov/services/files/7EC06E87-9F6F-4E22-8877-8D519CF25A32.
[209] Letter from Sen. Ron Johnson, to Janet Woodcock, Acting Commissioner, Food and Drug Admin., and Rochelle Walensky, Dir., Centers for Disease Control and Prevention, Dec. 29, 2021, https://www.ronjohnson.senate.gov/services/files/F564153D-89FD-40C9-A1B1-8663C22D2F0A.
[210] Tom Shimabukuro, Presentation before the Vaccines and Related Biological Products Advisory, Oct. 22, 2020, transcript available at https://www.fda.gov/media/143982/download at 94.

to federal health agencies and continuously presented troubling data from their own safety surveillance system, his warnings were unheeded.

As of April 25, 2025, VAERS reported 38,607 deaths and 1,663,348 total adverse events worldwide associated with the administration of COVID-19 injections.[211] Of the 38,607 deaths, 9,228 (25%) have occurred on Day 0, 1, or 2 following injection.[212] This compares to 2,663 deaths reported to VAERS associated with the flu vaccine over a period of 35 years.[213] No other reports of adverse events associated with any other drug or vaccine even come close to these statistics.[214] And yet, those who oversaw the development and distribution of the COVID-19 vaccines continue to insist it is safe and effective, without providing the data to prove their claims.[215]

The full extent of the Biden administration's failure to immediately warn the public about all COVID-19 vaccine adverse events must be completely exposed. While the Trump administration has promised "radical transparency," achieving that goal will be challenging.[216] The institutional roadblocks that have been constructed over decades will take time to dismantle, and the Subcommittee is aware of allegations suggesting document destruction and purposeful evasion of FOIA.[217]

The American people fund the federal health departments and agencies with their hard-earned tax dollars. The information developed by these departments and agencies belong to the American people, and should be made fully and transparently available. As the roadblocks are removed and more documents that have been hidden and withheld for years become available,

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[211] *See* VAERS database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/25/2025, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers html on May 12, 2025 12:16:08 PM. Query criteria –Vaccine Products: COVID-19 Vaccine (COVID19); COVID-19-2 (COVID-192). Group By: Month Received. State/Territory: All locations. Event Category: All Events. Show Totals: True. Show Zero Values: False; VAERS database query: United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/25/2025, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on May 12, 2025 12:16:08 PM. Query criteria – Vaccine Products: COVID-19 Vaccine (COVID19); COVID-19-2 (COVID-192). Group By: Month Received. State/Territory: All locations. Event Category: Death. Show Totals: True. Show Zero Values: False.

[212] CDC VAERS system. Reports from all locations worldwide. COVID-19 & Influenza vaccines. Deaths onset intervals, 0 days, 1 day, 2 days. Data as of April 25, 2025; downloaded May 12, 2025.

[213] FDA FAERS system, CDC VAERS system. Reports from all locations worldwide. Data as of April 25, 2025; downloaded May 12, 2025.

[214] *Id.*

[215] *See, e.g.*, Mary Kekatos, FDA approves updated COVID-19 vaccines for upcoming fall and winter season, ABC News, Aug. 22, 2024, https://abcnews.go.com/Health/fda-approves-updated-covid-19-vaccines-upcoming-fall/story?id=113066054.

[216] Fact Sheet: President Donald J. Trump Requires Transparency for the American People About Wasteful Spending, White House, Feb. 18, 2025, https://www.whitehouse.gov/fact-sheets/2025/02/fact-sheet-president-donald-j-trump-requires-transparency-for-the-american-people-about-wasteful-spending/.

[217] *See, e.g.*, Letter from Ron Johnson, Chairman, Permanent Subcomm. on Investigations, to Pamela Bondi, Attorney General, Dep't of Justice, et al., Apr. 9, 2021, https://www.ronjohnson.senate.gov/services/files/7EC8AB4F-A151-4ADD-8603-7AA906295FC9.

the Permanent Subcommittee on Investigations will provide transparency and let the American public see what is their right to see.