

United States Senate

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

DAVID M. WEINBERG, STAFF DIRECTOR
WILLIAM E. HENDERSON III, MINORITY STAFF DIRECTOR
LAURA W. KILBRIDE, CHIEF CLERK

November 19, 2024

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services

The Honorable Robert Califf
Commissioner
Food and Drug Administration

Dr. Mandy Cohen
Director
Centers for Disease Control and Prevention

Dear Secretary Becerra, Commissioner Califf, and Director Cohen:

The lack of transparency from your agencies during the Biden presidency has been appalling. Your agencies' refusal to provide complete and unredacted responses and documents to my numerous oversight letters on the development and safety of the COVID-19 vaccines has hindered Congressional oversight and has jeopardized the public's health.

In addition to hiding relevant information from Congress, your agencies have applied heavy redactions to public documents released under Freedom of Information Act (FOIA) requests. These redactions have made many of these public documents hard to understand and, in countless instances, impossible to read. What is clear from these excessive redactions, however, is a concerted effort to obscure Congress' and the public's understanding of your agencies' detection of and response to COVID-19 vaccine adverse events such as myocarditis and pericarditis. The following three examples from May 2021 highlight only a small fraction of communications and documents on myocarditis and pericarditis your agencies continue to conceal.

I. Heavily Redacted Pfizer Report on Myocarditis and Pericarditis

FOIA documents and public reporting indicate that in early 2021, the Centers for Disease Control and Prevention (CDC) received reports about post-vaccinated cases of myocarditis and pericarditis.¹ By May 22, 2021, heavily redacted documents reveal that then-CDC Director

¹ 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?utm_source=ref_share&utm_campaign=twitter&rs=SHRNCMMW; 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/>; FOIA production: <https://childrenshealthdefense.org/wp-content/uploads/23-00056-for-2-24-2023-Close.pdf> at 666-668,

Rochelle Walensky received Pfizer data regarding myocarditis cases as well as an attachment of a document with the file name, "APPENDIX 3.7 SAFETY EVALUATION OF MYOCARDITIS AND PERICARDITIS.pdf."² The 14-page attachment is completely redacted except for the cover page which indicates that the document is a "Report Prepared by: BioNTech-Pfizer."³

May 22, 2021: Partial email, then-CDC Director Walensky receives Pfizer report on myocarditis/pericarditis⁴

From: (b)(6)
Sent: Sat, 22 May 2021 16:12:05 -0700
To: Walensky, Rochelle (CDC/OD)
Subject: Fwd: Myocarditis //// This is the right attachment
Attachments: APPENDIX 3.7 SAFETY EVALUATION OF MYOCARDITIS AND PERICARDITIS.pdf

The attachment has the Israeli data included. It has all been sent to your team.

Sent from my iPhone

Begin forwarded message:

From: "Caubel, Patrick" <Patrick.Caubel@pfizer.com>
Date: May 22, 2021 at 4:02:35 PM PDT
To: (b)(6)
Subject: Myocarditis //// This is the right attachment

Larry,

This is the data for MYOCARDITIS (excluding pericarditis). Cut-off date is today.

(b)(4)

Number of valid Adverse Events cases reported to Pfizer as of today is (b)(4) are myocarditis cases).

(b)(4)

Attached our latest monthly aggregate analysis .

Patrick

Month	# cases received
Jan 2021	(b)(4)
Feb 2021	
Mar 2021	

710-713; FOIA production: <https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view> at 301-302.

² FOIA production: <https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view> at 424.

³ *Id.* at 426-440.

⁴ *Id.* at 424. FOIA code (b)(4) is used to protect trade secrets and other confidential business information. FOIA code (b)(6) is used to protect information involving matters of personal privacy. *What information is available under the FOIA?* Dep't of Health & Hum. Servs. <https://www.hhs.gov/foia/faqs/what-information-is-available-under-the-foia/index.html> (last visited Nov. 19, 2024).

Cover of 14-Page heavily redacted April 2021 Pfizer report on Myocarditis and Pericarditis⁵

PF-07302048 (BNT162b2) Summary Monthly Safety Report (SMSR) 5	Reporting Period 01 April 2021 through 29 April 2021
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Pfizer-BioNTech COVID-19 Vaccine

Myocarditis and Pericarditis

Report Prepared by:

BioNTech-Pfizer

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Page 1

⁵ FOIA production: <https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view> at 426.

As a result of the redactions contained in this Pfizer report and the CDC's May 22, 2021 email, it is unclear what information then-CDC Director Walensky received regarding cases of myocarditis and pericarditis associated with the Pfizer COVID-19 vaccine.

II. CDC's Draft Alert on Myocarditis Risk

Shortly after receiving Pfizer's data on myocarditis and pericarditis then-CDC Director Walensky and other CDC officials, contemplated whether to issue a warning to the public about the risk of myocarditis among the vaccinated.⁶ In May 2021, CDC officials had drafted a Health Alert Network (HAN) message that would have warned the public about the risk of myocarditis.⁷ According to CDC's website, the HAN 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."⁸

A partially redacted document shows that on May 23, 2021, then-CDC Director Rochelle Walensky received a draft of the HAN message on myocarditis.⁹ The draft HAN cited in the FOIA document was not produced.¹⁰

⁶ 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>.

⁷ *Id.*

⁸ Health Alert Network (HAN), Centers for Disease Control and Prevention, Last Reviewed: Mar. 7, 2022, <https://emergency.cdc.gov/han/>.

⁹ FOIA production: <https://drive.google.com/file/d/1K6B25XjBdKmjW5yEIEpZ1cvnr6jp3RAY/view> at 315.

¹⁰ *Id.* (records released in connection with this FOIA request do not contain a copy of the draft HAN attached to the May 23, 2021 email).

May 23, 2023: Then-CDC Director Walensky receives draft warning on myocarditis¹¹

From: Walensky, Rochelle (CDC/OD)
Sent: Sun, 23 May 2021 19:16:09 +0000
To: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Subject: RE: DRAFT_Myocarditis_Advisory_05232021_1109

Great – sounds good...thank you!
R

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Sunday, May 23, 2021 1:33 PM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Subject: RE: DRAFT_Myocarditis_Advisory_05232021_1109

Perfect, will push it through.

I think Health advisory, (b)(5)
(b)(5)

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Sent: Sunday, May 23, 2021 1:17 PM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Subject: RE: DRAFT_Myocarditis_Advisory_05232021_1109

Thank you – Will it be a full HAN –
I’m fine with how this reads...grateful.
R

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Sunday, May 23, 2021 1:12 PM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Subject: DRAFT_Myocarditis_Advisory_05232021_1109

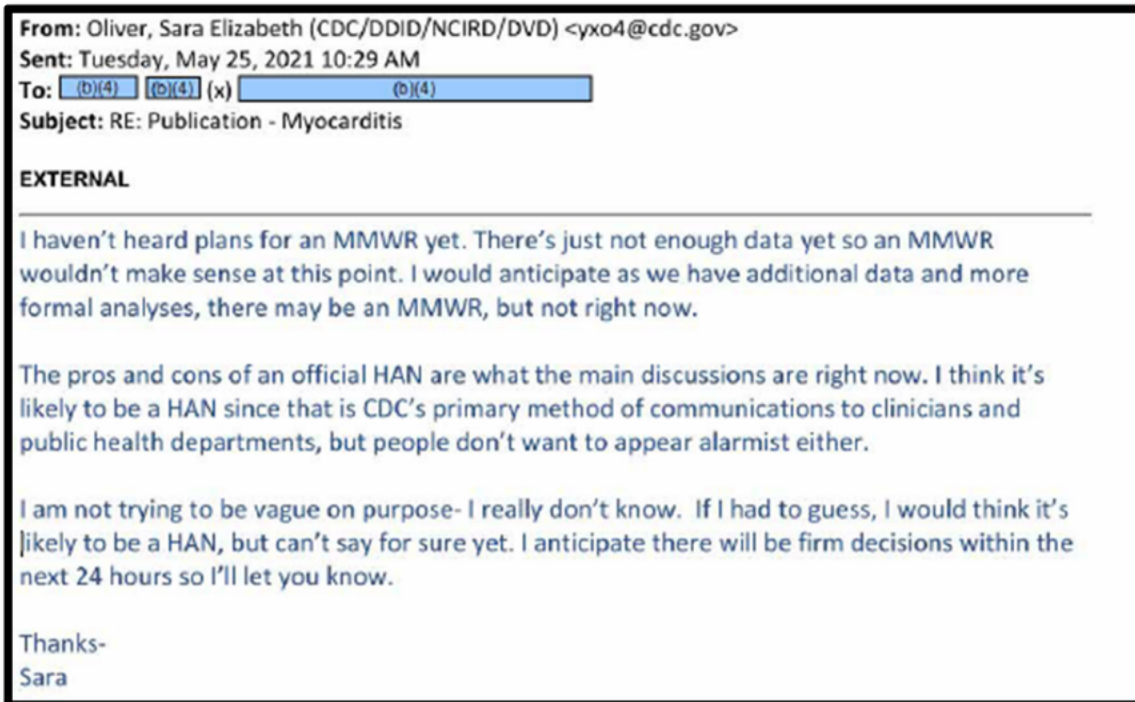
Latest HAN.

In a May 25, 2021 email, a CDC official wrote to a redacted individual—reportedly a Pfizer or Moderna employee—and shared that there are ongoing discussions about the “pros” and “cons” of issuing a HAN and that “people don’t want to appear alarmist[.]”¹²

¹¹ *Id.* FOIA code (b)(5) 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 & Hum. Servs. <https://www.hhs.gov/foia/faqs/what-information-is-available-under-the-foia/index.html> (last visited Nov. 19, 2024).

¹² 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.

*May 25, 2021: CDC official tells Pfizer or Moderna employee about HAN discussions*¹³



CDC never issued the HAN alert and, according to public reports, that decision may have been influenced by the Food and Drug Administration (FDA).¹⁴ Instead, on May 28, 2021, CDC published “clinical considerations” on its website regarding myocarditis, 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.”¹⁵

Starting in January 2024, following public reporting on the CDC's draft HAN alert, my office requested CDC provide all versions of the draft alert, all communications regarding the decision to not issue the HAN and instead publish the clinical consideration, and briefings with the CDC officials involved in the drafting of the HAN. To date, CDC has refused to cooperate with any of these requests.

¹³ *Id.*

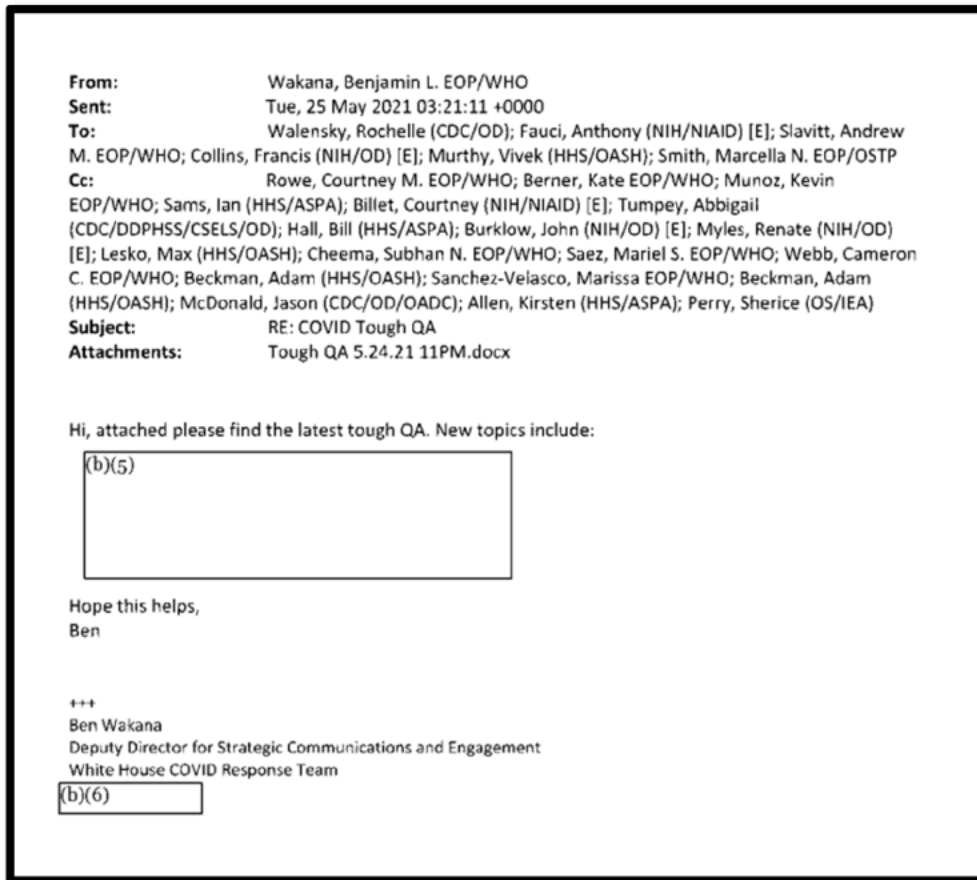
¹⁴ Zachary Stieber, FDA Influenced Decision Not to Send Alert on Post vaccination Heart Inflammation: Emails, Epoch Times, Jan. 21, 2024, https://www.theepochtimes.com/health/fda-influenced-decision-not-to-send-alert-on-postvaccination-heart-inflammation-emails-5570033?utm_medium=social&utm_source=twitter&utm_campaign=digitalsub.

¹⁵ *Id.*; 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://archive.is/AnF6y#selection-507.0-507.128>. Other FOIA documents indicate that the clinical considerations on myocarditis were posted on May 27, 2021 and then were “pulled down” after ten minutes. Email from Abbigail Tumpsey, Centers for Disease Control and Prevention, to Rochelle Walensky, Dir., Centers for Disease Control and Prevention, May 27, 2021 (on file with Subcomm.).

III. The White House's Talking Points to Rochelle Walensky, Anthony Fauci, and Francis Collins

In late May 2021, as CDC officials reviewed Pfizer data on post-vaccinated cases of myocarditis and pericarditis and as CDC and FDA officials hesitated to issue a public alert about these risks, the Biden White House sent the U.S.'s top public health officials 17 pages of apparent talking points for "tough QA" on COVID.¹⁶ On May 25, 2021, Benjamin Wakana, the White House's Deputy Director for Strategic Communications and Engagement, emailed then-CDC Director Walensky, then-National Institute of Allergy and Infectious Diseases Director Anthony Fauci, and then-National Institutes of Health Director Francis Collins, among others, a document writing, "attached please find the latest tough QA. New topics include:"¹⁷ The "new topics" listed in the email as well as the 17-page attachment are completely redacted.

*May 25, 2021 email from White House to Walensky, Fauci, Collins
with completely redacted 17-page attachment¹⁸*



¹⁶ 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/>; FOIA production: https://drive.google.com/file/d/1wgr-jdUTvvc8MgPnngjhcYlX1uC3L_tJ/view at 28-45.

¹⁷ FOIA production: https://drive.google.com/file/d/1wgr-jdUTvvc8MgPnngjhcYlX1uC3L_tJ/view at 28.

¹⁸ *Id.*

The redactions in this email and the attachment make it impossible to know what “tough QA” the Biden White House wanted Walensky, Fauci, and Collins to have on hand. Ultimately, despite your agencies’ awareness of the risks associated with the COVID-19 vaccines, the main talking point from these and other public health officials was uniform and entirely deceptive: the vaccines are safe and effective.

####

For the last several years, I have sent over 60 public letters to federal agencies on COVID-19 regarding the virus’ origins, early treatment, and the development and safety of the vaccines. While your agencies have largely ignored or failed to fully cooperate with my oversight efforts, I can assure you that your obstruction will soon come to an end. In the next Congress, when I become chairman of the Permanent Subcommittee on Investigations, any attempt by your agencies to withhold documents will be met with a subpoena.

Until then, my oversight work must continue and I, once again, call on you to provide full and complete responses to the following requests:

1. An unredacted version of Enclosure 1.
2. All versions of the draft 2021 HAN on myocarditis and communications referring or relating to the drafting of the HAN, the drafting of the clinical considerations on myocarditis, the decision to not release the HAN, and an unredacted version of Enclosure 2.
3. An unredacted version of Enclosure 3.

I also call on your agencies to immediately preserve all records¹⁹ referring or relating to the development, safety, and efficacy of the COVID-19 vaccines. Please provide the requested information no later than December 3, 2024. Thank you for your attention.

Sincerely,



Ron Johnson
Ranking Member
Permanent Subcommittee on Investigations

Enclosures

¹⁹ “Records” include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (emails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents).

November 19, 2024

Page 9

cc: The Honorable Richard Blumenthal
Chairman
Permanent Subcommittee on Investigations

The Honorable Christi Grimm
Inspector General
Department of Health and Human Services

Enclosure 1

From: (b)(6)
Sent: Sat, 22 May 2021 16:12:05 -0700
To: Walensky, Rochelle (CDC/OD)
Subject: Fwd: Myocarditis //// This is the right attachment
Attachments: APPENDIX 3.7 SAFETY EVALUATION OF MYOCARDITIS AND PERICARDITIS.pdf

The attachment has the Israeli data included. It has all been sent to your team.

Sent from my iPhone

Begin forwarded message:

From: "Caubel, Patrick" <Patrick.Caubel@pfizer.com>
Date: May 22, 2021 at 4:02:35 PM PDT
To: (b)(6)
Subject: Myocarditis //// This is the right attachment

Larry,

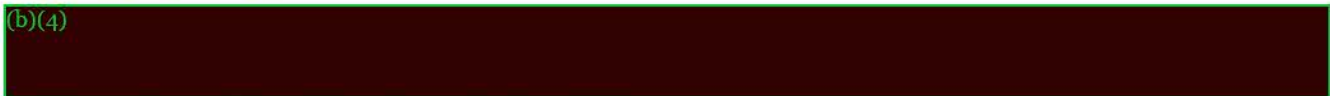
This is the data for MYOCARDITIS (excluding pericarditis). Cut-off date is today.

(b)(4)



Number of valid Adverse Events cases reported to Pfizer as of today is (b)(4) are myocarditis cases).

(b)(4)



Attached our latest monthly aggregate analysis .

Patrick

Month	# cases received
Jan 2021	(b)(4)
Feb 2021	(b)(4)
Mar 2021	(b)(4)

Apr 2021	(b)(4)
May 2021	(b)(4)

Country	# cases
Austria	(b)(4)
Belgium	(b)(4)
Canada	(b)(4)
Czech Republic	(b)(4)
Denmark	(b)(4)
Finland	(b)(4)
France	(b)(4)
Germany	(b)(4)
Greece	(b)(4)
Ireland	(b)(4)
Israel	(b)(4)
Italy	(b)(4)
Japan	(b)(4)
Poland	(b)(4)
Portugal	(b)(4)
Serbia	(b)(4)
Spain	(b)(4)
Sweden	(b)(4)
Switzerland	(b)(4)
UK	(b)(4)
US	(b)(4)

Pfizer-BioNTech COVID-19 Vaccine

Myocarditis and Pericarditis

Report Prepared by:

BioNTech-Pfizer

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090177e197046c26\Final\Final On: 13-May-2021 14:08 (GMT)

Enclosure 2

From: Walensky, Rochelle (CDC/OD)
Sent: Sun, 23 May 2021 19:16:09 +0000
To: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Subject: RE: DRAFT_Myocarditis_Advisory_05232021_1109

Great – sounds good...thank you!
R

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Sunday, May 23, 2021 1:33 PM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Subject: RE: DRAFT_Myocarditis_Advisory_05232021_1109

Perfect, will push it through.

I think Health advisory, (b)(5)

(b)(5)

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Sent: Sunday, May 23, 2021 1:17 PM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Subject: RE: DRAFT_Myocarditis_Advisory_05232021_1109

Thank you – Will it be a full HAN –
I'm fine with how this reads...grateful.
R

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Sunday, May 23, 2021 1:12 PM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Subject: DRAFT_Myocarditis_Advisory_05232021_1109

Latest HAN.

From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Sun, 23 May 2021 17:12:18 +0000
To: Walensky, Rochelle (CDC/OD)
Subject: DRAFT_Myocarditis_Advisory_05232021_1109
Attachments: DRAFT_Myocarditis_Advisory_05232021_1109.docx

Latest HAN.

From: (b)(4) (b)(4) (x)
Sent: Tue, 25 May 2021 15:03:08 +0000
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)
Subject: Re: Publication - Myocarditis

Thanks, Sara. That is very helpful.

(b)(4)

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>

Sent: Tuesday, May 25, 2021 10:29 AM

To: (b)(4) (b)(4) (x) (b)(4)

Subject: RE: Publication - Myocarditis

EXTERNAL

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

From: (b)(4) (b)(4) (x) (b)(4)
Sent: Tuesday, May 25, 2021 10:24 AM
To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Subject: Re: Publication - Myocarditis

Hi Sara,

Thanks for your note. Can I just ask what are the possible options where this might be published?

(b)(4)

From: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>
Sent: Tuesday, May 25, 2021 10:20 AM

To: (b)(4) (b)(4) (x) (b)(4)

Subject: RE: Publication - Myocarditis

EXTERNAL

(b)(4)

Apologies that there hasn't been more solid communication on this. Unfortunately, I still don't have a firm update to share. Things have been changing rapidly here. As we know more, I will share.

Thanks-
Sara

From: (b)(4) (b)(4) (x) (b)(4)

Sent: Tuesday, May 25, 2021 9:45 AM

To: Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>

Subject: Publication - Myocarditis

Hi Sara,

I am just checking in to see if you have decided where you will publish your statement on myocarditis. Will it be the MMWR or somewhere else please? And if you have any update on timing, that would be a big help.

We hope to send CDC the report that we are submitting to PRAC sometime this week.

Many thanks.

(b)(4)

 Please consider the environment before printing this email

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From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)
Sent: Wed, 26 May 2021 17:49:23 +0000
To: Walensky, Rochelle (CDC/OD); Schuchat, Anne MD (CDC/OD)
Cc: Goldstein, Robert (CDC/OD/OADPS); Berger, Sherri (CDC/OCOO/OD); McDonald, Jason (CDC/OD/OADC)
Subject: Draft HAN - still in clearance
Attachments: DRAFT Brief Myocarditis HAN 5.25.2021 to JIC - clean.docx

Draft attached. This is still in clearance.

Sharing as preview.

Enclosure 3

From: Wakana, Benjamin L. EOP/WHO
Sent: Tue, 25 May 2021 03:21:11 +0000
To: Walensky, Rochelle (CDC/OD); Fauci, Anthony (NIH/NIAID) [E]; Slavitt, Andrew M. EOP/WHO; Collins, Francis (NIH/OD) [E]; Murthy, Vivek (HHS/OASH); Smith, Marcella N. EOP/OSTP
Cc: Rowe, Courtney M. EOP/WHO; Berner, Kate EOP/WHO; Munoz, Kevin EOP/WHO; Sams, Ian (HHS/ASPA); Billet, Courtney (NIH/NIAID) [E]; Tumpey, Abigail (CDC/DDPHSS/CSELS/OD); Hall, Bill (HHS/ASPA); Burklow, John (NIH/OD) [E]; Myles, Renate (NIH/OD) [E]; Lesko, Max (HHS/OASH); Cheema, Subhan N. EOP/WHO; Saez, Mariel S. EOP/WHO; Webb, Cameron C. EOP/WHO; Beckman, Adam (HHS/OASH); Sanchez-Velasco, Marissa EOP/WHO; Beckman, Adam (HHS/OASH); McDonald, Jason (CDC/OD/OADC); Allen, Kirsten (HHS/ASPA); Perry, Sherice (OS/IEA)
Subject: RE: COVID Tough QA
Attachments: Tough QA 5.24.21 11PM.docx

Hi, attached please find the latest tough QA. New topics include:

(b)(5)

Hope this helps,
Ben

+++
Ben Wakana
Deputy Director for Strategic Communications and Engagement
White House COVID Response Team

(b)(6)

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