Houry, Debra E. (CDC/IOD)

From: Nixon, Andrew (HHS/ASPA) <[redacted]>
Sent: Wednesday, February 26, 2025 8:59 PM
To: Griffis, Kevin (CDC/OD/OC); Houry, Debra E. (CDC/IOD); Shockey, Caitlin E. (CDC/OD/OC); Cutler, Diane (HHS/IOS); Spear, Stefanie (HHS/IOS); Corry, Thomas (HHS/ASPA); Ford, Kenya S. (CDC/OGC)
Cc: Monarez, Susan (CDC/IOD)
Subject: RE: CDC ACIP transparency - FYSA

Hi Kevin –

Nice to finally hear from you. It is likely to be proactive from HHS, but we will circle back.

Thank you,

Andrew G. Nixon
Director of Communications
U.S. Department of Health and Human Services
Email: andrew.nixon@hhs.gov
Cell: 202-549-8655

From: Griffis, Kevin (CDC/OD/OC) <[redacted]>
Sent: Wednesday, February 26, 2025 8:02 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>; Cutler, Diane (HHS/IOS) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Corry, Thomas (HHS/ASPA) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>
Cc: Monarez, Susan (CDC/IOD) <[redacted]>
Subject: Re: CDC ACIP transparency - FYSA

For clarity, does HHS envision a proactive announcement around the posting of the COI information? If so, are we right to assume that it will be a HHS announcement? If reactive, we'll need to get moving on a statement and QA.

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From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, February 26, 2025 3:21:20 PM
To: Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>; Cutler, Diane (HHS/IOS) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Corry, Thomas (HHS/ASPA) <[redacted]>; Griffis, Kevin (CDC/OD/OC) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>
Cc: Monarez, Susan (CDC/IOD) <[redacted]>
Subject: RE: CDC ACIP transparency - FYSA

Hi all
Circling back and wanted to close the loop on a few things

- Cate is routing language through HHS so that we can contact current and past ACIP members to let them know we will be posting COI (Cate- do you also want to have Kenya help with language re asking about voluntary disclosure of info on 450s? I know that is part 2 re COI, but may want to do in a single message)
- Cate/ Melinda have info going back 20+ years on COI mentioned at meetings
- I did check in on ACIP/MMWR issue Diane flagged for us
    - ACIP did not vote on MMWR and per staff, the slides were accurate that were presented to ACIP for vote
    - MMWR during the editing process by senior staff (unclear who) to make it more lay friendly changed language in one paragraph that made it less specific. This MMWR document was published days after the ACIP meeting The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine — United States, December 2020 | MMWR This is what language Rep Massie noted and it resulted in a subsequent erratum in MMWR Erratum: Vol. 69, No. 50 | MMWR *Consistent high efficacy (≥92%) was observed across age, sex, race, and ethnicity categories and among persons with underlying medical conditions. Efficacy was similarly high in a secondary analysis including participants both with or without evidence of previous SARS-CoV-2 infection*

Deb Houry, MD, MPH
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention
[redacted]
Executive Assistant: Latrisha Smith [redacted]
Special Assistant: Melissa O'Connor [redacted]

From: Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>
Sent: Tuesday, February 25, 2025 9:53 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Cutler, Diane (HHS/IOS) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Corry, Thomas (HHS/ASPA) <[redacted]>; Griffis, Kevin (CDC/OD/OC) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>
Cc: Monarez, Susan (CDC/IOD) <[redacted]>
Subject: RE: CDC ACIP transparency - FYSA

Hi all,

I just wanted to give an update on the ACIP meeting disclosures. The team here has gone back through meetings from 2024-2000, documenting disclosures of members. We're still working on identifying all of the member terms (as requested on Friday evening), but that should be wrapped up today.

In the meantime, we are working with a web developer/IT to work on the best way to present this information, given that this is currently a long table of content. We should have some UX recommendations this morning and will start building out the dev site this afternoon.

Cate

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Sunday, February 23, 2025 7:06 PM
To: Cutler, Diane (HHS/IOS) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>; Corry, Thomas (HHS/ASPA) <[redacted]>; Coffin, Nicole

(CDC/PHIC/OD) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>
Cc: Monarez, Susan (CDC/IOD) <[redacted]>
Subject: RE: CDC ACIP transparency - FYSA

Thanks for sending this- I wasn't on the COVID response back then so I wasn't aware of the video or this issue so I will see what I can find out- very helpful for us to see this as we look at how CDC can ensure transparency in the process and with our work. I know you said you didn't need answers, but it helps me to think through all of these questions/ issues to understand where we can improve or what we need to be cognizant of

- I pulled up the ACIP COI- and looks like 3 had COI and abstained from COVID vaccine vote
- I know Amanda Cohn and Anne Schuchat are no longer at CDC; will check on the other scientist
- I will find out timing of MMWR and erratum with the vote; usually the MMWR publication is done a few weeks after the vote and I don't think ACIP votes on the publication
- I'm not aware of other ACIP stories like this other than the one from 2002/2003 (but I also wasn't aware of this story)

Deb Houry, MD, MPH
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention
[redacted]
Executive Assistant: Latrisha Smith[redacted]
Special Assistant: Melissa O'Connor [redacted]

From: Cutler, Diane (HHS/IOS) <[redacted]>
Sent: Sunday, February 23, 2025 1:11 PM
To: Spear, Stefanie (HHS/IOS) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>; Corry, Thomas (HHS/ASPA) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Coffin, Nicole (CDC/PHIC/OD) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>
Cc: Monarez, Susan (CDC/IOD) <[redacted]>
Subject: CDC ACIP transparency - FYSA

HHS/CDC ACIP transparency team,

Flagging this story for potential use/reference related to the need for ACIP accountability. For clarification, Stefanie is the final word on comms strategy – I am only raising this story for awareness in case it can be useful in story-telling about the need for ACIP transparency/accountability!

Please see this Sharyl Attkisson/Tom Massie story about ACIP allegedly certifying false information about COVID vaccine effectiveness. In short, Rep Massie (a scientist) reviewed actual scientific data and discovered discrepancies between the data and CDC's conclusions. Rep Massie recorded his interactions with CDC. At first, CDC apologized and said the errors would be corrected, but the errors were not corrected. Rep Massie questioned CDC further. Rep Massie, amplified by Attkisson, questions the intent of CDC's representations and the unanimous consent and support from ACIP members.

Questions that come to my mind are:

- What is the timing of the ACIP-sanctioned CDC report? Who were the ACIP members at the time and what were their disclosed COIs? Did any of the COI's related to COVID-19 vaccine manufacturing/production/research?
- Did the "unanimous" supporting members include those with COI's? If so, were the COI's disclosed in the report? If not, why not?
- While ACIP members currently disclose COI's in meetings and those with conflicts abstain from voting, does that same exclusion of voting/participation extend also to certifying/supporting reports?
- Are other similar-type stories about questionable ACIP reports/certifications circulating? (if not, that's fine. This one example is egregious)

- Are the two CDC staff still employed at CDC?

I'm not posing the questions because I need answers but instead, ask them in case the answers might support the story about ACIP accountability and transparency.

Thank you,

Diane

This is the link to the story on X, followed immediately with two excerpts (with my highlights and colored font) immediately below.

https://x.com/SharylAttkisson/status/1893135372273541351

- "Here's the story where @RepThomasMassie recorded top CDC scientists/officials lying about what the original studies said about Covid vaccine effectiveness in those with natural immunity. **ALL of the vaccine advisers had signed off on the false info. They should not be advisers.** Either they don't read the info they sign (disqualifier) or they read it and agreed to mislead the public (disqualifier). I'm not sure which is worse. Clip is in the post below.

- In late 2020, @RepThomasMassie secretly recorded top CDC officials in what could be their first big Covid vaccine lie. Many would follow. @DrJBhattacharya weighed in on my TV program @FullMeasureNews Nobody has been held accountable."

  "Full video is here: https://fullmeasure.news/news/cover-story/cdc-investigation#"

I want to thank you for all your help, your time, and your hard work. We recognize this is a weekend and appreciate your diligence on complying with the presidential EO's.

Thomas Corry
Office of the Assistant Secretary for Public Affairs
U.S. Dept. of Health and Human Services
[redacted]

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Saturday, February 1, 2025 2:33 PM
To: Corry, Thomas (HHS/ASPA) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>; Thalken, Stacey (CDC/OD/OC) <[redacted]>; Smith, Fred (CDC/OD/OC) <[redacted]>; Layden, Jennifer (CDC/OD/OPHDST) <[redacted]>; Bonander, Jason (CDC/OCOO/OCIO/OD) <[redacted]>; Aleshire, Noah (CDC/OD/OPPE) <[redacted]>; Griffis, Kevin (CDC/OD/OC) <[redacted]>; Monarez, Susan (CDC/IOD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>
Subject: Re: notes and follow up questions - for review/feedback

Hi again,

Checking in on two things. First, do you know when we'll get a determination on clinical guidelines and data/journals? We have some questions in the tabs and just want to get a sense of when we'll know for our web folks.

Thank you!
Sara

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From: Corry, Thomas (HHS/ASPA) <[redacted]>
Sent: Saturday, February 1, 2025 12:56 PM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>; Thalken, Stacey (CDC/OD/OC) <[redacted]>; Smith, Fred (CDC/OD/OC) <[redacted]>; Layden, Jennifer (CDC/OD/OPHDST) <[redacted]>; Bonander, Jason (CDC/OCOO/OCIO/OD) <[redacted]>; Aleshire, Noah (CDC/OD/OPPE) <[redacted]>; Griffis, Kevin (CDC/OD/OC) <[redacted]>; Monarez, Susan (CDC/IOD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>
Subject: RE: notes and follow up questions - for review/feedback

Sara, I think you've accurately memorialized the notes from this morning's call. For your questions I'd like us to work through them as a group.

Thomas Corry
Office of the Assistant Secretary for Public Affairs
U.S. Dept. of Health and Human Services
[redacted]

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Saturday, February 1, 2025 12:35 PM
To: Corry, Thomas (HHS/ASPA) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>; Thalken, Stacey (CDC/OD/OC) <[redacted]>; Smith, Fred (CDC/OD/OC) <[redacted]>; Layden, Jennifer (CDC/OD/OPHDST) <[redacted]>; Bonander, Jason (CDC/OCOO/OCIO/OD) <[redacted]>; Aleshire, Noah (CDC/OD/OPPE) <[redacted]>; Griffis, Kevin (CDC/OD/OC) <[redacted]>; Monarez, Susan (CDC/IOD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>
Subject: notes and follow up questions - for review/feedback

Hi again,

I want to send notes from our call this morning just to be sure we are on the same page and we know our next steps. Our outstanding questions (so far) are below, and I've also attached the questions we sent up through Exec Sec yesterday. Please let us know if you have any additional questions, feedback, or specific notes to add/correct.

Thanks,
Sara

- Per HHS direction, the ACIP and the VIS websites are back up and all other vaccine content will go back up today. This excludes the ACIP recommendations for mpox. **Please provide guidance if this recommendation should be put back on the website as is until process for making changes can be finalized with OGC guidance.**
- Per HHS direction, data.cdc.gov has been turned on and is working its way back up online (all human activity to get it back on is completed and now it's dependent upon technology updates – people have already started getting access and this will fill out on a rolling basis).
- Per HHS direction, MMWR is back up on the web. All scientific content will be put back up/un-archived, including journals.
    - We will send a list of all journals with a link to the home page. As noted on the call, all journals reflect scientific content and do not change by Administration.
- All social media channels are live but some posts were removed. We stopped removing historical posts per ASPA guidance Friday morning. Any focus in the future will be on posts that are under the current administration, beginning on 1/20/2025.
- All web changes and data changes will focus on outward facing content.
- CDC will use the HHS-approved banner language at the top of the re-posted but unedited web pages that explains that the website is being updated to comply with the EO.
- CDC will propose buckets of content that will go back up in priority order while we are also working through the spreadsheet feedback. This includes:
    - Clinical guidelines – We need guidance on transgender-specific clinical guidelines.
    - Data – We specifically need guidance on things like YRBS data and reports.
- HHS has asked us to hold on removing any sites that are still in the ticketing system and report back how many pages were still in the queue for removal or editing. This guidance has been shared with communication leaders agency-wide.
- HHS will look at the existing spreadsheet to identify what does not need to go back up. CDC will use the color green to identify web pages that have gone back up. Red coding will mean the web page should stay down. Yellow will indicate that it should go back up (per HHS directive). We noticed some blue highlights in the spreadsheet. Can HHS confirm what that reflects?
    - When content isn't clear, HHS will want access to content to see whether or not to restore the content.

Houry, Debra E. (CDC/IOD)

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Tuesday, July 15, 2025 6:04 PM
To: Houry, Debra E. (CDC/IOD)
Subject: FW: Hepatitis B ACIP Question

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Tuesday, July 15, 2025 4:59 PM
To: Langer, Adam J. (CDC/NCHHSTP/OD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Ellington, Renata (CDC/NCHHSTP/OD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: Hepatitis B ACIP Question

Hi Adam and Mina-

I just wanted to connect you all after the ACIP agenda discussion I was a part of. Defer to Mina to provide more detail, but it sounds as if a Hep B question on birth dose may be on the agenda for a meeting sometime in September.

Mina- I think it would be GREAT to get Adam/NCHHSTP the question that HHS folks want to have discussed/voted on at that meeting. Seems like briefing materials from the program will be the basis for discussion at the actual meeting rather than a topic for a future workgroup given the desire to open and close the case in September.

Seems like DVH, once they have the actual question, could develop a briefer (like the MMRV one) so that the ACIP members could review the science on the question as a basis for discussion. Leave it to Mina to see if there are other presentations that might also be considered, as was the case for thimerosal and MMRV.

I will leave it to you all to iron out details, but it would be important to get the DVH folks the basis for their materials soon so they can get to working since September is getting close. Imagine good to get OSBI and OGC to agree to such a path forward.

Thanks
Demetre

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 4:14 PM
To: Houry, Debra E. (CDC/IOD); Burns, Stuart (CDC/IOD); Archer, William (HHS/IOS); Mccormick, Cortney (HHS/IOS)
Cc: Zadeh, Mina (CDC/OD/OCS); Hawkins, Jamar (HHS/OS); Buzzelli, Matthew J (Matt) (CDC/IOD); Hamilton, Sarah (CDC/OD/OCS); Robinson, Wilma (HHS/IOS)
Subject: RE: urgent update: ACIP recommendation memos RE: re proprietary information on your document

Hi Debra,
FDA is included because of the impact on manufacturing, and FDA was included in the review of the April ACIP recommendations, focused on the point/memo that mentioned FDA.
Jill

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 3:57 PM
To: Aksamit, Jill (HHS/OS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>
Cc: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Subject: RE: urgent update: ACIP recommendation memos RE: re proprietary information on your document

Appreciate the update- I'm not aware of FDA previously clearing CDC recommendations from ACIP- is this new policy or focused only on the one memo because of the impact on manufacturing for FDA?

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 3:55 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>
Cc: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: urgent update: ACIP recommendation memos RE: re proprietary information on your document

Status: FDA is still reviewing and have not cleared the documents and the edit to remove the table. Dr. Archer noted that the memos needed to be signed by the Secretary today. I am standing by to assist if the memos are cleared. The memos are otherwise cleared by OGC and CDC.
Jill

Jill E. Aksamit
Policy Coordinator – Science and Public Health Team

Immediate Office of the Secretary | Exec Sec
U.S. Department of Health and Human Services
[redacted]

Visit us on The Executive Secretariat (Exec Sec) | HHS Intranet
https://intranet.hhs.gov/about-hhs/exec-sec

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 12:40 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Subject: RE: re proprietary information on your document

+ Sarah for awareness

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD)
Sent: Monday, July 21, 2025 12:36 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Subject: RE: re proprietary information on your document

This removal of chart looks fine to me thx

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 12:30 PM
To: Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Subject: FW: re proprietary information on your document

Jill,

This looks fine to me. I am lopping in Dr. Houry here at CDC for her review.

Stuart

Stuart Burns
Senior Advisor
Office of the Director
Centers for Disease Control and Prevention
[redacted]

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PREDECISIONAL

From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 11:41 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>
Subject: RE: re proprietary information on your document

If helpful, I made the edit: attached is a markup and clean version with the chart removed, and the sentence referring to the chart. Copying my boss Jamar.
Jill

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 10:59 AM
To: Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Subject: Re: re proprietary information on your document

if we can remove that chart That has the proprietary data in it Then I think the bullets cover the information we need to cover. I have copied Mina, the DFO for ACIP who will work on this end with you gel and other others who need to resolve this issue.

Stuart

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From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 10:54:30 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>
Subject: RE: re proprietary information on your document

Thanks – attached is the only version I have - there were no edits or comments from OGC or ASL reviewers.
Jill

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 10:47 AM
To: Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>
Subject: Re: re proprietary information on your document

Thank you, if it has not been signed yet, it would be good to completely remove that, but if you could share the current version, I wanna make sure that removal does not leave a complete gap. I think the bullets will cover it, but I can't recall what was in the final one that was sent forward. Thank you. Stuart.

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From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 10:45:10 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>
Subject: Re: re proprietary information on your document

Reyn and Stuart,
Understood, regarding the chart needing to be removed (not just edited but removed, right?) from the memo. I meet with CDC Exec Sec/Office of the Director contacts at 11am and I will check in with division contacts/reviewers that had for this round of review.
Jill

Jill E. Aksamit
Policy Coordinator – Science and Public Health Team
Immediate Office of the Secretary | Exec Sec
U.S. Department of Health and Human Services
[redacted]

Visit us on The Executive Secretariat (Exec Sec) | HHS Intranet
https://intranet.hhs.gov/about-hhs/exec-sec

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 10:01 AM
To: Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>
Subject: RE: re proprietary information on your document

Jill,

Please call me regarding this. If it has not been signed yet, we could remove the chart and resubmit for signature/review.

Stuart

Stuart Burns
Senior Advisor
Office of the Director
Centers for Disease Control and Prevention
[redacted]

DRAFT, INTERNAL, DELIBERATIVE, NOT FOR DISTRIBUTION
PREDECISIONAL

From: Archer, William (HHS/IOS) <[redacted]>
Sent: Sunday, July 20, 2025 8:42 PM
To: Aksamit, Jill (HHS/OS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: Fw: re proprietary information on your document

Jill. See this concern from CDC.

Can we correct it?

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From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Sunday, July 20, 2025 8:31:26 PM
To: Archer, William (HHS/IOS) <[redacted]>
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Subject: Fw: re proprietary information on your document

Reyn, Apparently, we need to remove the table that was included in the decision memo on thimerosal. It included a table that had information on the number of vaccines by manufacturer, of Mercury, free vaccines. It appears that is proprietary, and we should remove that from the decision memo. I think those may have already gone up. I'm not sure whose desk they are on currently.

Stuart

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From: Hoeg, Tracy Beth <[redacted]>
Sent: Sunday, July 20, 2025 6:34:10 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: re proprietary information on your document

Stuart,
Could you please also ensure that anyone who has seen the document not share any of the information from the table with the vaccine manufacturers' names? You will note I actually removed the row with the names so it does not get sent further.
Should I also write to Nina about this or will you be able to let her know?
Thank you and I apologize I didn't make this clear when I sent this to you.

Tracy Beth Høeg, MD, PhD
Senior Advisor for Clinical Sciences
Office of the Commissioner (OC) &
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration
[redacted]

U.S. FOOD & DRUG ADMINISTRATION

From: Hoeg, Tracy Beth
Sent: Sunday, July 20, 2025 5:53 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Subject: re proprietary information on your document
Importance: High

Dear Stuart,

I was just forwarded the ACIP decision memos and will get them reviewed by the appropriate people and back to you by 7/22. There is one extremely important edit: no proprietary information/drug manufacturers names or information can be included. I should have been clear that the table I sent you could not be shared/that it contained cc nfidential information. So the table needs to be removed. I actually made an alternative table but decided it is probably best without exact numbers. Are you still getting <10%? Based on which numbers? What I quoted at ACIP (between 4-5%) was from doses distributed, as you probably remember. I was told I should not share the exact numbers/names so gave a %. Maybe you could say the numbers of millions of estimated doses it decreased by year total but just round since these are estimates? Please send me an edited version when you get a chance so I can forward it to our legal team and get this completed on time. Thank you!

Tracy Beth Høeg, MD, PhD
Senior Advisor for Clinical Sciences
Office of the Commissioner (OC) &
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration
[redacted]

U.S. FOOD & DRUG ADMINISTRATION

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Friday, May 9, 2025 8:52 PM
To: Burns, Stuart (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD); Witkofsky, Nina (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD); Faircloth, Jordan (CDC/OD/OCS)
Subject: FW: Request for current and historical ACIP information - Updated OSBI response
Attachments: ACIP Data Request - 5-9-2025 .docx

Categories: 4

Can we discuss? Staff had to pull 28 boxes for this request. Going forward, I think it would be helpful to prioritize and determine what is needed and hone these types of request down as with limited staff p RIF lots of competing priorities right now

From: Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>
Sent: Friday, May 9, 2025 2:53 PM
To: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Smagh, Kalwant (CDC/OCOO/OSBI) <[redacted]>; Wharton, Melinda (CDC/NCIRD/OD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: Request for current and historical ACIP information - Updated OSBI response

Good afternoon – Abby,

The attached word document now includes ACIP historical documents that OSBI retrieved during a site visit to the National Archives – Atlanta in Morrow, Georgia. The new pdfs have been highlighted to make it easier to identify what has been added. Although we have not been able to locate the 1964 charter establishment package, this update includes a document that summarizes discussions about ACIP responsibilities at the first two meetings in 1964.

I hope the additional information is useful and please let me know if you have any questions. Thank you.

Gladys G. Lewellen
Director
Office of the Federal Advisory Committee Act Program (FACAP)
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, April 21, 2025 8:26 PM
To: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>; Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>

Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Smagh, Kalwant (CDC/OCOO/OSBI) <[redacted]>; Wharton, Melinda (CDC/NCIRD/OD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: Re: Request for current and historical ACIP information - Updated OSBI response

Thank you for the time and effort put in to gathering this information. This is very helpful. Stuart

Get Outlook for iOS

From: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Sent: Monday, April 21, 2025 7:47:41 PM
To: Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Smagh, Kalwant (CDC/OCOO/OSBI) <[redacted]>; Wharton, Melinda (CDC/NCIRD/OD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: Request for current and historical ACIP information - Updated OSBI response

Wow—thank you for this! We greatly appreciate this sleuthing.

Abigail Viall
Senior Advisor
Centers for Disease Control and Prevention
Department of Health and Human Services
[redacted]

From: Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>
Sent: Monday, April 21, 2025 3:32 PM
To: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Smagh, Kalwant (CDC/OCOO/OSBI) <[redacted]>; Wharton, Melinda (CDC/NCIRD/OD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>
Subject: RE: Request for current and historical ACIP information - Updated OSBI response

Good afternoon, Abby,

The attached word document now includes copies of the ACIP charters from **1974-1994** provided by the CDC Museum. In addition, attached is an updated spreadsheet that summarizes the documents in the custody of NARA.

Please let me know if you have any questions. Thank you.

Gladys G. Lewellen
Director
Office of the Federal Advisory Committee Act Program (FACAP)
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)

From: Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>
Sent: Friday, April 18, 2025 2:46 PM
To: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Smagh, Kalwant (CDC/OCOO/OSBI) <[redacted]>; Wharton, Melinda (CDC/NCIRD/OD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>
Subject: RE: Request for current and historical ACIP information - OSBI response

Good afternoon, Abby,

We are able to find charters and packages for the previous 20 years, however unable to access items at CDC now with the national archives pertaining to years prior to 2002 (including the requested 1986 charter).

The attached word document includes copies of the signed charter renewals and amendments that have been located thus far (2002 – 2024). OSBI has included copies of the complete packages, if available. Also attached are the results of the email exchange and the spreadsheet provided by the Director of the National Archives at Atlanta regarding records for previous years. As noted in his email, all of these records are now in the custody of the National Archives and cannot be loaned back to the CDC. Retrieval of additional ACIP charter records now requires a physical visit to NARA to conduct an onsite search and may incur fees. Is that desired?

Regarding charter amendments, sharing the process for general awareness. Please note that, a charter amendment package submission includes several documents in addition to the specific edited draft charter. Proposed changes to the ACIP charter will also need to be made in the pertinent sections of the membership balance plan. OSBI staff can assist as needed with the development of the complete amendment package for clearance. Discretionary charter renewals and amendments including ACIP are required to be reviewed by the General Services Administration (two levels of review) in addition to the review by the HHS Office of the White House Liaison. Finally, upon approval by HHS and GSA, CDC has the delegated authority to sign the charter amendment package documents (copy of the delegation attached).

Regarding the status of the ACIP workgroup rosters and COI forms, please note that NCIRD is compiling the information and will share the results in a separate response.

I hope this information is helpful. Thanks.

Gladys G. Lewellen
Director
Office of the Federal Advisory Committee Act Program (FACAP)
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)

From: Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>
Sent: Friday, April 18, 2025 12:19 PM
To: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>; Smagh, Kalwant (CDC/OCOO/OSBI)

<[redacted]>; Wharton, Melinda (CDC/NCIRD/OD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>
Subject: RE: Request for current and historical ACIP information

Good afternoon, Abby,

OSBI's draft response has been prepared and I will send it forward after the review/approval. Thanks.

Gladys G. Lewellen
Director
Office of the Federal Advisory Committee Act Program (FACAP)
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)

From: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Sent: Friday, April 18, 2025 12:08 PM
To: Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>; Wharton, Melinda (CDC/NCIRD/OD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: Request for current and historical ACIP information

HI Folks,

I wanted to check back in and get a status update. I recognize some of this takes time to pull, but also wanted to check if any of it might be available today.

Thanks
Abby

Abigail Viall
Senior Advisor
Centers for Disease Control and Prevention
Department of Health and Human Services
[redacted]

From: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Sent: Thursday, April 17, 2025 9:18 AM
To: Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>; Wharton, Melinda (CDC/NCIRD/OD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: Request for current and historical ACIP information

Good Morning Gladys, Melinda, and Rebecca,

As I think you are aware, CDC is in ongoing conversations with HHS regarding ways to increase transparency and inclusivity in ACIP deliberations and decision-making. I know NCIRD has some ideas in this regard, and IOD we will be setting some time in the future to discuss those and other ideas.

Ultimately, we expect to effect most if not all of the most transformative changes through a charter update.

To that end, Stuart Burns, who has been tapped to lead this effort, has requested the following items to inform his understanding of the current state of ACIP operations, as well as the historical glide path that brought us here.

Is it possible for you to find and send me the following items by COB tomorrow?

- Historical versions of the charter and rationale for each change:
  - Eps. The see original charter, pre 1986 charter, immediate post 1986 charter, and whatever charter was in place immediately before the 2024 update
- Lists of members for a sample of standing and time limited workgroups, as well as their COI submissions
  - Adult, child/adolescent, influenza
  - Child/maternal RSV and meningococcal workgroup COIs

If any of this is in the CDC library, I'm also happy to go hunting there and remove whatever response burden I can.

Thanks
Abby

Abigail Viall
Senior Advisor
Centers for Disease Control and Prevention
Department of Health and Human Services
[redacted]

Houry, Debra E. (CDC/IOD)

From: Burns, Stuart (CDC/IOD)
Sent: Monday, April 14, 2025 2:53 PM
To: Houry, Debra E. (CDC/IOD)
Subject: RE: NIH and FDA ex officio members on ACIP

Categories: 4

Thank you. This is helpful.

Stuart

Stuart Burns
Senior Advisor
Office of the Director
Centers for Disease Control and Prevention
[redacted]

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Monday, April 14, 2025 2:49 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: NIH and FDA ex officio members on ACIP

Yes- thay are able to participate, but should not be dominant speakers. They are also asked about things salient to their agency. Anything I can help with or should be aware of re ACIP? I helped Susan with a memo 2 months ago for HHS but program and I haven't been involved since then

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, April 14, 2025 2:15 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: NIH and FDA ex officio members on ACIP

I assume that the ex officio members of ACIP are afforded the opportunity to engage in discussion throughout the ACIP meeting. Is that correct?

Stuart

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Thursday, April 17, 2025 10:12 AM
To: Monarez, Susan (CDC/IOD)
Subject: FW: FDA rep

Categories: 4

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD)
Sent: Wednesday, April 16, 2025 6:53 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Subject: RE: FDA rep

The one time the FDA rep was not able to ask her question was because the presenter ran over time- I heard she was able to raise her point later in the meeting and also address the Novavax question from the day prior. Usually there is time for folks to ask ?s, but this was also a shortened meeting because it was postponed. Ex officio also usually don't speak as much as we want the voting members prioritized and not have feds do most of the speaking.

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Wednesday, April 16, 2025 5:48 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Subject: Re: FDA rep

Deb, is that typical for not everyone to be able to speak due to time limitations? Was that the case for most of the sessions. I was tied up in other meetings today, but will tune in over the weekend or later in the week. Stuart

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From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, April 16, 2025 10:18:57 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Subject: Re: FDA rep

Lmk if any other issues today- thx for reaching out
Below/ attached is what was on social media yesterday

Get Outlook for iOS

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, April 16, 2025 10:03 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Subject: Re: FDA rep

Just talked to Demetre. Sounds like session ran over and several folks ahead of Tracy also not able to ask questions bc of time limit

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From: Houry, Debra E. (CDC/IOD)
Sent: Wednesday, April 16, 2025 9:51:10 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Subject: FDA rep

I just reached out to Demetre to see if there is an issue this morning. Waiting to hear back. I know she participated yesterday and was asked too about novavax and was unable to provide an update as that was most of the comments received in frn

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Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Wednesday, July 9, 2025 7:03 PM
To: Hamilton, Sarah (CDC/OD/OCS); Witkofsky, Nina (CDC/IOD); Burns, Stuart (CDC/IOD)
Cc: Mahmood, Aisha (CDC/NCIPC/OD); Hill, La'Kashia (CDC/OD/OCS) (CTR); Zadeh, Mina (CDC/OD/OCS); Cashman, Sandra (CDC/OD/OCS)
Subject: RE: For IOD Review/Clearance: ACIP Decision Memos from June 25-26, 2025 Meeting

I finished my review of all 3
RSV and seasonal influenza incorporated or addressed my comments in prior round
Thimerosal- I updated the statement (pulled it directly from MMWR); added in con re costs (program will need to review); and focused on ethyl mercury vs all mercury to be more scientifically precise re the issue.
Sorry for delay
Deb

From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Sent: Wednesday, July 9, 2025 2:12 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Hill, La'Kashia (CDC/OD/OCS) (CTR) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Subject: For IOD Review/Clearance: ACIP Decision Memos from June 25-26, 2025 Meeting
Importance: High

Action Requested by CDC's Office of the Executive Secretariat

Attached and also pasted at the below Teams links for your review and clearance are three decision memos from the ACIP June 25-26, 2025, meeting. The redline versions with edits are also attached for reference.

v3 CLEAN ACIP Decision Memo Thimerosal June 2025.docx
v2 CLEAN ACIP Decision Memo_Influenza_June 2025.docx
v3 CLEAN ACIP Decision Memo Clesrovimab 2025.docx

Please provide feedback, including any tracked edits/additions/questions in the CLEAN versions, or respond that you concur.

Clearance Due: End of day today, July 9th, if possible

Background: On July 7, 2025, the ACIP Executive Secretary shared three decision memos from the June 25-26, 2025, ACIP meeting for the HHS Secretary's review.

Reviewed/Cleared By: NCIRD, the ACIP Executive Secretary, Senior Advisor Stuart Burns, the CDC Office of the Executive Secretariat, and OGC

Please let me know if you have any questions.

Thank you,
Sarah

Sarah Hamilton
Correspondence Public Health Analyst
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Hamilton, Sarah (CDC/OD/OCS)
Sent: Friday, July 11, 2025 9:34 AM
To: Malone, Kevin M. (CDC/OGC); Houry, Debra E. (CDC/IOD); Burns, Stuart (CDC/IOD)
Cc: Thombley, Melisa L. (CDC/OGC); Greco Kone, Rebecca (CDC/NCIRD/OD); Cashman, Sandra (CDC/OD/OCS); Daskalakis, Demetre (CDC/NCIRD/OD); Zadeh, Mina (CDC/OD/OCS); McMillen, Amy (CDC/NCEZID/OD); Sayer, Janna (CDC/NCEZID/OD); Eiring, Hilary (CDC/NCIRD/OD); Beauvais, Denise (CDC/NCIRD/OD); Limbago, Brandi (CDC/NCIRD/OD)
Subject: RE: Updated Thimerosal ACIP Decision Memo
Attachments: v6 REDLINE ACIP Decision Memo Thimerosal June 2025.docx

Thank you, Kevin. Do you want NCIRD to address your comment on p. 3 regarding the below bullet?

- The recommendation for thimerosal-free seasonal influenza vaccine will ensure that CDC's childhood schedule is 100 percent free of vaccines containing ethyl mercury as a preservative.

  Comment: *I understand that some single dose influenza vaccine formulations contain trace amounts of thimerosal from the manufacturing process.*

Best,
Sarah

From: Malone, Kevin M. (CDC/OGC) <[redacted]>
Sent: Friday, July 11, 2025 12:42 AM
To: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Thombley, Melisa L. (CDC/OGC) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; McMillen, Amy (CDC/NCEZID/OD) <[redacted]>; Sayer, Janna (CDC/NCEZID/OD) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Limbago, Brandi (CDC/NCIRD/OD) <[redacted]>
Subject: RE: Updated Thimerosal ACIP Decision Memo

Sarah –

OGC clears with the edits/comments noted in the attached.

Thanks.

Kevin

From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Sent: Thursday, July 10, 2025 8:13 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>; Thombley, Melisa L. (CDC/OGC) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; McMillen, Amy (CDC/NCEZID/OD) <[redacted]>; Sayer, Janna (CDC/NCEZID/OD) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD)

[redacted]; Beauvais, Denise (CDC/NCIRD/OD) [redacted]; Limbago, Brandi (CDC/NCIRD/OD) [redacted]
Subject: RE: Updated Thimerosal ACIP Decision Memo

Thank you, Dr. Houry. **Kevin/Lisa**: please review this latest version on behalf of OGC.

Best,
Sarah

From: Houry, Debra E. (CDC/IOD) [redacted]
Sent: Thursday, July 10, 2025 7:44 PM
To: Burns, Stuart (CDC/IOD) [redacted]; Hamilton, Sarah (CDC/OD/OCS) [redacted]; Malone, Kevin M. (CDC/OGC) [redacted]; Thombley, Melisa L. (CDC/OGC) [redacted]
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) [redacted]; Cashman, Sandra (CDC/OD/OCS) [redacted]; Daskalakis, Demetre (CDC/NCIRD/OD) [redacted]; Zadeh, Mina (CDC/OD/OCS) [redacted]; McMillen, Amy (CDC/NCEZID/OD) [redacted]; Sayer, Janna (CDC/NCEZID/OD) [redacted]; Eiring, Hilary (CDC/NCIRD/OD) [redacted]; Beauvais, Denise (CDC/NCIRD/OD) [redacted]; Limbago, Brandi (CDC/NCIRD/OD) [redacted]
Subject: RE: Updated Thimerosal ACIP Decision Memo

I accepted the deletions. Added two more edits in the attached- I removed one historical reference in the issues section as it is not relevant today and made one edit in the pro section (removed "unnecessary" as that is more subjective vs scientific statement)

From: Burns, Stuart (CDC/IOD) [redacted]
Sent: Thursday, July 10, 2025 4:39 PM
To: Hamilton, Sarah (CDC/OD/OCS) [redacted]; Houry, Debra E. (CDC/IOD) [redacted]; Malone, Kevin M. (CDC/OGC) [redacted]; Thombley, Melisa L. (CDC/OGC) [redacted]
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) [redacted]; Cashman, Sandra (CDC/OD/OCS) [redacted]; Daskalakis, Demetre (CDC/NCIRD/OD) [redacted]; Zadeh, Mina (CDC/OD/OCS) [redacted]; McMillen, Amy (CDC/NCEZID/OD) [redacted]; Sayer, Janna (CDC/NCEZID/OD) [redacted]; Eiring, Hilary (CDC/NCIRD/OD) [redacted]; Beauvais, Denise (CDC/NCIRD/OD) [redacted]; Limbago, Brandi (CDC/NCIRD/OD) [redacted]
Subject: RE: Updated Thimerosal ACIP Decision Memo

Please see attached with several bullets deleted per discussion between Stuart and Deb.
Deb, please review and confirm changes are as we discussed.

Stuart

Stuart Burns
Senior Advisor
Office of the Director
Centers for Disease Control and Prevention
[redacted]

DRAFT, INTERNAL, DELIBERATIVE, NOT FOR DISTRIBUTION
PREDECISIONAL

From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Sent: Thursday, July 10, 2025 4:18 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>; Thombley, Melisa L. (CDC/OGC) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; McMillen, Amy (CDC/NCEZID/OD) <[redacted]>; Sayer, Janna (CDC/NCEZID/OD) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Limbago, Brandi (CDC/NCIRD/OD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Subject: Updated Thimerosal ACIP Decision Memo

Stuart and Dr. Houry,

Attached is the latest clean version of the thimerosal ACIP decision memo, along with a redline version showing Dr. Houry's edits.

I've added OGC attorneys who cleared the previous draft version to the email so they are aware of and can review these edits, and any additional edits.

Thank you,
Sarah

Sarah Hamilton
Correspondence Public Health Analyst
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Hamilton, Sarah (CDC/OD/OCS)
Sent: Thursday, July 10, 2025 4:13 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Limbago, Brandi (CDC/NCIRD/OD) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; McMillen, Amy (CDC/NCEZID/OD) <[redacted]>; Sayer, Janna (CDC/NCEZID/OD) <[redacted]>
Subject: RE: Request for NCIRD to Review Edit in Thimerosal ACIP Decision Memo

Hi Stuart, NCIRD just concurred on that addition. I'll send you and Dr. Houry a clean word document ASAP.

Thank you,
Sarah

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Thursday, July 10, 2025 4:09 PM
To: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Limbago, Brandi (CDC/NCIRD/OD) <[redacted]>

Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; McMillen, Amy (CDC/NCEZID/OD) <[redacted]>; Sayer, Janna (CDC/NCEZID/OD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Subject: Re: Request for NCIRD to Review Edit in Thimerosal ACIP Decision Memo

Sarah, I'm checking in on the thimerosal flu memo. We were waiting NCIRD review of Dr. Houry's comment on the con. Do we have a word version now that Deb and I will work through for a few additional changes before approval to go up.

Thanks,

Stuart

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From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Sent: Thursday, July 10, 2025 10:01:20 AM
To: Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Limbago, Brandi (CDC/NCIRD/OD) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; McMillen, Amy (CDC/NCEZID/OD) <[redacted]>; Sayer, Janna (CDC/NCEZID/OD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Subject: Request for NCIRD to Review Edit in Thimerosal ACIP Decision Memo

Good morning NCIRD Team:

Dr. Houry added a bullet under the "Cons" section of the attached thimerosal decision memo on p. 3 (edit also pasted below).

Cons:

- *Could result in increased costs due to less multi-dose influenza vaccine*

Could you please review that addition and provide feedback this morning?

Thank you,
Sarah

From: Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>
Sent: Tuesday, July 8, 2025 3:09 PM
To: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Limbago, Brandi (CDC/NCIRD/OD) <[redacted]>; Sayer, Janna (CDC/NCEZID/OD) <[redacted]>; McMillen, Amy (CDC/NCEZID/OD) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: +NCEZID/OD - Request for NCIRD to Review & Address Comments in ACIP Decision Memos from June 25-26, 2025, Meeting

Hi Sarah,

NCIRD has completed the review our memos and the two VFC related bullets in the thimerosal memo, with some edits.

Please let us know if you need anything else.

Best,

Hilary

Hilary Eiring
Team Lead
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)

From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]
Sent: Tuesday, July 8, 2025 11:02 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Limbago, Brandi (CDC/NCIRD/OD) <[redacted]>; Sayer, Janna (CDC/NCEZID/OD) <[redacted]>; McMillen, Amy (CDC/NCEZID/OD) <[redacted]
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: +NCEZID/OD - Request for NCIRD to Review & Address Comments in ACIP Decision Memos from June 25-26, 2025, Meeting

Thank you, Demetre. I'm adding Janna Sayer and Amy McMillen from EZID OD to the chain, and they can coordinate review of the scientific content in the Thimerosal decision memo with ISO.

Janna/Amy: the Teams link to the ACIP Thimerosal decision memo for ISO scientific content review is here: https://cdc.sharepoint.com/:w:/t/OfficeoftheExecutiveSecretariat/EWqrZrJoClBHgdRD3x8hNFcBq_A-6rtOi7Tb1PfjGhc5Wg?e=VOuBHW

If ISO needs more time for review than by end of day today, that's okay. Please let me know if you have questions.

Thank you,
Sarah

Sarah Hamilton
Correspondence Public Health Analyst
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]
Sent: Tuesday, July 8, 2025 10:50 AM
To: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Limbago, Brandi (CDC/NCIRD/OD) <[redacted]

Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: Request for NCIRD to Review & Address Comments in ACIP Decision Memos from June 25-26, 2025, Meeting

+ @Limbago, Brandi (CDC/NCIRD/OD)

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Tuesday, July 8, 2025 10:39 AM
To: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: Request for NCIRD to Review & Address Comments in ACIP Decision Memos from June 25-26, 2025, Meeting

Sarah-

Spoke to Dr Houry @Houry, Debra E. (CDC/IOD) and she agrees that the Thimerosal memo should go to ISO-EZID for review the scientific content. Recommend you loop them in.

Also, the NCIRD team will take a look at the section on VFC/Federal purchase in the thimerosal memo to confirm what we know and to review appropriateness of including specific dollar amounts in those two bullets.

Thanks
Demetre

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Sent: Tuesday, July 8, 2025 10:29 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Beauvais, Denise (CDC/NCIRD/OD) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>

Subject: Request for NCIRD to Review & Address Comments in ACIP Decision Memos from June 25-26, 2025, Meeting
Importance: High

Hi NCIRD Team:

Dr. Houry reviewed the RSV and annual flu decision memos from your program and had a couple of content additions and also two comments/questions in the RSV memo for you to address. In addition, she requested that you review the thimerosal decision memo before she and OGC review.

The three memos are pasted at the below Teams links (please let me know if you cannot access). Could you please review and provide feedback/any tracked edits and comments by end of day today?

- https://cdc.sharepoint.com/:w:/t/OfficeoftheExecutiveSecretariat/EWqrZrJoClBHgdRD3x8hNFcBq_A-6rtOi7Tb1PfjGhc5Wg?e=VOuBHW
- https://cdc.sharepoint.com/:w:/t/OfficeoftheExecutiveSecretariat/Ef_gAOTOix5Mi4qrm_pgh-QBvghMkQMFxGfKJyA591_5Bw?e=AKD1zM
- https://cdc.sharepoint.com/:w:/t/OfficeoftheExecutiveSecretariat/EVtu6bO9SBhKo3TskRq9EhcBsNOyCmAd3pEODy5keTG5Bg?e=9aw4x5

Please let me know if you have questions or if more time is needed for your review.

Thank you,
Sarah

Sarah Hamilton
Correspondence Public Health Analyst
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Burns, Stuart (CDC/IOD)
Sent: Tuesday, July 8, 2025 10:28 AM
To: Hamilton, Sarah (CDC/OD/OCS); Houry, Debra E. (CDC/IOD); Zadeh, Mina (CDC/OD/OCS)
Cc: Cashman, Sandra (CDC/OD/OCS)
Subject: Re: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

Please check all the appropriate boxes.

Stuart

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From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]
Sent: Tuesday, July 8, 2025 10:14 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]; Zadeh, Mina (CDC/OD/OCS) <[redacted]; Burns, Stuart (CDC/IOD) <[redacted]
Cc: Cashman, Sandra (CDC/OD/OCS) <[redacted]
Subject: RE: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

Sounds good, Dr. Houry. I will send you updated versions for your review after NCIRD and OGC complete their review.

Best,
Sarah

From: Houry, Debra E. (CDC/IOD) <[redacted]
Sent: Tuesday, July 8, 2025 10:08 AM
To: Zadeh, Mina (CDC/OD/OCS) <[redacted]; Hamilton, Sarah (CDC/OD/OCS) <[redacted]; Burns, Stuart (CDC/IOD) <[redacted]
Cc: Cashman, Sandra (CDC/OD/OCS) <[redacted]
Subject: RE: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

Ok- thx
I will hold off on reviewing until after NCIRD and OGC review
Would prefer to review all after OGC per our standard process

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Zadeh, Mina (CDC/OD/OCS) <[redacted]
Sent: Tuesday, July 8, 2025 9:58 AM

To: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Cashman, Sandra (CDC/OD/OCS) <[redacted]>
Subject: RE: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

I didn't send thimerosal to NCIRD. I will do so now.

From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Sent: Tuesday, July 8, 2025 9:57 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Cashman, Sandra (CDC/OD/OCS) <[redacted]>
Subject: RE: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

Hi Dr. Houry,

Based on the email chain I received with the decision memos, my understanding was that all three decision memos were cleared by NCIRD, but I defer to Mina and Stuart on this.

Regarding clearance, OGC does typically review before IOD but I was instructed to send these decision memos to both you and OGC at the same time. If you prefer, I'll work with OGC first on their clearance and then send to you for clearance.

Thank you,
Sarah

Sarah Hamilton
Correspondence Public Health Analyst
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Tuesday, July 8, 2025 9:49 AM
To: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

I reviewed the RSV and annual flu memo
For thimerosal, before I review- checking to see if this was cleared by NCIRD- your note says:
Previously Reviewed/Cleared By: NCIRD, the ACIP Executive Secretary, Senior Advisor Stuart Burns, and the CDC Office of the Executive Secretariat
But not clear to me if SMEs reviewed or not- just wanted to check before I review too
And I thought OGC usually reviewed before it came to IOD?

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)

[redacted]

From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Sent: Tuesday, July 8, 2025 9:09 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Tress, Deborah W. (CDC/OGC) <[redacted]>
Cc: Malone, Kevin M. (CDC/OGC) <[redacted]>; Thombley, Melisa L. (CDC/OGC) <[redacted]>; Lester, Brenda (CDC/OGC) <[redacted]>; Epps, Tanya (CDC/OGC) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>
Subject: RE: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

Hi Demetre,

We will remove your name from the thimerosal decision memo.

Thank you,
Sarah

Sarah Hamilton
Correspondence Public Health Analyst
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Sent: Tuesday, July 8, 2025 8:09 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Tress, Deborah W. (CDC/OGC) <[redacted]>
Cc: Malone, Kevin M. (CDC/OGC) <[redacted]>; Thombley, Melisa L. (CDC/OGC) <[redacted]>; Lester, Brenda (CDC/OGC) <[redacted]>; Epps, Tanya (CDC/OGC) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>
Subject: RE: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

Thanks Deb.

I worked with the NCIRD team to produce the RSV and seasonal flu memos, but did not participate in the development of the thimerosal decision memo. I should not be on the "FROM" line on that memo.

Thanks for a chance to look at the memos again. I defer to others on content of the memo that did not get developed at NCIRD.

Demetre

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Monday, July 7, 2025 5:43 PM
To: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Tress, Deborah W. (CDC/OGC) <[redacted]>
Cc: Malone, Kevin M. (CDC/OGC) <[redacted]>; Thombley, Melisa L. (CDC/OGC) <[redacted]>; Lester, Brenda (CDC/OGC) <[redacted]>; Epps, Tanya (CDC/OGC) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: RE: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

+ Demetre as I see his name on memos as well

From: Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Sent: Monday, July 7, 2025 2:28 PM
To: Ford, Kenya S. (CDC/OGC) <[redacted]>; Tress, Deborah W. (CDC/OGC) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Malone, Kevin M. (CDC/OGC) <[redacted]>; Thombley, Melisa L. (CDC/OGC) <[redacted]>; Lester, Brenda (CDC/OGC) <[redacted]>; Epps, Tanya (CDC/OGC) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Cashman, Sandra (CDC/OD/OCS) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Subject: For Review/Clearance: ACIP Decision Memos from June 25-26, 2025, Meeting

Action Requested by CDC's Office of the Executive Secretariat

Request: Attached and also pasted at the below Teams links for your review and clearance are three decision memos from the ACIP June 25-26, 2025, meeting:

- https://cdc.sharepoint.com/:w:/t/OfficeoftheExecutiveSecretariat/EWqrZrJoClBHgdRD3x8hNFcBq_A-6rtOi7Tb1PfjGhc5Wg?e=VOuBHW
- https://cdc.sharepoint.com/:w:/t/OfficeoftheExecutiveSecretariat/Ef_gAOTOix5Mi4qrm_pgh-QBvghMkQMFxGfKJyA591_5Bw?e=AKD1zM
- https://cdc.sharepoint.com/:w:/t/OfficeoftheExecutiveSecretariat/EVtu6bO9SBhKo3TskRq9EhcBsNOyCmAd3pEODy5keTG5Bg?e=9aw4x5

Please provide feedback, including any tracked edits/additions/questions, or respond that you concur.

Clearance Due: Tuesday, July 8th by end of day

Background: On July 7, 2025, the ACIP Executive Secretary shared three decision memos from the June 25-26, 2025, ACIP meeting for the HHS Secretary's review.

Previously Reviewed/Cleared By: NCIRD, the ACIP Executive Secretary, Senior Advisor Stuart Burns, and the CDC Office of the Executive Secretariat

Please let me know if you have any questions.

Thank you,
Sarah

Sarah Hamilton
Correspondence Public Health Analyst
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Patterson, Sara S. (CDC/PHIC/OD)
Sent: Thursday, February 13, 2025 9:35 AM
To: Monarez, Susan (CDC/IOD)
Cc: Houry, Debra E. (CDC/IOD); Burns, William S. (Stuart) (CDC/IOD)
Subject: ACIP operational ideas
Attachments: ACIP Ideas Plans.docx

Hi Susan,

Attached is the plan for how we might operationalize the ACIP recommendations around COI, public engagement, and transparency. Please let us know if you have any questions or feedback.

Thanks!

Sara

Increase Transparency in Conflicts of Interest (COI) for ACIP Members to help the public assess the independence of decision-making and reduce skepticism.

- The current COI process involves a required confidential OGE450 filing, which is reviewed by the ACIP Executive Secretary, the Office of the Federal Advisory Committee Act Program, and the Office of General Counsel (if necessary). This COI process is updated annually. ACIP's COI public disclosure requirements and restrictions are stricter and more comprehensive than OGE's to avoid even the appearance of a conflict. Work group representatives also screened for conflicts of interest by the ACIP Secretariat.
- Screening for conflicts of interest focuses primarily on relationships (financial or otherwise) with pharmaceutical companies.
- Members must verbally declare conflicts of interest at ACIP meetings. Members with conflicts recuse themselves from participating in deliberations and/or votes on issues related to that interest.
- While the conflicts are stated in the meeting and captured in meeting minutes, they are not currently available online.
- To improve transparency around the COI process and individual members' conflicts, the ACIP website could be updated with all publicly disclosable conflict information for each ACIP member.
- After each ACIP meeting this info could be included on the web page with the other materials from the meeting as a link called "ACIP Member Declarations of Interest" and list the declarations from that meeting. This would be consistent with the practices of FDA's VRPAC, which includes documenting COIs online and posting a letter explaining why they are giving a waiver, when applicable.
- This can only be done after the meeting because we have to rely on the public statements at the meeting.
- FDA posts a document online sharing which members of VRPAC have COIs to declare and also posts a letter which explains why any waivers were granted allowing members to participate. This model could be followed for ACIP.
- CDC could go back to Feb 2024 and list the declared interests from previous meetings and start posting them after meetings going forward, beginning with the February 2025 meeting. CDC could note that these are COIs as known since they would be updated over time based on any changes in COI status among members.
- CDC would welcome OGC's advice on what is legally allowed in terms of disclosures via FACA law and confidential disclosure filing. CDC would be interested in the maximum public COI disclosure within the bounds of what is legally allowed. Ideally, CDC could obtain approval from all ACIP members to publish more details about conflicts based on what is in their confidential disclosures and meeting declarations. OGC input on these issues would help determine how transparent this information can be on the internet.

Improve Public Engagement in ACIP Meetings to increase public input and make ACIP's process more inclusive.

- ACIP meetings are open to the public and allow for oral public comment, but these opportunities are often short, difficult to navigate, and not well-publicized.
- A Federal Register Notice is posted online approximately 30 days prior to the meeting, starting the written public comment period. The link to this notice is posted on the CDC ACIP website and through the Federal Register.
- CDC could post salient summaries of analyses and other information reviewed by the work group on the website prior to the day of the ACIP meetings. Currently, those materials are available on the website but often not early enough to inform the public comment period. With sufficient resources dedicated to increasing the transparency of the work groups, these materials could be posted simultaneously to the public comment period opens (assuming work groups have content) and associated with the public comment period links to drive comments specific to content being discussed by work groups and the full ACIP.
- In addition to increasing public comment opportunities, another way to improve public engagement would be to increase the number of consumers represented on the ACIP. Currently, the ACIP generally has one or two ACIP members that represent the public. CDC could work with partner and constituency groups to increase outreach to and participation of members of the public in the ACIP membership as well as in the written and oral public comment process.
- In most circumstances, there is more oral public comment time than speakers to fill the time. ACIP could expand public comment time and conduct additional outreach to a broader range of constituents to stimulate more public discourse.
- CDC could host town hall meetings with ACIP members and/or CDC experts to share more information about ACIP with the public and solicit feedback on what we can do better or differently. These town hall meetings would not be about specific recommendations but rather focused on the ACIP itself and its overall processes. This may be an additional way to seek input on increasing transparency and engagement with the public.

Increase Transparency in Vote Rationales - This would clarify decision-making processes and reinforce accountability.

- ACIP members vote on recommendations, but while the overall discussion is available, individual rationales for voting decisions are not systematically explained. However, asking each member to explain their vote has precedent from other FACAs and could be explored.
- To improve transparency in vote rationales, individual members of the ACIP could be required to publicly state their rationale for key votes, either during the meeting (captured in minutes) or in a written statement.
- The ACIP could identify opportunities to enhance efforts to educate consumers about the recommendations and individual considerations in more plain language for a non-provider population.
- Well in advance of the public comment period, CDC could post a summary of the Evidence to Framework tables that the ACIP workgroups use to document the

process and the considerations used to move from evidence to decisions. This would provide the public and others to review the considerations in advance of the public comment period and the ACIP meeting. This could be accompanied by the data presented to support the work groups' discussions and votes.

- In addition to sharing the EtR materials/summary for a given vote, ACIP could also publish a more plain language summary that describes the EtR framework and how that framework is used to evaluate the data to generate recommendations and decisions.

Houry, Debra E. (CDC/IOD)

From: Monarez, Susan (CDC/IOD)
Sent: Friday, January 31, 2025 10:30 PM
To: Lubar, Debra (CDC/OD/OPPE); Bonander, Jason (CDC/OCOO/OCIO/OD)
Cc: Houry, Debra E. (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD)
Subject: ACIP website

Jason/Deb -

Apologies for the late request, but we need to get the ACIP website up and functioning. It looks like several of the links are no longer functional. This is likely due to language modifications needing to be implemented.

If you could call me when you get this message, we can discuss the best approach for an expedited process.

Thanks!

Susan

[redacted]

Houry, Debra E. (CDC/IOD)

From: Monarez, Susan (CDC/IOD)
Sent: Friday, January 31, 2025 10:40 PM
To: Patterson, Sara S. (CDC/PHIC/OD); Lubar, Debra (CDC/OD/OPPE); Bonander, Jason (CDC/OCOO/OCIO/OD)
Cc: Houry, Debra E. (CDC/IOD)
Subject: Re: ACIP website

Hi Sara -

That would be great. I just need the info on ACIP.

THANKS!

Susan

Get Outlook for iOS

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Friday, January 31, 2025 10:35:49 PM
To: Monarez, Susan (CDC/IOD) <[redacted]>; Lubar, Debra (CDC/OD/OPPE) <[redacted]>; Bonander, Jason (CDC/OCOO/OCIO/OD) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: Re: ACIP website

Hi Susan,

Jumping up from cc to share that NCIRD worked with the group that runs FACAs and OGC to determine what could be maintained and what might need to be modified before it can be made available. Rebecca Greco Kone sent a summary of what they did today. Would it be helpful to have? I can also loop her in if helpful.

Thanks,
Sara

Get Outlook for iOS

From: Monarez, Susan (CDC/IOD) <[redacted]>
Sent: Friday, January 31, 2025 10:30:20 PM
To: Lubar, Debra (CDC/OD/OPPE) <[redacted]>; Bonander, Jason (CDC/OCOO/OCIO/OD) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: ACIP website

Jason/Deb -

Apologies for the late request, but we need to get the ACIP website up and functioning. It looks like several of the links are no longer functional. This is likely due to language modifications needing to be implemented.

If you could call me when you get this message, we can discuss the best approach for an expedited process.

Thanks!

Susan

[redacted]

Houry, Debra E. (CDC/IOD)

From: Patterson, Sara S. (CDC/PHIC/OD)
Sent: Saturday, February 1, 2025 8:06 AM
To: Houry, Debra E. (CDC/IOD)
Subject: Fw: prep for 8:30

Get Outlook for iOS

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Saturday, February 1, 2025 7:45 AM
To: Monarez, Susan (CDC/IOD) <[redacted]>
Cc: Griffis, Kevin (CDC/OD/OC) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>; Coffin, Nicole (CDC/PHIC/OD) <[redacted]>
Subject: prep for 8:30

Hi Susan,

I'm confirming with comms but I believe this is the list of questions that we both discussed with ASPA and discussed/sent up through Exec Sec when ASPA told us most were policy positions and needed to be discussed with Exec Sec. Questions about the Memo.docx

Below are my notes from our calls with HHS ASPA and Exec Sec. As you can see, we did not get many of our questions answered so we had to take them down due to the language of the EO guidance. I'm also attaching Cate's note from when she talked with ASPA who told her we should shut down data.cdc.gov if we didn't hear back by 4:50.

The comms team has a master spreadsheet in the works of everything that came down but the programs need to either their information and had until Wednesday to do that. We have a larger report due Friday that Exec Sec is planning to coordinate, and this was going to be used for that report. I'm not sure we'll have a full scale and scope of what came down at our 8:30 but they relate to all of the areas listed in the questions that couldn't easily be changed.

Cate, Nicole, Kevin, please correct anything I got wrong or add anything further that may be helpful.

Here are the notes:

- Submitted journal articles that have not been published – retract
  - Language should say we are following the language of the President's EO
- BRFSS in the field
  - Pull the question if possible or change to male/female
  - SOGI policy from HHS – push up through Exec Sec
  - Pull off website
- Terms globally recognized like gender-based violence
  - Ask via Exec Sec – policy question
  - LGBTQ raise to Exec Sec
- Forms, birth certificate data – Exec Sec
  - Animals – gender? raise to Exec Sec

    - All technical guidance – Exec Sec
- Data collection – Exec Sec
- Grants/coags – Exec Sec
- Campaigns – label as historical
- Social media – leave posts up for now
    - Remove or modify anything Jan 20 to now
    - Change descriptions, images, banners that don't comply
- Yes to communicate with partners about infectious disease threats and outbreaks
    - Meeting on Monday to discuss overall pause so bear with them until then but should be OK
- Send up normal FACA process around ACIP
    - Share normal process and what we plan to do via Nicole/Cate (this was about not posting the FRN Monday re: the public comment period)
- Journal submissions – ASPA will get an answer
- Media/ad buys – OK

Exec Sec – took questions and said they would share up but could not guarantee an answer. We did not hear back.

Sara

Houry, Debra E. (CDC/IOD)

From: Corry, Thomas (HHS/ASPA) <[redacted]>
Sent: Saturday, February 1, 2025 9:41 AM
To: Patterson, Sara S. (CDC/PHIC/OD); Spear, Stefanie (HHS/IOS); Nixon, Andrew (HHS/ASPA)
Cc: Houry, Debra E. (CDC/IOD); Monarez, Susan (CDC/IOD); Greco Kone, Rebecca (CDC/NCIRD/OD); Shockey, Caitlin E. (CDC/OD/OC); Malone, Kevin M. (CDC/OGC); Ford, Kenya S. (CDC/OGC); Griffis, Kevin (CDC/OD/OC); Daskalakis, Demetre (CDC/NCIRD/OD); Aleshire, Noah (CDC/OD/OPPE)
Subject: RE: ACIP web content

I know everything is going back up but I googled CDC vaccine information and it took me to a CDC.gov site but said the page you're looking for was not found. We need to make sure everything is back up. Just confirming this is happening.

Thomas Corry
Office of the Assistant Secretary for Public Affairs
U.S. Dept. of Health and Human Services
[redacted]

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Saturday, February 1, 2025 9:00 AM
To: Spear, Stefanie (HHS/IOS) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>; Corry, Thomas (HHS/ASPA) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>; Monarez, Susan (CDC/IOD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Griffis, Kevin (CDC/OD/OC) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Aleshire, Noah (CDC/OD/OPPE) <[redacted]>
Subject: RE: ACIP web content

Hi all,

Here is the spreadsheet just so you can see so far what we have. We will figure out how to share it live so you can see more real time updates.

Thanks,

Sara

-----Original Appointment-----
From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Friday, January 31, 2025 11:04 PM
To: Monarez, Susan (CDC/IOD); Spear, Stefanie (HHS/IOS); Greco Kone, Rebecca (CDC/NCIRD/OD); Daskalakis, Demetre (CDC/NCIRD/OD); Ford, Kenya S. (CDC/OGC); Malone, Kevin M. (CDC/OGC); Aleshire, Noah (CDC/OD/OPPE)
Cc: Houry, Debra E. (CDC/IOD); Shockey, Caitlin E. (CDC/OD/OC); Griffis, Kevin (CDC/OD/OC); Nixon, Andrew (HHS/ASPA); Corry, Thomas (HHS/ASPA)
Subject: ACIP web content
When: Saturday, February 1, 2025 8:30 AM-9:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

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For organizers: Meeting options Reset dial-in PIN

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Wednesday, June 25, 2025 11:14 AM
To: Burns, Stuart (CDC/IOD)
Subject: FW: ACIP background documents on Thimerosal and MMRV

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Zadeh, Mina (CDC/OD/OCS) <[redacted]
Sent: Tuesday, June 24, 2025 1:21 AM
To: Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; MacNeil, Jessica R. (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Kroop, Seth (CDC/NCEZID/OD) <[redacted]>; Kuhnert, Wendi (CDC/NCEZID/OD) <[redacted]>; Nordlund, Kristen (CDC/NCEZID/OD) <[redacted]>; Oliver, Angela (CDC/NCEZID/OD) <[redacted]>; Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <[redacted]>
Subject: RE: ACIP background documents on Thimerosal and MMRV

Received, thank you.

From: Braden, Chris (CDC/NCEZID/OD) <[redacted]
Sent: Monday, June 23, 2025 2:20 PM
To: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; MacNeil, Jessica R. (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Kroop, Seth (CDC/NCEZID/OD) <[redacted]>; Kuhnert, Wendi (CDC/NCEZID/OD) <[redacted]>; Nordlund, Kristen (CDC/NCEZID/OD) <[redacted]>; Oliver, Angela (CDC/NCEZID/OD) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <[redacted]>
Subject: ACIP background documents on Thimerosal and MMRV

Mina and Stuart,
Please find attached background documents on summary of evidence for safety of thimerosal-containing vaccines and MMRV in pdf format for sharing/posting. The MMRV Word version document was shared previously. These have been cleared by NCEZID.
Let us know if you have questions.
Thanks
Chris

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Wednesday, June 25, 2025 11:13 AM
To: Burns, Stuart (CDC/IOD)
Subject: FW: ACIP background documents on Thimerosal and MMRV
Attachments: MMRV safety summary_20JUN2025_final.pdf; Thimerosal-Containing Vaccines - Summary of Evidence_23JUN2025.pdf

Here is one email

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Braden, Chris (CDC/NCEZID/OD) <[redacted]>
Sent: Monday, June 23, 2025 2:20 PM
To: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; MacNeil, Jessica R. (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Kroop, Seth (CDC/NCEZID/OD) <[redacted]>; Kuhnert, Wendi (CDC/NCEZID/OD) <[redacted]>; Nordlund, Kristen (CDC/NCEZID/OD) <[redacted]>; Oliver, Angela (CDC/NCEZID/OD) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <[redacted]>
Subject: ACIP background documents on Thimerosal and MMRV

Mina and Stuart,
Please find attached background documents on summary of evidence for safety of thimerosal-containing vaccines and MMRV in pdf format for sharing/posting. The MMRV Word version document was shared previously. These have been cleared by NCEZID.
Let us know if you have questions.
Thanks
Chris

Houry, Debra E. (CDC/IOD)

From: Greco Kone, Rebecca (CDC/NCIRD/OD)
Sent: Wednesday, June 25, 2025 3:42 PM
To: Houry, Debra E. (CDC/IOD)
Subject: FW: Thimerosal presenation on ACIP website

Forwarding per our conversation and given the inquiry regarding this document.

From: Greco Kone, Rebecca (CDC/NCIRD/OD)
Sent: Tuesday, June 24, 2025 2:16 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Subject: RE: Thimerosal presenation on ACIP website

Hi Stuart,

When this was originally posted it was confusing. The web team has updated the site to clearly indicate that document was a review of the evidence prepared by CDC. Mrs. Redwood's presentation is now posted too so I hope this is clearer.

ACIP Meeting Materials: June 25-26, 2025 Meeting | ACIP | CDC

Rebecca

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Tuesday, June 24, 2025 12:20 PM
To: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>
Subject: Thimerosal presenation on ACIP website

Rebecca and Mina,

I'm a bit confused about the Thimerosal presentation posted on ACIP website.

That is not Mrs. Redwood's presentation. Whose presentation is that as there is no reference.

Why is the

Stuart

Stuart Burns
Senior Advisor
Office of the Director
Centers for Disease Control and Prevention
[redacted]

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Wednesday, June 25, 2025 7:30 AM
To: Monarez, Susan (CDC/IOD)
Subject: FW: reviewing external SME presentations

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD)
Sent: Wednesday, June 25, 2025 7:17 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Subject: reviewing external SME presentations

Hi Stuart and Mina
I saw the news articles and X about Lyn's presentation that was taken down and put back up with 2 reference errors including wrong information from a study. I looked at website and don't see Kulsdorf slides. Have either of you reviewed these? As DFO for ACD I reviewed all the presentations not cleared by our SMEs. Even if it is from an outside presenter, these errors hurt our reputation, are labeled as CDC, and erode trust in our agency's credibility.

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

[redacted]; Thomas, Stephanie B. (CDC/NCIRD/OD) <[redacted]; Early, Megan S. (CDC/OD/OCS)
<[redacted]; Smagh, Kalwant (CDC/OCOO/OSBI) <[redacted]; Thombley, Melisa L. (CDC/OGC)
<[redacted]; Patel, Manisha (Mo) (CDC/NCIRD/OD) <[redacted]
Subject: COVID-19 TOR (please use as model for other WG TORs)

Hi Rebecca,
Apologies, I didn't attach the latest COVID-19 TOR in the last email I just sent.
As you mentioned, this document has been posted on the ACIP site (thanks to Dayle and her group). The attached TOR has been reviewed by OSBI/OGC (CDC and HHS) and IOD and others in HHS have approved it. I've received direction to have the WGs use this TOR as the model.
Please note, for the RSV WG, the Chair is already drafting the activities and running it by other ACIP members on that WG; I will forward the draft as soon as I receive it.
I am adding NCEZID and NCHHSTP, so they also have the same TOR version to work with.
Thank you all!
Mina

Houry, Debra E. (CDC/IOD)

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Monday, August 25, 2025 3:03 PM
To: Houry, Debra E. (CDC/IOD)
Subject: FW: COVID-19 TOR (please use as model for other WG TORs)

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Malone, Kevin M. (CDC/OGC) <[redacted]>
Sent: Monday, August 25, 2025 2:45 PM
To: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Ellington, Renata (CDC/NCHHSTP/OD) <[redacted]>; Langer, Adam J. (CDC/NCHHSTP/OD) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>
Cc: Ford, Kenya S. (CDC/OGC) <[redacted]>; Thombley, Melisa L. (CDC/OGC) <[redacted]>; Ghosh, Sudevi (CDC/OGC) <[redacted]>; Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Burns, Stuart (CDC/OD/OCS) <[redacted]>; Faircloth, Jordan (CDC/IOD) <[redacted]>; Thomas, Stephanie B. (CDC/NCIRD/OD) <[redacted]>; Early, Megan S. (CDC/OD/OCS) <[redacted]>; Smagh, Kalwant (CDC/OCOO/OSBI) <[redacted]>; Patel, Manisha (Mo) (CDC/NCIRD/OD) <[redacted]>
Subject: RE: COVID-19 TOR (please use as model for other WG TORs)

Mina –

To clarify, while OGC reviewed earlier drafts of the Terms of Reference for the COVID-19 Work Group, we did not see the final nor clear it. In its reviews, OGC expressed legal concerns regarding the proposed role of the Work Group Chair relative to that of the committee DFO and Work Group Lead given FACA's clear statutory provisions that the agency maintains responsibility to define agendas/scope of topics addressed and membership. In addition, we provided legal advice to narrow WG topics to those that are within the scope of CDC's mission and authorities. While the ultimate content of the TOR is with the policymakers, those legal concerns remain.

Please send drafts of all additional Work Group TORs to OGC for review.

Kevin

From: Zadeh, Mina (CDC/OD/OCS) <[redacted]
Sent: Saturday, August 23, 2025 11:23 AM
To: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Ellington, Renata (CDC/NCHHSTP/OD) <[redacted]>; Langer, Adam J. (CDC/NCHHSTP/OD) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>
Cc: Malone, Kevin M. (CDC/OGC) <[redacted]>; Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Burns, Stuart (CDC/OD/OCS) <[redacted]>; Faircloth, Jordan (CDC/IOD)

Houry, Debra E. (CDC/IOD)

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Monday, August 25, 2025 10:20 AM
To: Houry, Debra E. (CDC/IOD)
Subject: Fw: DRAFT, PREDECISIONAL, AND CONFIDENTAL – NOT FOR DISTRIBUTION; ACIP COVID-19 Workgroup Materials

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From: Retsef Levi <[redacted]>
Sent: Monday, August 25, 2025 10:15:25 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Levi, Retsef (CDC/NCIRD/OD) <[redacted]>; MacNeil, Adam (CDC/NCIRD/CORVD) <[redacted]>; Link-Gelles, Ruth (CDC/NCIRD/CORVD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Aleshire, Noah (CDC/OD/OPPE) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>; James Pagano <[redacted]>; Robert Malone <[redacted]>
Subject: RE: DRAFT, PREDECISIONAL, AND CONFIDENTAL – NOT FOR DISTRIBUTION; ACIP COVID-19 Workgroup Materials

Dear Demetre (and Adam),

Thanks for sharing with us the slide deck and the document summary. I shared the material with the other ACIP members who are part of the WG, and they are cc'd on this email.

We much appreciate the hard work put into this and hope we can work together to prepare a comprehensive report for the upcoming ACIP meeting.

Upon very careful review, we amend below a detailed list of questions and requests. We also attach the presentation with comments/questions added on specific slides.

These should add to the pending questions and requests we already shared with you regarding the data and analyses that would be important in informing our upcoming recommendations. We look forward to discussing with you, the WG leads and the CDC staff the next steps!

Beyond the detail feedback, we would like to share several key high-level issues:

1. The presentation should include more explicit analysis of risk of severe covid outcomes (hospitalization, ICU and death) per sub-groups. In fact, we believe that this should be a focus point versus providing a lot of detail on overall hospitalization load that does not translate to direct understanding of the individual risk. One potential way to communicate this is the overall risk of experiencing an outcome of 12-month season. It seems that some of this is already

presented (somewhat implicitly) in the slides provided, and below you can find specific suggestions (see 6)-8) below). Additionally, we repeat our request to see analysis of non-specific outcomes like all cause and flu-like hospitalizations and deaths.

2. Related to the analysis in 1) above, we would like to have better understanding of the precise definition of covid-associated hospitalizations/deaths. It seems like the current definition relies, at least partially on PCR tests which is not necessarily clinically meaningful. The data provided and existing literature suggest that there is a real concern of confounding of events 'because of covid' versus ' incidentally with covid', and this seems critical to have reliable risk assessment. Nominally, one should use admission diagnosis and discharge diagnosis to better discern which events are truly because of covid. We feel that this should be a central point of discussion. (see 1) below, and the data on children mortality that suggest that many of the counted deaths do not have covid on the death certificate).
3. Related to 1) above, we feel that there should be explicit analysis of prior exposure to infections and the implications it has on risk for severe outcomes. The data provided (end of 2022 – is there any updated data) suggest very high population exposure rates and given the known literature on the long and robust protection of prior infections with respect to severe outcomes, this should be more explicitly considered in the risk-benefit analysis.
4. The discussion re the risk from long covid and the respective potential protection of vaccination seems to rely on very shaky evidence. First, the analysis mixes old variants with omicron variants. Second, it is often based on papers that are methodologically weak and prone to bias and ignores papers that show contradictory results. They also do not analyze the impact of prior infections on the risk of long covid. We believe that the analysis should be revised accordingly. This analysis should be revised accordingly.
5. We have similar thoughts to 4) above with respect to the analysis of the risk to pregnant women, and the protection vaccination provides to the woman and the baby. This analysis should be revised accordingly and incorporate the fact that the risks and the benefits of vaccination during pregnancy were never evaluated appropriately in clinical trials.
6. We would like to underscore again our questions (and concerns) re the current safety and risk analysis of the covid vaccines (please see separate emails we shared).
7. We would like to underscore again out questions related to the definition of high risk patients and what more specific factors play a role in increased risk of severe covid outcome and potentially increased risk of AEs.
8. We feel that the very low uptake of the vaccine among healthcare professionals is a major ethical issue. How can medical professional recommend a vaccine that they elect not to take?
9. We ask that the cost-benefit analysis, will include assessment of the waste incurred by vaccines that are ultimately not used. There seems to be significant economic waste in that respect.

Thanks!

Robert, James and Retsef

List of questions:

1. We need clear definitions of what is counted as COVID hospitalization and death - and how with vs. because COVID is determined:

   - In particular, it will be important to consider the admission diagnosis and discharge diagnosis (should be available in hospital systems)

- Also from slide 29 it seem like covid deaths are counted even when it does not appear as the cause of death on the death certificate (see detail comment) – we need to have clarity on these definitions!

2. Data on long covid (slide 7) do not seem relevant to decision since it is related to pre-omicron times. What we need is assessment of the number of new long covid cases during the last season (under Omicron variants) and also assessment of the vaccine protection (how many needed to be vaccinated to prevent a long covid case:

   - The presentation seems to ignore the most rigorous study on long covid (https://www.bmj.com/content/380/bmj-2022-072529) that showed that the risk is significantly reduced for children and that vaccination has minimal to no impact. This is the only study that had rigorous control

3. Decrease of MIS-C over time reinforces item 2) above (slide 8)
4. Is there updated data on seroprevalence among children and also what data available on adults? This is super critical because it seems like most of the population has been exposed and has natural immunity (slide 9 and https://covid.cdc.gov/covid-data-tracker/#pediatric-seroprevalence)
5. Slides 11-12 shows decreased covid-associated hospitalization rates - do you have any thoughts on this?
6. Pediatric COVID-19–Associated Hospitalizations/mortality (Slide 15-29) – please create two slides (the rest is unnecessary and does not present relevant information):

   - Slide that includes the following: cumulative rate (per 100K) of covid-associated hospitalization per age group (< 6 mo, 6-23, 2-4, 5-11, 12-17) and separated to >= underlying condition and no condition.
   - Same slide but on ICU hospitalizations
   - Same slide but hospital mortality

7. As a control, please provide the overall annual rate of hospitalization (per 100K) of the < 6 mo and 6-23 mo. This will show whether covid is a specific reason for hospitalization or mostly incidental to hospitalizations that occur for other reasons.
8. Similar analysis to 6) for adults, broken by age groups 0f 19-29, 30-49, 50-64, 65-74 and over 75.
9. Slide 36 – Is misleading and in fact suggestive that most pregnant women do not get hospitalized because of covid. We need similar analysis to above re the risk of pregnant women to be hospitalized because of covid (how many covid hospitalizations per 100K pregnant women occurred over a year based on admission diagnoses). Then we need assessment as to the extent that vaccination will reduce this risks, and how well we understand the risks of vaccination during pregnancy.
10. Slide 42 – please add to the outcome all cause mortality and hospitalization, and all flu-like hospitalizations.
11. Slides 45-46 – please provide the data that supports these slides.
12. Slide 50 – can you please provide the data and analyses supporting the statements on the slide? There are strong statements in the slide re the efficacy of vaccination, and I am not sure I see data to support that.

13. Slide 51 – can you explain why do you think vaccinated children are over represented in the MISC group?
14. Slide 52 – the papers cited are weak methodologically and prone to bias. Also they do not consider individuals with prior infections/exposure which is almost all the population at the moment.
15. Slide 53 – the evidence provided re the protection of vaccination against infection/transmission is not convincing. The papers cited often provide statistically insignificant results, and also do not discern between the protection of prior infection versus vaccination. They also look mostly on symptomatic infections.
16. Slides 54-55 – can we please get the details of the study re the impact of vaccination against secondary attack rate. One concern is that vaccination could be confounded with other behaviors and conditions that could impact the attack rate,
17. Slide 57-59 – the vaccine safety analysis of the CDC requires the following clarifications: (i) what the working definitions of safety signal are; (ii) what are the risk windows being studied; (iii) how likely the current surveillance systems are to capture non specific AE that emerge over a long run; (iv) to what extent the CDC reviewed existing literature and several large scale studies that do show concerning safety issues and risks.
18. Please provide details on the model mentioned on slides 60-61. This model does not seem to address the most important questions: what is the risk level from covid to different sub-populations (as per different outcomes)? What is the risk reduction and its duration from vaccination per sub-population, and how it changes given prior infection? What are the potential risks of vaccination per sub-population?
19. Slide 62-65 re the risk of covid in pregnancy and the efficacy of vaccination to protect the mother and infants are highly misleading since and are based on papers that often study non omicron variants or using methodologies that highly prone to biases and confounding and questionable outcome definition (see discussion re covid associated hospitalizations. The also ignore other literature that shows different results. Finally, they do not account for the fact that the safety of vaccination during pregnancy was never evaluated in clinical trials.
20. Slides 66-71 are as summary that needs to be radically updated per all the comments above.
21. Slides 72-79 are based on multiple surveys – please add analysis of each survey re the potential biases and how representative the population sampled is. Also please add summary of surveys that ask about the perception re vaccine injuries.
22. Slides 80-91 – please explain better how the different surveys were conducted. It looks like the covid vaccines have relatively low trust in the population and particularly among HC professionals. These results seem to contradict the surveys in 21) above. This creates a moral issues – how medical professionals can recommend to the public something they do not do themselves....
23. Slides 92-100 – Given the low acceptance and high cost, could you please do an assessment based on prior season data of estimated wasteful cost of unused vaccines?
24. Slides 101-104 – Please explain the details of the different models and what extent they consider the significant waste of unused vaccines?
25. Slides 105-113 – I am not sure what the relevance is to the discussion, and some of the results presented seem to be contradictory to the actual uptake of the vaccine.

From: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Sent: Friday, August 22, 2025 2:25 PM

To: Levi, Retsef (CDC/NCIRD/OD) <[redacted]>; MacNeil, Adam (CDC/NCIRD/CORVD) <[redacted]>; Link-Gelles, Ruth (CDC/NCIRD/CORVD) <[redacted]>; Retsef Levi <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Aleshire, Noah (CDC/OD/OPPE) <[redacted]>; Eiring, Hilary (CDC/NCIRD/OD) <[redacted]>
Subject: DRAFT, PREDECISIONAL, AND CONFIDENTAL – NOT FOR DISTRIBUTION; ACIP COVID-19 Workgroup Materials

Retsef-

Ae per our meeting yesterday, I am attaching the EtR and an executive summary reflecting work that has occurred on the COVID-19 25-26 recommendation before the current terms of reference were implemented. We have color coded the document so you and other workgroup members can see where we had and had not yet completed work group finalization of the EtR document.

As always, these materials are subject to the confidentiality agreements that govern workgroup participation.

@Zadeh, Mina (CDC/OD/OCS) we look to you to advise Dr. Levi on the specifics of when this may or not be shared within the workgroup as you work to onboard new members.

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Monday, July 28, 2025 7:59 AM
To: Burns, Stuart (CDC/IOD); Jernigan, Daniel B. (CDC/NCEZID/OD); Zadeh, Mina (CDC/OD/OCS); Meyer, Sarah (CDC/NCEZID/DHQP/ISO)
Cc: Braden, Chris (CDC/NCEZID/OD); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Early, Megan S. (CDC/NCHHSTP/DVH); Terminello, Amanda (CDC/NCHHSTP/DVH); Witkofsky, Nina (CDC/IOD); Fountain, Alison (CDC/OD/OCS)
Subject: RE: ISO current and past studies for ACIP committee members

Thanks Stuart. Happy to talk with you and team about this too
Would suggest each of the CIOs get the specific ?s needed for lit review by the work group NLT today (and this may have already happened but Hep B as of Thursday PM hadn't received anything yet). I know this is needed for the workgroups to develop draft data-driven recommendations; our SMEs need some time to do this. For the COVID ?s below, would suggest prioritizing those that correlate with information needed for a vote. The DFO and the ACIP staff have an important role in working with ACIP and workgroups to prioritize, streamline, and hone in on the ?s needed to be answered and then go to program with these requests. Dr. Alison Fountain who is in the OD can also help with fine tuning these questions from a clinical perspective and prioritizing with the ACIP staff team

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Sunday, July 27, 2025 9:32 PM
To: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>
Cc: Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <[redacted]>; Early, Megan S. (CDC/NCHHSTP/DVH) <[redacted]>; Terminello, Amanda (CDC/NCHHSTP/DVH) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Subject: Re: ISO current and past studies for ACIP committee members

We will talk through this in the morning to prioritize. I should be in at 10 am

Get Outlook for iOS

From: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>
Sent: Sunday, July 27, 2025 9:16:38 PM
To: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <[redacted]>; Early, Megan S. (CDC/NCHHSTP/DVH) <[redacted]>; Terminello, Amanda (CDC/NCHHSTP/DVH) <[redacted]>; Houry,

Debra E. (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Subject: RE: ISO current and past studies for ACIP committee members

All:
I believe Sarah is on leave this week, so let's take that into account as we address this list below. We may need to have a better process for prioritizing requests than a list like this below. There are other meetings with ISO that the administration has requested that we are working to schedule this week. Stuart, can you help us prioritize these efforts with the other requests we have?
Dan.

From: Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Sent: Sunday, July 27, 2025 7:46 PM
To: Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <[redacted]>; Early, Megan S. (CDC/NCHHSTP/DVH) <[redacted]>; Terminello, Amanda (CDC/NCHHSTP/DVH) <[redacted]>
Subject: RE: ISO current and past studies for ACIP committee members

Hi Sarah,

Thank you so much for the information you provided. This is very helpful; I've shared it with the ACIP members.

I'd like to schedule a meeting this week with you, Chris, the COVID-19 WG Chair (Retsef Levi) to follow up on Vaccine Safety related questions. Would you please provide times that you or your delegates would be available (for 45 minutes-1 hr) this week?

The COVID-19 WG Chair has also asked to provide further information about the following studies (i.e., data, methodology, status including preliminary results):

- Mortality and Vaccination with COVID-19 vaccines
- Surveillance for Adverse Pregnancy and Birth Outcomes following COVID-19 Vaccine Exposures During Pregnancy
- COVID-19 Vaccine Safety, Spontaneous abortion (SB) and Stillbirth in the Vaccine Safety Datalink; two case control studies
- The Association Between COVID-19 mRNA Vaccination and Type 1 Diabetes in Children
- Modified self-controlled case series design for assessing mortality risk after COVID-19 vaccination
- Safety of Concomitant Seasonal Influenza, COVID-19 and Respiratory Syncytial (RSV) Vaccine Administration in the U.S. Elderly Population Aged 65+
- Ischemic stroke after bivalent COVID-19 vaccination: a self-controlled case series study in the Vaccine Safety Datalink
- Chronic Urticaria and Dermographism after COVID 19 Vaccine Booster
- COVID-19 Vaccination and Risk of Febrile Seizures in Young Children 6-59 months old in the Vaccine Safety Datalink, 6/18/22 – 12/31/24
- Examining the association between COVID-19 vaccination and oral lichen planus
- Risk of pulmonary embolism (PE) following simultaneous seasonal influenza, COVID-19 and RSV vaccination compared to sequential vaccination among older adults in the U.S.
- Safety of Simultaneous and Sequential Vaccination during Pregnancy in the VSD
- Evaluation of the Risk of Ischemic Stroke after SARS-CoV-2 mRNA Vaccines Using a Vaccinated Concurrent Comparator Analysis within the Vaccine Safety Datalink
- Association between juvenile idiopathic arthritis and the childhood schedule and COVID-19 vax
- Simultaneous mRNA COVID-19 and IIV4 Vaccination in Pregnancy Study

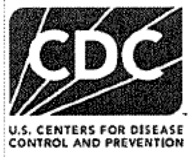
- Safety of simultaneous mRNA COVID-19 vaccine with other childhood vaccines in young children
- Safety of Pediatric COVID-19 Vaccination
- Simultaneous mRNA COVID-19 and Quadrivalent Inactivated Influenza Vaccine (IIV4) Vaccination Study
- A Prospective Observational Study to Evaluate the Safety of COVID-19 Vaccination in Pregnant Women
- Assessment of hypertensive disorders of pregnancy in women who received COVID-19 vaccine during pregnancy
- Assessment of maternal ICU admission + cardiovascular postpartum conditions in women who received COVID-19 vaccines during pregnancy
- Assessment of medical conditions in infants born to women who received COVID-19 vaccine during pregnancy
- Assessment of perinatal death and preterm birth in infants born to women who received COVID-19 vaccine during pregnancy
- Assessment of spontaneous abortion in women who received COVID-19 vaccine during pregnancy
- Assessment of birth defects in infants born to women who received COVID-19 vaccine during pregnancy
- Assessment of NICU admission in infants born to women who received COVID-19 vaccine during pregnancy

Is this something that your team can pull together easily?

Many thanks!

V/R
Mina

Mina Zadeh, PhD, MPH
Designated Federal Officer, ACIP Executive Secretary
Director, Scheduling and Advance
Centers for Disease Control and Prevention (CDC)



DRAFT, INTERNAL, DELIBERATIVE, NOT FOR DISTRIBUTION
PREDECISIONAL

From: Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>
Sent: Sunday, July 27, 2025 5:39 PM
To: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]; Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <[redacted]>
Subject: ISO current and past studies for ACIP committee members

Dear Mina and Stuart,
Attached are the lists of ISO's current projects on vaccine safety, as well as ISO's past studies. Please feel free to share with the ACIP committee members, as this information was requested during last week's briefing on safety systems.
Best regards,
Sarah

Sarah Meyer, MD MPH
Director, Immunization Safety Office
Centers for Disease Control and Prevention
US Department of Health and Human Services
[redacted]

Houry, Debra E. (CDC/IOD)

From: Monarez, Susan (CDC/IOD)
Sent: Thursday, August 21, 2025 4:12 AM
To: Houry, Debra E. (CDC/IOD)
Cc: Daskalakis, Demetre (CDC/NCIRD/OD)
Subject: Re: ACIP - COVID 19 TOR --- for posting please

Good morning Deb -

Thanks for looping me in. Indeed I was not aware. I'll see if Matt and Mina are open to revising, but I understand they are getting direction from IOS so not sure how much I can do.

Best,
Susan

From: Houry, Debra E. (CDC/IOD) <[redacted]
Sent: Wednesday, August 20, 2025 7:39 PM
To: Monarez, Susan (CDC/IOD) <[redacted]
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]
Subject: FW: ACIP - COVID 19 TOR --- for posting please

Hi Susan
Just ensuring you are aware as I don't see you on the email below or in the approval chain. Demetre reviewed and this doesn't include his/my edits or the CDC OGC edits
Deb

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]
Sent: Wednesday, August 20, 2025 6:10 PM
To: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]; Zadeh, Mina (CDC/OD/OCS) <[redacted]; Kern, Dayle (CDC/NCIRD/OD) <[redacted]
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]; Houry, Debra E. (CDC/IOD) <[redacted]; Witkofsky, Nina (CDC/IOD) <[redacted]; Burns, Stuart (CDC/OD/OCS) <[redacted]; Faircloth, Jordan (CDC/IOD) <[redacted]; Aleshire, Noah (CDC/OD/OPPE) <[redacted]; Early, Megan S. (CDC/OD/OCS) <[redacted]
Subject: Re: ACIP - COVID 19 TOR --- for posting please

The TOR language is approved. Mina has the final version.

Matt Buzzelli
Chief of Staff

CDC
U.S. Department of Health and Human Services
[redacted]

From: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>
Sent: Wednesday, August 20, 2025 4:42:58 PM
To: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Kern, Dayle (CDC/NCIRD/OD) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/OD/OCS) <[redacted]>; Faircloth, Jordan (CDC/IOD) <[redacted]>; Aleshire, Noah (CDC/OD/OPPE) <[redacted]>; Early, Megan S. (CDC/OD/OCS) <[redacted]>
Subject: RE: ACIP - COVID 19 TOR --- for posting please

Hi Mina,

Can you confirm that CDC IOD/senior leadership would like these posted? I understand that there was still some discussion around the TOR so would like to be sure we have approval to post.

Dayle's team is standing by once we receive clearance/approval in writing from IOD leadership.

Note that the web content language is relatively easy to post. Typical practice would be for the PDF version of the document to be 508 compliant before posting. We can certainly post first and then make it 508 compliant. I just want to be sure Nina or others in OC are ok with this approach since my understanding is that is not preferred practice/policy but defer to Nina and her team on this.

Thank you
Rebecca

Rebecca Greco Koné
Deputy Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Sent: Wednesday, August 20, 2025 2:42 PM
To: Kern, Dayle (CDC/NCIRD/OD) <[redacted]>
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/OD/OCS) <[redacted]>; Faircloth, Jordan (CDC/IOD) <[redacted]>; Aleshire, Noah (CDC/OD/OPPE) <[redacted]>; Early, Megan S. (CDC/OD/OCS) <[redacted]>
Subject: ACIP - COVID 19 TOR --- for posting please
Importance: High

Hi Dayle,

I hope you are well. Attached are the Word and PDF versions of ACIP's COVID-19 WG TOR. This version has been reviewed by OSBI, OGC CDC/HHS, NCIRD, IOD, other HHS POCs and the WG Chair/ACIP members on the WG. Would you please update the ACIP WG site today – under COVID 19 (ACIP Work Groups | ACIP | CDC) – with the information below and a link at the bottom to the full document: (please feel free to change the font color to black, I used blue to separate it from my email text)

COVID-19 Immunizations

TOPICS UNDER DISCUSSION BY THE WORKGROUP

The following topics relevant to COVID-19 immunization for effective control of COVID-19 disease in the civilian population of the United States will be under discussion in the WG in multi-year efforts.

1. Risk-benefit and cost-benefit analyses of existing and newly FDA-authorized mRNA and other COVID-19 immunizations, and immunization schedules as it relates to COVID-19 immunization to inform use recommendations, personalized per age-group, major risk factors and health status.
2. To identify critical gaps in the existing scientific and clinical knowledge and methodologies related to the safety and efficacy of the COVID-19 immunizations, to inform the development of policy recommendations and further analyses and research by the CDC, other related federal agencies, and the scientific community.
3. To review and summarize data, clinical and scientific knowledge related to adverse events associated with COVID-19 immunizations to inform immunization recommendations in terms of precautions and contraindications to receipt of immunization.

DESCRIPTION of WORKGROUP ACTIVITIES

The following activities provide a framework for the COVID-19 immunization WG multi-year efforts which may involve data requests from other Federal and private partners:

1. Review and summarize existing data and published and unpublished research and clinical knowledge related to the safety, effectiveness, and immunogenicity of COVID-19 immunizations authorized or approved in the United States.
2. Summarize literature reviews of the epidemiology of COVID-19 disease and SARS-CoV-2 virus.
3. Assess the benefit-risk balance for administration of COVID-19 immunization products at the same time as other immunizations.
4. Identify areas where additional data and research are needed to inform COVID-19 immunization recommendations.
5. Develop COVID-19 immunization recommendations.
6. Review and summarize the existing clinical and scientific information available; and gaps in the existing knowledge, including from other federal agencies like the FDA, where appropriate relating to bio distribution, pharmacokinetics and persistence of the spike protein, mRNA, and lipid nanoparticles to inform immunization recommendations.
7. Review and summarize the existing clinical and scientific information (including from federal agencies like the FDA, where appropriate); gaps in the existing knowledge regarding potential impurities (e.g., DNA contamination and endotoxins) in existing immunization products and their health impacts to inform immunization recommendations.
8. Review and summarize the existing scientific knowledge, and gaps, regarding the cumulative short- and long-term impact of repeated boosting immunization including non-specific effects (e.g., IgG4 class switching, immune imprinting, viral evolution under leaky immunizations) to help inform immunization recommendations.
9. Examine the impact of COVID-19 immunization on COVID-19 and all cause deaths, hospitalizations, and disability to inform immunization recommendations.
10. Analyze existing data and scientific knowledge regarding cardiovascular, thrombotic, neurological, immunological and other serious adverse events potentially caused by COVID-19 immunization.

11. Review and summarize available data, information, and gaps regarding long-term Covid effects from scientific literature and clinical experience associated with COVID-19 immunization products and COVID-19 infection to inform policy recommendations.
12. Map existing COVID-19 immunization policies in countries around the world and how they compared to the US.
13. Analyze existing data and scientific knowledge related to the safety of COVID-19 immunization during pregnancy.

[LINK TO FULL TOR]

Many thanks!

V/R
Mina

Mina Zadeh, PhD, MPH
Designated Federal Officer, ACIP Executive Secretary
Director, Scheduling and Advance
Immediate Office of the Director / Office of Chief of Staff
Centers for Disease Control and Prevention (CDC)

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Advisory Committee on Immunization Practices,
Centers for Disease Control and Prevention (ACIP, CDC)
COVID-19 Immunization Workgroup
Terms of Reference
UPDATED: July 22, 2025

PURPOSE

This document defines the activities, membership, and administrative requirements associated with the establishment of a **COVID-19 Immunization Workgroup** under the Advisory Committee on Immunization Practices, Centers for Disease Control and Prevention (ACIP, CDC). ACIP utilizes subgroups of the Committee, known as Workgroups (WGs), to review relevant published and unpublished data, and clinical and scientific knowledge, and develop options for presentation to the full ACIP parent committee during its public meetings to facilitate discussion, deliberation and development of recommendations. ACIP WGs are intended to augment the effectiveness of ACIP. The direction, focus, and pace of both ACIP and the individual WGs are guided by CDC and HHS policies and priorities, and by the perceived need for expert input to inform development of CDC immunization policy. ACIP WGs serve a key **scientific role** in support of immunization policy development by ACIP. The COVID-19 Immunization WG has been specifically established to review data, as well as clinical and scientific knowledge on COVID-19 immunizations, to help develop COVID-19 immunization policy options for ~~and recommendations for~~ ACIP consideration to formulate advice to CDC and HHS leadership.

Commented [DD1]: I wonder if this is correct. Is the clinical direction guided by policy? Seems like rather than direction, it should be "policy questions asked, its focus and pace..." is more appropriate. The data should drive the direction of the WG.

Commented [DH2]: Would not say perceived need- FACA mandates this- plus I would suggest for gold standard science you want external input for validation

Commented [DD3]: What does that mean? Seems like if its part of a FACA there is legislated need for external expert input, right?

Commented [DD4]: CDC and HHS develop the policy. ACIP recommends a direction

Commented [DD5]: Needs to be VERY clear that ACIP does not MAKE policy

For the purposes of this document, Immunization refers to vaccines and other antibody protective products, to prevent disease, e.g., immunoglobulins.

BACKGROUND

COVID-19 is a disease caused by the SARS-CoV-2 virus. For some patients, COVID-19 can ~~still~~ be severe, causing significant morbidity and mortality. Currently there are three vaccine manufacturers (Moderna, Novavax, and Pfizer) with a combined four COVID-19 vaccines authorized or approved for use in the United States. As the SARS-CoV-2 virus evolves, new formulations of the COVID-19 vaccine have been developed to better ~~match~~ approximate currently circulating strains.

Commented [DD6]: Does this include pediatric formulations to make the count 4?

Commented [DD7]: Match not a preferred way of describing this updating of the vaccine.

The COVID-19 WG was established in 2020 and met frequently to discuss immunization recommendations as the COVID-19 pandemic evolved. ACIP ~~meets three times per year~~has three scheduled meetings per year, and as needed, to provide recommendations on existing and/or newly developed vaccines.

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According to the 21st Century Cures Act (PL 114-255), ACIP shall also, as appropriate, consider new vaccines or new indications at its next regularly scheduled meeting after licensure; if the Committee defers making a recommendation, it will provide an update on the status of its review. Additionally, ACIP shall make recommendations in a timely manner for vaccines that are designated as breakthrough interventions ~~therapy~~ or could be used in a public health emergency.

Commented [DD8]: Almost no vaccines are a therapy.

The purpose of this WG is to review available data, as well as clinical and scientific knowledge, to support the development of recommendations for ACIP consideration that are used to advise CDC and HHS.

Commented [DD9]: ACIP consideration is not the final step.

In accordance with the ACIP Charter, the COVID-19 WG will prepare information for the ACIP members to enable them to:

- Advise on population groups and/or circumstances in which a vaccine or related agent is recommended.
- Provide recommendations on contraindications and precautions for use of the vaccine and related agents and provide information on recognized adverse events.
- Provide recommendations that address the general use of vaccines and immune globulin preparations as a class of biologic agents, use of specific antibody products for prevention of infectious diseases, and special situations or populations that may warrant modification of the routine recommendations.
- Support committee deliberations on use of immunization to control disease including consideration of disease epidemiology and burden of disease, immunization safety, immunization efficacy and effectiveness, the quality of evidence reviewed, economic analyses, and implementation issues.
- Revise or withdraw their recommendation(s) regarding a particular immunization as new information on disease epidemiology, immunization effectiveness or safety, economic considerations, or other data that becomes available.

Commented [DD10]: These are great

The WG will also assist and support ACIP, in accordance with Section 1928 of the Social Security Act, to be able to establish and periodically review and, as appropriate, revise the list of immunization for administration to children and adolescents eligible to receive immunizations through the Vaccines for Children Program, along with schedules regarding the appropriate dose and dosing interval, and contraindications to administration of the pediatric immunization.

TOPICS UNDER DISCUSSION BY THE WORKGROUP

The following topics relevant to COVID-19 immunization for effective control of COVID-19 disease in the civilian population of the United States will be under discussion in the WG in multi-year efforts.

1) Risk-benefit and cost-benefit analyses of existing and newly FDA-authorized mRNA and other COVID-19 immunizations, and immunization schedules as it relates to COVID-19

immunization to inform use recommendations, personalized per age-group, major risk factors and health status.

2) To identify critical gaps in the existing scientific and clinical knowledge and methodologies related to the safety and efficacy of the COVID-19 immunizations, to inform the development of policy recommendations and further analyses and research by the CDC, other related federal agencies, and the scientific community.

3) To review and summarize data, clinical and scientific knowledge related to adverse events associated with COVID-19 immunizations to inform immunization recommendations in terms of precautions and contraindications to receipt of immunization.

Commented [DH11]: What about benefits as well? Would suggest this statement be more balanced

DESCRIPTION of WORKGROUP ACTIVITIES

The following activities provide a framework for the COVID-19 immunization WG multi-year efforts which may involve data requests from other Federal and private partners:

1. Review and summarize existing data and published and unpublished research and clinical knowledge related to the safety, effectiveness, and immunogenicity of COVID-19 immunizations authorized or approved in the United States.
2. Summarize literature reviews of the epidemiology of COVID-19 disease and SARS-CoV-2 virus.
3. Assess the benefit-risk balance for administration of COVID-19 immunization products at the same time as other immunizations.
4. Identify areas where additional data and research are needed to inform COVID-19 immunization recommendations.
5. Develop COVID-19 immunization ~~policy~~ recommendations.
6. Review and summarize the existing clinical and scientific information available; and gaps in the existing knowledge, including from other federal agencies like the FDA, where appropriate relating to bio distribution, pharmacokinetics and persistence of the spike protein, mRNA, and lipid nanoparticles to inform immunization recommendations.
7. Review and summarize the existing clinical and scientific information (including from federal agencies like the FDA, where appropriate); gaps in the existing knowledge regarding potential impurities (e.g., DNA contamination and endotoxins) in existing immunization products and their ~~scientifically known~~ health impacts to inform immunization recommendations.
8. Review and summarize the existing scientific knowledge, and gaps, regarding the cumulative short- and long-term impact of repeated boosting immunization including non-specific effects (e.g., IgG4 class switching, immune imprinting, viral evolution under leaky immunizations) to help inform immunization recommendations.

Commented [DD12]: This is the key part of this sentence. This review does not exist to relitigate regulatory action.

Commented [DD13]: Seems like this phrase is implicit in the deliberations at ACIP WGs.

Commented [DD14]: There should be a why here as in the above. I wonder if the title of this section should be:

DESCRIPTION of WORKGROUP ACTIVITIES THAT INFORM THE DEVELOPMENT OF IMMUNIZATION RECOMMENDATIONS.

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9. Examine the impact of COVID-19 immunization on COVID-19 and all cause deaths, hospitalizations, and disability to inform immunization recommendations.
10. ~~Analyze~~ Review and help interpret existing data and scientific knowledge regarding cardiovascular, thrombotic, neurological and other ~~major~~ serious adverse events potentially caused by COVID-19 immunization.
11. Review and summarize available data, information, and gaps regarding long-term Covid effects from scientific literature and clinical experience associated with COVID-19 immunization products and COVID-19 infection to inform policy recommendations.
12. Map existing COVID-19 immunization policies in countries around the world and how they compared to the US.
13. ~~Analyze~~ Review and help interpret existing data and scientific knowledge related to the safety of COVID-19 immunization during pregnancy.

Commented [DD15]: Not sure the WG's job is to analyze data.

Commented [DD16]: Should change major to serious?

Commented [DH17]: This is ok, but see this more in NIH lane re long COVID

Commented [DD18]: WG doesn't analyze data,

MEMBERSHIP

Workgroup Leadership: The COVID-19 Immunizations WG is chaired by one of the ACIP, CDC members appointed to serve as Special Government Employees. The Workgroup Lead (WGL) is a federal employee, identified by the Immediate Office of the Director in consultation with the appropriate CDC program. The WG Chair, in consultation with the WGL, ACIP, CDC DFO, determines the WG's membership and work priorities and deliverables to the full committee.

Workgroup Membership: The COVID-19 Immunizations WG is composed of experts who are appointed based on their professional, scientific, technical, or other expertise. They are experts who are regarded as an authority or a practitioner of unique competence and skill by other persons in their profession, or occupation. Upon request, HHS federal agencies named in the ACIP charter may also appoint members to serve on WGs. The COVID-19 Immunizations WG will be composed of members from a variety of disciplines. The WG will engage with the following disciplines on WG activities to:

- Public health science and practice;
- Public health policy development, analysis, and implementation, including development and execution of immunization programs for children and adults;
- Clinical and medical practice, and patience-care experience;
- Epidemiology;
- Molecular biology;
- Immunology;
- Virology;
- Drug and vaccine safety; and
- Consumer perspectives and/or social and community aspects of immunization programs

Commented [DD19]: And vaccine

DRAFT
DELIBERTAIVE PRE_DECISIONAL
CONFIDENTIAL

Due to the complexity and variability of information to be gathered, additional external subject matter experts may also be invited to provide data and presentations to the WG and answer questions during COVID-19 Immunization WG meetings on an ad hoc basis. Such additional external subject matter experts will not be members of the WG and will not participate in any deliberations or WG discussions.

MEETINGS, ADMINISTRATION, and TIMELINES

1. Administrative Oversight: The WGL will work with the WG Chair to arrange meetings, document meeting proceedings, and report to the ACIP on the COVID-19 Immunization WG's activities and findings.
2. Meeting frequency and location: The COVID-19 Immunization WG will meet on an as needed basis as determined by the WG Chair and WGL. All COVID-19 Immunization WG meetings are convened virtually via teleconference.
3. Meeting structure: In addition to the WGL, at least two ACIP Special Government Employee members (one of whom serves as the COVID-19 Immunization WG Chair) must be present at each meeting for a quorum. An agenda, relevant publications, and background documents will be circulated as read ahead material prior to each meeting.
4. Conflicts of Interest: WG members will complete an ACIP WG Agreement and Conflict of Interest Certification process prior to participation on the WG. They will consent to abide by several guiding principles and disclose interests (e.g., employment, special interests, grants, or contracts) that a reasonable person could view as conflicts or potential conflicts of interest with their COVID-19 Immunization WG participation. Members will also disclose any potential conflicts of interest before each meeting. If a COVID-19 Immunizations WG member indicates a potential or actual conflict of interest, the ACIP, CDC DFO in consultation with the WGL will review and make a determination as to whether the individual must recuse themselves from participating in WG discussions that implicate such a conflict-of-interest concern.
5. Confidentiality: The discussions of the COVID-19 Immunizations WG may include information that is unpublished, protected, privileged, or confidential. WG deliberations, including policy options under consideration by the WG, are also considered confidential. Information of this nature must not be disseminated, distributed, or copied to persons not authorized to receive such information. When these types of information are distributed, the person/s presenting will identify the information as such, so all members are duly informed; and written materials shall be clearly marked as such. Unlike ACIP meetings, which are open to the public, COVID-19 Immunizations WG teleconferences are not subject to the open meeting requirements of the Federal Advisory Committee Act or the GSA Final Rule; data presented during these meetings/teleconferences are often proprietary and should not be distributed to people other than approved COVID-19 Immunizations WG members.
6. CDC Staff Involvement: CDC staff do not serve as members of the COVID-19 Immunizations WG but may provide administrative support and technical expertise to ACIP WGs, bringing subject matter expertise and current professional focus in areas relevant to the goas of the COVID-19 Immunizations WG. Consultation or informational presentations by CDC staff will be transparent and evident to minimize the risk of, or the appearance of, undue influence that would compromise the independence of the WG. The ACIP, CDC DFO and WGL of COVID-

19 Immunizations WG, in consultation with the Chair of the COVID-19 Immunizations WG, will monitor the interaction between the WG and the agency staff to ensure that the WG activities and work products are appropriate and that there is not undue influence by the CDC or by any special interest group on the activities or work products of the WG.

7. Timelines: ACIP WGs are established when needed and terminated once the activities and work products stated in the terms of reference have been completed and the WG's charge has been fulfilled.
8. Subject content: Findings and opinions of the COVID-19 Immunizations WG members will be discussed at meetings. The COVID-19 Immunizations WG's findings will be presented to ACIP for consideration for action (discussion, deliberation and decision).
9. Workgroup Meeting Summaries: Meeting minutes will be created to capture the information gathered during each COVID-19 Immunizations WG meeting and teleconference.
10. Workgroup findings: The COVID-19 Immunizations WG will present findings (briefing documents, background materials, presentations) to ACIP for consideration and deliberation in a public meeting. Final versions of all slides presented at the ACIP meeting will be posted on the ACIP website following the meeting and included in the committee's official records.
11. Workgroup Record Keeping: All CDC FACA committees, subcommittees, and WGs are subject to the Federal Records Act. All records will be uploaded in the Federal Advisory Committee Management Portal. The summary report and other WG documents will become part of the ACIP's official records as required by GENERAL RECORDS SCHEDULE 6.2: Federal Advisory Committee Records

RECORDKEEPING and REPORTING

The WG Chair and WGL will present findings/outcomes/observations/recommendations to the ACIP parent committee for discussion, deliberations, further development of recommendations and vote in an open public forum. Approved ACIP recommendations adopted by the CDC Director will be published in the Morbidity and Mortality Weekly Report (MMWR). In addition, approved ACIP recommendations will be included in the ACIP meeting minutes and annual report.

Houry, Debra E. (CDC/IOD)

From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 4:14 PM
To: Houry, Debra E. (CDC/IOD); Burns, Stuart (CDC/IOD); Archer, William (HHS/IOS); Mccormick, Cortney (HHS/IOS)
Cc: Zadeh, Mina (CDC/OD/OCS); Hawkins, Jamar (HHS/OS); Buzzelli, Matthew J (Matt) (CDC/IOD); Hamilton, Sarah (CDC/OD/OCS); Robinson, Wilma (HHS/IOS)
Subject: RE: urgent update: ACIP recommendation memos RE: re proprietary information on your document

Hi Debra,
FDA is included because of the impact on manufacturing, and FDA was included in the review of the April ACIP recommendations, focused on the point/memo that mentioned FDA.
Jill

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 3:57 PM
To: Aksamit, Jill (HHS/OS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>
Cc: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Subject: RE: urgent update: ACIP recommendation memos RE: re proprietary information on your document

Appreciate the update- I'm not aware of FDA previously clearing CDC recommendations from ACIP- is this new policy or focused only on the one memo because of the impact on manufacturing for FDA?

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 3:55 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>
Cc: Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: urgent update: ACIP recommendation memos RE: re proprietary information on your document

Status: FDA is still reviewing and have not cleared the documents and the edit to remove the table. Dr. Archer noted that the memos needed to be signed by the Secretary today. I am standing by to assist if the memos are cleared. The memos are otherwise cleared by OGC and CDC.
Jill

Jill E. Aksamit
Policy Coordinator – Science and Public Health Team

Immediate Office of the Secretary | Exec Sec
U.S. Department of Health and Human Services
[redacted]

Visit us on The Executive Secretariat (Exec Sec) | HHS Intranet
https://intranet.hhs.gov/about-hhs/exec-sec

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 12:40 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Hamilton, Sarah (CDC/OD/OCS) <[redacted]>
Subject: RE: re proprietary information on your document

+ Sarah for awareness

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD)
Sent: Monday, July 21, 2025 12:36 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Subject: RE: re proprietary information on your document

This removal of chart looks fine to me thx

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 12:30 PM
To: Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Subject: FW: re proprietary information on your document

Jill,

This looks fine to me. I am lopping in Dr. Houry here at CDC for her review.

Stuart

Stuart Burns
Senior Advisor
Office of the Director
Centers for Disease Control and Prevention
[redacted]

DRAFT, INTERNAL, DELIBERATIVE, NOT FOR DISTRIBUTION
PREDECISIONAL

From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 11:41 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Hawkins, Jamar (HHS/OS) <[redacted]>
Subject: RE: re proprietary information on your document

If helpful, I made the edit: attached is a markup and clean version with the chart removed, and the sentence referring to the chart. Copying my boss Jamar.
Jill

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 10:59 AM
To: Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Subject: Re: re proprietary information on your document

if we can remove that chart That has the proprietary data in it Then I think the bullets cover the information we need to cover. I have copied Mina, the DFO for ACIP who will work on this end with you gel and other others who need to resolve this issue.

Stuart

Get Outlook for iOS

From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 10:54:30 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>
Subject: RE: re proprietary information on your document

Thanks – attached is the only version I have - there were no edits or comments from OGC or ASL reviewers.
Jill

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 10:47 AM
To: Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>
Subject: Re: re proprietary information on your document

Thank you, if it has not been signed yet, it would be good to completely remove that, but if you could share the current version, I wanna make sure that removal does not leave a complete gap. I think the bullets will cover it, but I can't recall what was in the final one that was sent forward. Thank you. Stuart.

Get Outlook for iOS

From: Aksamit, Jill (HHS/OS) <[redacted]>
Sent: Monday, July 21, 2025 10:45:10 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>
Subject: Re: re proprietary information on your document

Reyn and Stuart,
Understood, regarding the chart needing to be removed (not just edited but removed, right?) from the memo. I meet with CDC Exec Sec/Office of the Director contacts at 11am and I will check in with division contacts/reviewers that had for this round of review.
Jill

Jill E. Aksamit
Policy Coordinator – Science and Public Health Team
Immediate Office of the Secretary | Exec Sec
U.S. Department of Health and Human Services
[redacted]

Visit us on The Executive Secretariat (Exec Sec) | HHS Intranet
https://intranet.hhs.gov/about-hhs/exec-sec

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, July 21, 2025 10:01 AM
To: Aksamit, Jill (HHS/OS) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>
Subject: RE: re proprietary information on your document

Jill,

Please call me regarding this. If it has not been signed yet, we could remove the chart and resubmit for signature/review.

Stuart

Stuart Burns
Senior Advisor
Office of the Director
Centers for Disease Control and Prevention
[redacted]

DRAFT, INTERNAL, DELIBERATIVE, NOT FOR DISTRIBUTION
PREDECISIONAL

From: Archer, William (HHS/IOS) <[redacted]>
Sent: Sunday, July 20, 2025 8:42 PM
To: Aksamit, Jill (HHS/OS) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: Fw: re proprietary information on your document

Jill. See this concern from CDC.

Can we correct it?

Get Outlook for iOS

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Sunday, July 20, 2025 8:31:26 PM
To: Archer, William (HHS/IOS) <[redacted]>
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Subject: Fw: re proprietary information on your document

Reyn, Apparently, we need to remove the table that was included in the decision memo on thimerosal. It included a table that had information on the number of vaccines by manufacturer, of Mercury, free vaccines. It appears that is proprietary, and we should remove that from the decision memo. I think those may have already gone up. I'm not sure whose desk they are on currently.

Stuart

Get Outlook for iOS

From: Hoeg, Tracy Beth <[redacted]>
Sent: Sunday, July 20, 2025 6:34:10 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: re proprietary information on your document

Stuart,
Could you please also ensure that anyone who has seen the document not share any of the information from the table with the vaccine manufacturers' names? You will note I actually removed the row with the names so it does not get sent further.
Should I also write to Nina about this or will you be able to let her know?
Thank you and I apologize I didn't make this clear when I sent this to you.

Tracy Beth Høeg, MD, PhD
Senior Advisor for Clinical Sciences
Office of the Commissioner (OC) &
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration
[redacted]

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Hoeg, Tracy Beth
Sent: Sunday, July 20, 2025 5:53 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Subject: re proprietary information on your document
Importance: High

Dear Stuart,

I was just forwarded the ACIP decision memos and will get them reviewed by the appropriate people and back to you by 7/22. There is one extremely important edit: no proprietary information/drug manufacturers names or information can be included. I should have been clear that the table I sent you could not be shared/that it contained confidential information. So the table needs to be removed. I actually made an alternative table but decided it is probably best without exact numbers. Are you still getting <10%? Based on which numbers? What I quoted at ACIP (between 4-5%) was from doses distributed, as you probably remember. I was told I should not share the exact numbers/names so gave a %. Maybe you could say the numbers of millions of estimated doses it decreased by year total but just round since these are estimates? Please send me an edited version when you get a chance so I can forward it to our legal team and get this completed on time. Thank you!

Tracy Beth Høeg, MD, PhD
Senior Advisor for Clinical Sciences
Office of the Commissioner (OC) &
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration
[redacted]

FDA U.S. FOOD & DRUG ADMINISTRATION

Houry, Debra E. (CDC/IOD)

From: Reczek, Jeffrey (CDC/OD/CDCWO)
Sent: Monday, May 19, 2025 9:03 AM
To: Houry, Debra E. (CDC/IOD)
Subject: Fw: DRAFT DELIBERATIVE

Categories: 4

As discussed. I think this was also meant for Buzzelli.

Jeff Reczek
Director
CDC Washington
[redacted]

From: Anderson, Hannah (HHS/IOS) <[redacted]>
Sent: Monday, May 19, 2025 8:28 AM
To: Archer, William (HHS/IOS) <[redacted]>; Thompson, Matthew (HHS/ASL) <[redacted]>
Cc: Reczek, Jeffrey (CDC/OD/CDCWO) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: DRAFT DELIBERATIVE

Reyn-

Bobby has asked for the following changes to be made for the next ACIP meeting:

1. Replace the members with the ten identified
2. Add votes on "joint decision making" for Hep B (for healthy children and potentially others) and multi-dose flu for pregnant women and children
3. Announce that we are bringing back the 7 year review and the biannual report on vaccines
4. Review of the definition of vaccine

Feel free to loop with Jeff and Stuart and then come check in with me.

Hannah

Hannah Anderson
Deputy Chief of Staff, Policy
U.S. Department of Health and Human Services (HHS)

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Monday, May 19, 2025 7:31 PM
To: Burns, Stuart (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD); Witkofsky, Nina (CDC/IOD)
Cc: Daskalakis, Demetre (CDC/NCIRD/OD)
Subject: RE: Draft Memo on ACIP- predecisional - please provide your thoughts/edits
Attachments: ACIP Reform Memo May 20 2025DH.docx

Categories: 4

+ Demetre too

Some quick thoughts in the attached- happy to review again in the morning or later tonight. Also, I didn't add in the 15 days info re public comment. Meeting with the OCOO team in morning to go over what is needed for onboarding and this process so will have more after that

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, May 19, 2025 7:17 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: Draft Memo on ACIP- predecisional - please provide your thoughts/edits

Please see attached draft. I welcome your edits. The yellow highlighted is from the original memo that Reyn had done – I didn't fact check it and I'm not a lawyer on the legal part.

Please let me know your thoughts and send your edits to me.

Stuart

Stuart Burns
Senior Advisor
Office of the Director
Centers for Disease Control and Prevention
[redacted]

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

[RECOMMENDATION] MEMO

Predecisional Draft

DATE: Tuesday, May 20, 2025
TO: Secretary Robert F. Kennedy, Jr.
THROUGH: Hannah Anderson, *Deputy Chief of Staff for Policy*
FROM: Reyn Archer, *Counselor to the Secretary*

SUBJECT: Replacing ACIP Members

ISSUE: ~~In 2023, the Biden administration expanded ACIP's membership count from 14 to 19. In December 2024, President Biden filled 3 open ACIP positions in an unprecedented post-election action. In January 2025, CDC began vetting candidates to fill a 4th vacant position. In addition, the Biden administration extended the terms of an additional 6 members.~~ With the current configuration the Trump Administration will only be able to add one member in 2024 with the majority of new members ~~be unable add new members~~ until 2027. This gives Biden appointees significant sway over ACIP and its recommendations until 2028.

Commented [DH1]: I'm not sure this is accurate so removed and added one sentence statement.

Recommendation – Two Options

Option #1

End the terms of all ~~19~~ existing ACIP Members and replace the entire membership with 9 new ACIP Members, making the Committee a more manageable size.

Commented [DH2]: Took number out since I think it is currently 17

Option #2 – Staff Recommendation

Replace at least ~~9~~10 of the current 1~~9~~7 Members of ACIP with new Trump Administration Appointees.

Considerations When Considering Current ACIP Member Terminations

In selecting members to remove and replace among the issues to consider are: (1) the expertise of the member, (2) the date on which the ACIP Member began service on ACIP, and (3) whether termination of a member who currently serves as a Work Group chair may have an adverse impact on ACIP due to the lack of continuity of knowledge on issues likely to come up for a vote in June including. ~~The more timely issues for the June meeting which are most likely to come up for votes are~~: Adult RSV, Maternal/Pediatric RSV, Influenza, HPV, and COVID-19. Other items that may come up for votes, but that are less timely are Meningococcal, and Mpox,

In selecting Members for replacement further considerations could be given to: (1) replacing the most recently appointed ACIP members based on their original appointment date, (2) replacing the longest-serving ACIP members though this would impact the current chair and next chair, (3)

replace the six who are not current work group chairs, or (4) ~~a~~some combination of the above. Whatever option is pursued, replacement members should fill expertise gaps left by terminated members.

A decision should be made this week on options as it could take several weeks to complete ethics and COI vetting, develop new ACIP member package, and process travel in time for the in-person June meeting. A FRN to request new members is also a consideration, but this would not allow new members to be in place.

Background on Current ACIP Members

End Dates for Current ACIP Members:

2025	1 vacancy
July 2026	No vacancies
July 2027	4 vacancies
July 2028	10 vacancies
July 2029	4 vacancies

Below is a table detailing current ACIP members, their term start and end dates, extensions, workgroup memberships, chair positions, and areas of expertise. The list is in order of the newest member being listed first. Note also that not listed below are: (1) one vacancy, and (2) _____, whose reappointment is pending.

Name	Start	End	Term Extension?	Area of Expertise added to Committee	Workgroup Assignments (Red=chair)	Workgroup Chair (Yes or No)
ZUCKER, Jane	12/23/2024	6/30/2028	N	internal medicine, public health, public health response	Anthrax, HPV	Yes
LYONS, Karyn	12/20/2024	6/30/2028	N	nursing, public health, immunization programs	Schedules, Meningococcal	No
ASTURIAS, Edwin José	7/1/2024	6/30/2028	N	Pediatric infectious diseases	Chikungunya, mpox, Lyme disease	Yes
BREWER, Noel T.	7/1/2024	6/30/2028	N	social and behavioral science	HPV, COVID, Lyme disease	No
CHEN, Lin H.,	7/1/2024	6/30/2028	N	Travel medicine	Chikungunya, mpox	No
CHU, Helen Y.,	7/1/2024	6/30/2028	N	Pediatric infectious diseases, RSV	Maternal peds RSV, adult RSV	Yes
KAMBOJ, Mini	7/1/2024	6/30/2028	N	infections in immunocompromised patients	Pneumococcal, adult RSV	No
KUCHEL, George A.,	7/1/2024	6/30/2028	N	infections in the elderly	COVID, Pneumococcal	No
MOSER, Charlotte A.,	7/1/2024	6/30/2028	N	health education, consumer representative	Meningococcal, Schedules, Lyme disease	No
SCHECHTER, Robert	3/6/2024	6/30/2027	N	pediatrics, immunization programs	COVID, HPV, Pneumococcal, Influenza	Yes
TALBOT, Helen Keipp	3/5/2024	6/30/2025	Y	expertise in adult immunization, influenza	**ACIP chair**, Influenza, COVID	COMMITTEE CHAIR
JAMIESON, Denise J.,	3/4/2024	6/30/2027	N	Obstetrics and gynecology	CMV, maternal peds RSV	Yes
MALDONADO, Yvonne (Bonnie)	3/4/2024	6/30/2027	N	pediatrics, pediatric infectious diseases	Mpox, CMV	Yes
SHAW, Albert C.,	3/4/2024	6/30/2027	N	immunology, infections in the elderly	Adult RSV, Influenza	Yes
CINEAS, Sybil	7/28/2021	6/30/2025	N	Pediatric and adult medicine	Schedules, HPV	Yes
BROOKS, Oliver	7/26/2021	6/30/2025	N	Pediatrics	HPV, COVID, Maternal peds RSV	Yes
LOEHR, Jamie	7/26/2021	6/30/2025	Y	family medicine, private practice, health economics	Meningococcal, Pneumococcal, Influenza	Yes

Conclusion:

Secretary Kennedy therefore has full control over ACIP under statute and the Unitary Executive Theory including the appointment and removal of ACIP members at will.

Legal Authority:

Under the Unitary Executive Theory, full control of the Executive Branch is vested in the President. The President has extended his authority over the Public Health Service to the Secretary of Health and Human Services. The Secretary can use his authority to establish or terminate discretionary advisory committees under 42 USC § 217(a); this authority was used to establish ACIP.

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Monday, May 19, 2025 7:51 PM
To: Patterson, Sara S. (CDC/PHIC/OD); Buzzelli, Matthew J (Matt) (CDC/IOD); Burns, Stuart (CDC/IOD); Witkofsky, Nina (CDC/IOD)
Cc: Daskalakis, Demetre (CDC/NCIRD/OD)
Subject: is this tthe question re definition of vaccine?

Categories: 4

Was trying to figure out what the email from Hannah meant- below is what comes up when googling CDC and vaccine definition. LMK if this refers to something else and I can look into it.

https://apnews.com/article/fact-checking-976069264061

Experts say changes to CDC's vaccination definition are normal

By SOPHIA TULP

Published 1:47 PM EDT, February 9, 2022

CLAIM: The Centers for Disease Control and Prevention has changed its definition of vaccination because COVID-19 vaccines are ineffective.

AP'S ASSESSMENT: Missing context. The CDC has altered the language in the definition of vaccination on its website, including after the development of COVID-19 vaccines, but the changes were made to prevent potential misinterpretations, and did not alter the overall definition, according to the agency. Experts confirmed to The Associated Press that the changes reflect the evolution of vaccine research and technology.

THE FACTS: The suggestion that COVID-19 vaccine ineffectiveness led the CDC to change its definition of the word online was amplified this week by U.S. Rep. Thomas Massie, a Kentucky Republican who has been critical of pandemic mask and vaccine mandates.

Massie shared an image containing three definitions for the word "vaccination" with his 326,000 followers on Sunday. One was labeled "pre-2015" and described vaccination as: "Injection of a killed or weakened infectious organism in order to prevent disease." Another was dated 2015-2021 and said: "The act of introducing a vaccine into the body to produce immunity to a specific disease." The third was from September 2021, calling vaccination: "The act of introducing a vaccine into the body to produce protection from a specific disease."

Massie added the caption: "The vaccine that redefined vaccination," and in a follow-up tweet stated that he made the image by compiling definitions from the CDC's website, "using wayback machine to find copies of their old websites."

The claim has previously spread online from other sources, with the false suggestion that the definition changes prove the vaccines don't work.

The AP was able to verify through web archives that the language on a CDC page titled "Immunization Basics," has changed in these ways over time. But this does not mean that the agency altered it because of problems with the coronavirus vaccines.

The CDC told the AP in a statement that it made the language shifts to add detail and increase transparency.

"While there have been slight changes in wording over time to the definition of 'vaccine' on CDC's website, those haven't impacted the overall definition," the statement said, noting that the previous

definition "could be interpreted to mean that vaccines were 100% effective, which has never been the case for any vaccine."

Dr. John P. Moore, a professor of microbiology and immunology at the Weill Cornell School of Medicine, said Massie's remarks amounted to "disinformation" and were based on "semantics not science."

"I have no problem with the CDC's language tweaks," Moore wrote in an email to the AP. "They are informative, not sinister."

Moore explained that the vaccines protect against disease, not against infections. He said that while the strength of the antibody response can decrease "over a multi-month period," leading to reduced protection against infection, the vaccines are still effective overall because they continue to protect against severe disease and death. This is true for the omicron variant as well, he said.

Dr. Ryan Langlois, a microbiology and immunology professor at the University of Minnesota, says the CDC's changes "make total sense," and add nuance following emerging vaccine developments such as mRNA technology.

"We've repurposed this word, vaccination, from 200 plus years ago," said Langlois, who teaches a course on the history of vaccination. "It's always difficult when a word is so entrenched but the technology is changing. I think it's very, very clear that one of the things the CDC is trying to do is to try to update the definition with the updating technology."

Langlois said the changes also help to make the definition more accurate. He said the word "immunity" can be misleading with any vaccine, as "it's incredibly rare that that immunity is perfect."

"Their first definition had protection, and ultimately that's what a vaccine is supposed to do," he explained. "Then their second definition used the word 'to generate immunity' which is how the protection is derived. But immunity can be a misleading term, because people think if they're immune it's all or none. Immunity is not that simple and I think that's what they tried to do with their third definition. They went back to this protection idea because that's really what vaccines do."

Houry, Debra E. (CDC/IOD)

From: Patterson, Sara S. (CDC/PHIC/OD)
Sent: Monday, May 19, 2025 9:51 PM
To: Houry, Debra E. (CDC/IOD)
Subject: Fw: new vettees

Categories: 4

See below.

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From: Smagh, Kalwant (CDC/OCOO/OSBI) <[redacted]>
Sent: Monday, May 19, 2025 7:15:46 PM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Aleshire, Noah (CDC/OD/OPPE) <[redacted]>
Subject: Fw: new vettees

Names at bottom from HHS.

Kevin

From: Turner, Doretha (Rita) (CDC/OCOO/OHR) <[redacted]>
Sent: Monday, May 19, 2025 12:42
To: Card Mina, Mary (HHS/OGC) <[redacted]
Cc: Hancock, Glenn (HHS/OGC) <[redacted]>; Jenkins, Joseph (CDC/OCOO/OHR) <[redacted]>; Smagh, Kalwant (CDC/OCOO/OSBI) <[redacted]>; Humphrey, Shelia L. (CDC/OCOO/OSBI) <[redacted]>; Lewellen, Gladys (CDC/OCOO/OSBI) <[redacted]>; Blanchette, Jason (HHS/OGC) <[redacted]>
Subject: RE: new vettees

Good afternoon, Mary-

Thanks for the heads up. Our FACA team has not received communication from the Whitehouse Liaison's Office about new ACIP FACA appointments.

I am looping in our FACA team leadership for awareness. Gladys Lewellen is the CDC FACA Director.

Any information you can share to point us in the right direction is appreciated.

Rita

Doretha (Rita) Turner, MS
Deputy Director
Ethics and Integrity Office
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Have an ethics-related question? Submit your inquiry to the HR Service Desk: Ethics Guidance and General Inquires

---

From: Card Mina, Mary (HHS/OGC) <[redacted]>
Sent: Monday, May 19, 2025 10:45 AM
To: Turner, Doretha (Rita) (CDC/OCOO/OHR) <[redacted]>
Cc: Blanchette, Jason (HHS/OGC) <[redacted]>; Hancock, Glenn (HHS/OGC) <[redacted]>
Subject: FW: new vettees
Importance: High

Hi Rita

By any chance are you vetting these individuals for roles as SGEs with the ACIP FACA for CDC? We just received an inquiry on status and are trying to sort out if a 450 has been assigned, if anyone is working with them etc. Thanks!

Mary

Last	First	Phone	Email
Malone	Robert	[redacted]	
Miesner	Cody		
Kulldorf	Martin		
Fogel	Sylvia		
Pebsworth	Vicky		
Ross	Michael		
Levi	Retsef		
Pagana	James		
Fisher	Barbara		

--- Malone, Kulldorf are both processing as SGEs for OASH and can be dual hatted.

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Tuesday, May 20, 2025 1:14 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD); Witkofsky, Nina (CDC/IOD); Burns, Stuart (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD)
Subject: onboarding/ offboarding FACA members
Attachments: CDC 1547(E) SGE Annual Certifications.pdf; CDC 0 1450(E) Research Support-Project Funding.pdf; OGE Form 450 Dec 2023.pdf; HHS-697.pdf

Categories: 4

Hi IOD
Sara and I had a productive meeting this morning with our SBI team re FACA-

- New members 9-10- we need their CVs now- that will allow us to start putting them in the system and doing some of the COI reviews
- Onboard (forms/vetting needed)- would be helpful to know what WH is doing vs what we will need to do- here are the forms we use for ACIP:
    - OGE Form 450, Confidential Financial Disclosure Report – Note: CDC uses an electronic system to complete the OGE 450 (Ethics Program Activity Tracking System) see attached pdf version. https://www.oge.gov/web/oge.nsf/OGE%20Forms/2026049D943E0C34852585B6005A23CE/$FILE/OGE%20Form%20450%20Confidential%20Financial%20Disclosure%20Report.pdf?open
    - CDC form 1450 – Research-Support Project Funding (see attached pdf).
    - Emolument disclosure - HHS Form 697 – At CDC, the form below is in EPATS for SGEs to complete – see attached pdf version. https://www.hhs.gov/sites/default/files/hhs-697.pdf
    - Lobbyist Certification Form – see CDC form 1547 (attached pdf).
    - SGE annual ethics training – CDC's SGE training is located on the web page- Ethics | FAC | CDC – Specifically, Ethics Training for Special Government Employees | NIH Ethics Program.

  After all of the above is completed, the CIO completes a form pertinent to the needs of the committee. This allows each committee to execute even more stringent criteria regarding the mitigation of conflicts of interest.
- Offboard existing- need decision from HHS on how to proceed this week
    - Risk to offboard if workgroup chairs are offboarded without being replaced
    - Quorum: up to 19 members, 13 needed for quorum at present.
- Timing of forms/vetting
    - Focus: (match same level of vetting as existing members)
        - Conflict of interest, ethics, FRN (needs to run 15 days prior to meeting ~ June 10 at latest, ideal is early June)
        - Forms: 450 (financial disclosure), HHS 697 (foreign activity disclosure), CDC 1450 (Research support), CDC 1547 (ethics training, non-lobbyist certification)
    - Orientation
        - ACIP roles/responsibilities, FACA functions, Ethics training (online and briefing so they can ask questions)
    - Other items
        - OHR onboarding
        - Travel

- Approval by HHS

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Tuesday, May 20, 2025 3:27 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD); Burns, Stuart (CDC/IOD); Witkofsky, Nina (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD)
Subject: additional info re FACA timelines/ process

Categories: 4

From our SBI team

Likely not needed given HHS direction:

- Designated Federal Officer and Committee Management Staff conduct strategic outreach to identify candidates from a variety of sources.
- CIO (Designated Federal Officer, Committee Management Specialist, CIO Director) critique candidates (NCIRD conducts multiple levels of review including utilizing a steering committee of experts to finalize candidates to serve on ACIP)
- CIO staff nominate members via a **draft** nomination package (consists of CVs, demographic information, summary of qualifications, etc.) for each candidate.
- OSBI edits/reviews the package and submits to OES for OD review/approval to transmit to HHS Office of the White House Liaison (WHL) .
- OES sends signed approval to OSBI for transmittal to HHS WHL.

Process would start here:

- HHS WHL sends OSBI the approved slate of candidates (may include substitutions by HHS or the White House),
- OSBI notifies CIO to prepare the **final** nomination package documents,
- CIO submits package to OSBI for review.
- OSBI finalizes the package and sends to OES for signature.
- OES sends signed documents to OSBI for transmittal
- OSBI transmits to HHS WHL for the Secretary's signature.
- Signed package documents returned to OSBI for processing.
- OSBI staff send out invitation package to approved candidates via email.
- Approved candidates accept or decline the invitation via email.
- Copies of the acceptance or declination shared with the sponsoring CIO.
- CIO sends out the welcome letters with instructions regarding the OHR onboarding process
- OHR sends email invitation regarding USA Staffing onboarding requirements.
- OHR facilitates the onboarding process including administering the oath of office.
- Simultaneously, the CIO enters the member into Navigator and initiates PARs action
- OSBI adds the new member into EPATS and send the invitation to complete the COI forms.
- OSBI facilitates completion of the on-line ethics training and all the conflict-of-interest forms.
- OSBI, CIO staff and OGC schedule new member orientation.

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Wednesday, May 21, 2025 8:57 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD)
Subject: RE: 5.19.2025 ACIP w iOD, 9:30am and 4pm

Yes, agree- that's why I said this can't happen with proposed items for agenda- can raise and ask this be looked at for the future.

Re candidates, I think we should wait to review bios and slate formally until this comes to us. OGC said that if candidates actively promoted misinformation, were fired from a university, or do not have expertise for ACIP they could still move forward from HHS if no COI. So, long way of saying let's have the process go forward first and then you and I can raise any concerns on nominees for Stuart and Matt to transmit to HHS.

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Daskalakis, Demetre (CDC/NCIRD/OD) <yzq5@cdc.gov>
Sent: Wednesday, May 21, 2025 8:29 AM
To: Houry, Debra E. (CDC/IOD) <vjz7@cdc.gov>
Subject: RE: 5.19.2025 ACIP w iOD, 9:30am and 4pm

One addition, although I know you know this.

It would be inappropriate to present a question with no supporting data and then request a vote.

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Wednesday, May 21, 2025 8:28 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: RE: 5.19.2025 ACIP w iOD, 9:30am and 4pm

It would also be great to get a better understanding of the background of possible new appointees. ACIP works hard to make sure it has people with the correct clinical expertise needed on the committee. An example is making sure we have enough peds folks and folks with immunocompromised host experience.

On the Hep b issue, yes, that's correct. There are three paths to get a topic on the agenda:

1) Regular workgroup reconstituted and question presented with full data review and Evidence to Recommendation (EtR) Framework completed to be presented to the committee at regular pace, may take a couple of months.
2) Accelerated workgroup review, ad hoc ACIP meeting with ETR presented- less optimal in a non-public health emergency
3) Present the data directly to the committee without a workgroup and no ETR (strongly not recommended) since this may be a 2-3 day meeting covering ONLY this topic and the critical discussions that happen in the workgroup to guide recommendations will not inform the process.

Hope that helps!

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, May 21, 2025 8:14 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: RE: 5.19.2025 ACIP w iOD, 9:30am and 4pm

Thanks for sending notes- two other things:
You and I mentioned that you can't just do votes on things at a meeting like Hep B- they need to reconstitute a workgroup to look at the data and evidence and then present at a subsequent ACIP meeting

Of note, Stuart had said all the people had been cleared by WH for ethics and were good to go, but when I asked to make sure all had done 450 forms and to connect with our FACA and SBI teams to ensure rest of paperwork done too it appears none of the ethics/ COI process has been started yet so it is not clear to me if these 10 members are "ready" as they need to go through FACA process before they would be confirmed. This is on my list to discuss with the SBI and OGC teams that review candidates

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Sent: Wednesday, May 21, 2025 8:07 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: 5.19.2025 ACIP w iOD, 9:30am and 4pm

Deb- Just sending my notes to make sure I haven't missed anything. Let me know.

5.19.2025 ACIP w iOD, 9:30am

Monday, May 19, 2025
9:29 AM

Secretary Request on Members.

Members:
Secretary wants to replace 10 members on the ACIP committee. He has a bench of 10 ready to replace. He doesn't care which members. They think last minute appointments were a way to block. Didn't ask us for help. They know who they want to put on. They want us to remove the newest people on whether they are newly appointed. Who is first on, who is first off, and what is their area that they bring to the table.

Agenda Items:
If they are going to bring 10 new members, there are several issues to be discussed. One item that is included:

- Hepatitis B for healthy infants-eliminating
- Multidose vial- Thimerisol Free recommendation
- Vitamin K dose in kids???
- 7 year review of the childhood immunization schedule- announcement

Is there a hep B workgroup? What's time sensitive on the current agenda?

The new members may have trouble voting because they have not been on for long. Some of the members may be

HPV voting plan?

Created with OneNote.

5.19.2025 ACIP w iOD, 4pm

Monday, May 19, 2025
4:02 PM
Meeting to discuss iOS plan for change in membership of ACIP

From Stuart Burns:
Option 1: Remove all members and replace with new members reflecting the priorities of the administration
Option 2: Roll off enough to have new members as voting majority on the committee to reflect new admin perspective.

Stuart Burns will be writing a new memo to support this plan. Stated objective was to "depoliticize" the committee by installing people more aligned to the Secretary's agenda.

One topic discussed was removal of thimerisol from flu vaccines. Dr. H and I encouraged this change to come from FDA that has dominion over ingredients of vaccines. Stuart commented that this was Dr. Weldon's plan 2o years ago. We highlighted that the ACIP may not support a change given the lack of evidence that this ingredient causes adverse events but that FDA could decide to do this as a matter of principal to avoid the criticism that this generates despite the lack of a safety signal.

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Malone, Kevin M. (CDC/OGC)
Sent: Monday, June 16, 2025 6:33 PM
To: Zadeh, Mina (CDC/OD/OCS); Aleshire, Noah (CDC/OD/OPPE); Greco Kone, Rebecca (CDC/NCIRD/OD); Burns, Stuart (CDC/IOD); Houry, Debra E. (CDC/IOD); Witkofsky, Nina (CDC/IOD)
Cc: Daskalakis, Demetre (CDC/NCIRD/OD); Ford, Kenya S. (CDC/OGC)
Subject: RE: ACIP UPDATE: Draft vote language and agenda

With regard to notice and comment, we have not considered ACIP recommendations to be rulemakings. However, in an abundance of caution, CDC has followed a notice/comment process to assure a legal defense if ACIP actions adopted by the CDC Director should be challenged as violating the Administrative Procedure Act (APA). In its simplest form, the APA requires that the public be given notice of an intended agency action and that the public be given an opportunity to comment prior to finalizing that action. Therefore, with ACIP, the Federal Register Notice of an upcoming ACIP meeting includes notice to the public of the topics expected to be addressed at the meeting, and then a public comment session is conducted during the meeting prior to votes by the committee. In this instance, as Noah notes, influenza has been announced as a topic on the agenda for the June ACIP meeting.

Substantively, recommendations of FACA committees are expected to be undergirded by robust fact-finding, discussion, and deliberation by the outside expert committee members to create a record to help the advised agency understand the basis and rationale for the committee's recommendation to the agency in order for the agency to make an informed decision about whether or not to accept the committee's recommendation. As such, a process of developing presentations for ACIP consideration through research and analysis by an ACIP Work Group, presentation of the Work Group's product at a public session of the parent ACIP meeting, additional input in that session by relevant stakeholders among the committee's liaison representatives, opportunity for public comment, and committee deliberation prior to a committee vote would be the regular order steps for the committee. As Noah suggests below, the topic of flu vaccine and thimerosal could be added to the agenda for the August/September meeting following that regular order process.

Kevin

From: Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Sent: Monday, June 16, 2025 3:28 PM
To: Aleshire, Noah (CDC/OD/OPPE) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>
Subject: RE: ACIP UPDATE: Draft vote language and agenda

Thank you, Noah.
Adding Kenya/Kevin.

From: Aleshire, Noah (CDC/OD/OPPE) <[redacted]>
Sent: Monday, June 16, 2025 3:25 PM
To: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: RE: ACIP UPDATE: Draft vote language and agenda

Good afternoon,

Rebecca is right; under the policies and procedures and charter, an ACIP member could introduce a motion to adopt a new recommendation outside of the workgroup process. This would be deviate from normal practice and I don't know of a recent example of them following such a process. The motion would then be discussed and, by majority vote, could be amended, postponed, adopted, or sent back to a workgroup. We might want to have OGC (Kevin) to make sure there are no notice/comment issues with a vote on a new recommendation, albeit for a topic announced for a vote in the FRN.

As others noted, it is helpful to the members to have a workgroup sort through the issues presented to the committee prior to a vote so the members can have good, precise recommendation language to work from and can think through potential or unanticipated issues (e.g., FDA regulatory equities, how to avoid vaccine shortages during flu season).

One option for the June meeting may be for the committee to direct the workgroup to examine the issue and present options at the August/September meeting. Then the issue can be presented in normal business in August/September, key stakeholders (e.g., FDA) could weigh in, public comment could be requested via FRN, and the issue could be openly presented and debated at the meeting. Then the members could amend and vote on the WG's presented options as they see fit.

Mina, I would be happy to chat tomorrow when I'm back in the office on the approach to think through approaches.

Thanks,

Noah

From: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>
Sent: Monday, June 16, 2025 2:24 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>; Aleshire, Noah (CDC/OD/OPPE) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Aleshire, Noah (CDC/OD/OPPE) <[redacted]>
Subject: Re: ACIP UPDATE: Draft vote language and agenda

Adding Noah to this chain for a policy read but will also ask the team here.

It would be atypical to have a vote when a workgroup has not considered the issue. I will try to see if this has ever happened before. That being said, I believe ACIP procedures would allow for an ACIP voting member to make a motion and then the other members could vote since flu is mentioned as a "vote" in the FRN. But there would NOT be a presentation or discussion on the science or evidence since the workgroup was not tasked with this issue.

I would appreciate Noah's read on this and we may also want OGC to confirm.

Thanks
Rebecca

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From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, June 16, 2025 1:46 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: Re: ACIP UPDATE: Draft vote language and agenda

Based on discussions and what I'm hearing from the secretary's office They are very interested In having ACIP Vote to recommend only thimerosal free flu vaccine to pregnant women and children 12 and under. What steps need to be take to consider this on the agenda?

Stuart

predecisional preliminary draft

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From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Monday, June 16, 2025 1:34:56 PM
To: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: RE: ACIP UPDATE: Draft vote language and agenda

Thanks Rebecca
I mentioned this morning, that things like strength of rec, shared decision making, etc usually come from workgroup discussions

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>
Sent: Monday, June 16, 2025 12:12 PM
To: Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: ACIP UPDATE: Draft vote language and agenda

Good morning, Stuart,

I just spoke with Nina who mentioned that you had requested more specific information related to the anticipated vote language for the upcoming ACIP meeting. Please see bottom of this email for the draft

language. Note that this typically is posted on the website during the public comment period and in advance of the meeting. We could post this at the same time as the agenda, once it is all cleared.

Do we have any updates on agenda clearance from HHS?

Also, the team has proposed a change in the order of topics on the agenda. We have historically done the sessions with votes first, followed by informational sessions, to ensure there was enough time to get through everything with the voting topics (see attached). The attached agenda reflects the order change.

Thanks
Rebecca

In addition, the team

Draft vote language for the ACIP June 2025 meeting
Several votes are planned during the June 2025, ACIP meeting.
The vote language shown below is considered draft. All vote language is subject to change and will continue to be updated in advance of the ACIP meeting.

Anticipated votes
RSV Vaccines – Maternal/Pediatric
Draft Vote: Long-acting* monoclonal antibodies are recommended as approved or authorized by FDA for infants <8 months of age born during or entering their first RSV season
Draft VFC Vote: Update the RSV vaccine VFC resolution to include recommendation for use of long-acting* monoclonal antibodies as approved or authorized by FDA for infants <8 months of age born during or entering their first RSV season
*Long-acting means only one dose is needed for protection during an RSV season

Influenza Vaccines
Draft Vote: Recommendations for influenza vaccination for the 2025-26 season

Rebecca Greco Koné
Deputy Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Monday, June 16, 2025 2:24 PM
To: Burns, Stuart (CDC/IOD); Houry, Debra E. (CDC/IOD); Greco Kone, Rebecca (CDC/NCIRD/OD); Witkofsky, Nina (CDC/IOD); Zadeh, Mina (CDC/OD/OCS)
Subject: RE: ACIP UPDATE: Draft vote language and agenda

The best option is still FDA declaring this from their regulatory/production side of vaccines. If there is a preference that ACIP make this decision, this ends up being mainly a question of meeting order. I think it would be GREAT for Mina to connect with Noah on this.

Normally discussions in work groups with data review would lead to vote language. Given the state of the data on Thimerosal and the fact that there will not be a lot of time before the next ACIP meeting, such language may have to be motioned by one of the voting members during the meeting. The voting member could motion to add a second vote to the flu docket that reflects this language on Thimerosal. The rest is rules of order in terms of seconding the motion and taking this to a vote.

Demetre

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, June 16, 2025 1:46 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: Re: ACIP UPDATE: Draft vote language and agenda

Based on discussions and what I'm hearing from the secretary's office They are very interested In having ACIP Vote to recommend only thimerosal free flu vaccine to pregnant women and children 12 and under. What steps need to be take to consider this on the agenda?

Stuart

predecisional preliminary draft

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Sent: Monday, June 16, 2025 1:34:56 PM
To: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: RE: ACIP UPDATE: Draft vote language and agenda

Thanks Rebecca
I mentioned this morning, that things like strength of rec, shared decision making, etc usually come from workgroup discussions

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>
Sent: Monday, June 16, 2025 12:12 PM
To: Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: ACIP UPDATE: Draft vote language and agenda

Good morning, Stuart,

I just spoke with Nina who mentioned that you had requested more specific information related to the anticipated vote language for the upcoming ACIP meeting. Please see bottom of this email for the draft language. Note that this typically is posted on the website during the public comment period and in advance of the meeting. We could post this at the same time as the agenda, once it is all cleared.

Do we have any updates on agenda clearance from HHS?

Also, the team has proposed a change in the order of topics on the agenda. We have historically done the sessions with votes first, followed by informational sessions, to ensure there was enough time to get through everything with the voting topics (see attached). The attached agenda reflects the order change.

Thanks
Rebecca

In addition, the team

> Draft vote language for the ACIP June 2025 meeting
> Several votes are planned during the June 2025, ACIP meeting.
> **The vote language shown below is considered draft. All vote language is subject to change and will continue to be updated in advance of the ACIP meeting.**
>
> Anticipated votes

RSV Vaccines – Maternal/Pediatric

Draft Vote: Long-acting* monoclonal antibodies are recommended as approved or authorized by FDA for infants <8 months of age born during or entering their first RSV season

Draft VFC Vote: Update the RSV vaccine VFC resolution to include recommendation for use of long-acting* monoclonal antibodies as approved or authorized by FDA for infants <8 months of age born during or entering their first RSV season

*Long-acting means only one dose is needed for protection during an RSV season

Influenza Vaccines

Draft Vote: Recommendations for influenza vaccination for the 2025-26 season

Rebecca Greco Koné
Deputy Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Tuesday, May 27, 2025 1:11 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD); Monarez, Susan (CDC/IOD); Houry, Debra E. (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD); Witkofsky, Nina (CDC/IOD); Burns, Stuart (CDC/IOD); Faircloth, Jordan (CDC/OD/OCS)
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD); Limbago, Brandi (CDC/NCIRD/OD); Malone, Kevin M. (CDC/OGC); Aleshire, Noah (CDC/OD/OPPE); Tress, Deborah W. (CDC/OGC); Thombley, Melisa L. (CDC/OGC); Beauvais, Denise (CDC/NCIRD/OD)
Subject: URGENT SARS-CoV-2 vaccine announcement follow up

Importance: High

All-

NCIRD has reviewed today's HHS announcement on SARS-CoV-2 vaccine and wanted to flag the following language:

"...as of today, the covid vaccine for healthy children and healthy pregnant women has been removed from the recommended immunization schedule."

As of this moment the schedule does not reflect the Secretary's announcement. I have met with OGC (copied) and recommend the following path forward to operationalize this announcement:

1. HHS drafts a "Secretary's directive" memo that memorializes this HHS policy change.
2. Add specificity in that memo around the populations for whom vaccine is no longer recommended per this HHS decision.
3. CDC address this change on the schedule based on the written directive from HHS, once signed.

We would be happy to review the memo to make sure that all of the operational steps are correct so that we can change the schedule to reflect the Secretary's decision/announcement. Per OGC we can't make the change until we have such an official directive in writing.

OGC and OPPE included on this chain.

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Tuesday, May 27, 2025 11:26 AM
To: Reczek, Jeffrey (CDC/OD/CDCWO); Witkofsky, Nina (CDC/IOD); Holloway, Rachel (CDC/OD/OBPA); Burns, Stuart (CDC/IOD)
Subject: RE: S1 announcement related to COVID vax

Sitting with Nina now – all comments will come from HHS

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Reczek, Jeffrey (CDC/OD/CDCWO) <[redacted]>
Sent: Tuesday, May 27, 2025 11:24 AM
To: Witkofsky, Nina (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Holloway, Rachel (CDC/OD/OBPA) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: S1 announcement related to COVID vax

Hi – getting a lot of incoming on what the video means in practice. Is there a reactive statement? Can we connect quick after SL?

Jeff Reczek
Director
CDC Washington
[redacted]

Houry, Debra E. (CDC/IOD)

From: Witkofsky, Nina (CDC/IOD)
Sent: Tuesday, May 27, 2025 1:55 PM
To: Thompson, Matthew (HHS/ASL)
Cc: Houry, Debra E. (CDC/IOD); Archer, William (HHS/IOS); Burns, Stuart (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD)
Subject: Re: Draft deliberative

Matt

According to OGC, CDC can operationize the Secretary's announcement on the COVID vaccine if we receive a written directive from HHS. CDC has no authority to pull down the current guidance until we receive a written directive. The directive needs to have as much specificity as possible. We need to define the age of "children", define healthy children, and define a healthy pregnant woman.

Once we the written directive has been sent through CDC OGC we can then adjust the vaccination schedule on the web site.

Thanks
Nina

Get Outlook for iOS

From: Witkofsky, Nina (CDC/IOD) <[redacted]>
Sent: Tuesday, May 27, 2025 1:17:50 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Melanson, Heather F.(HHS/IOS) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Anderson, Hannah (HHS/IOS) <[redacted]>
Subject: Re: Draft deliberative

I'm working with the center on language for CDC's web site. Will have an update shortly.

Nina

Get Outlook for iOS

From: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Sent: Tuesday, May 27, 2025 12:24:08 PM
To: Witkofsky, Nina (CDC/IOD) <[redacted]>
Subject: Fw: Draft deliberative

Nina please address.

Matt Buzzelli
Chief of Staff
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
[redacted]

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

Draft/Deliberative/Pre-decisional

From: Anderson, Hannah (HHS/IOS) <[redacted]>
Sent: Tuesday, May 27, 2025 11:58 AM
To: Chertman, Willy (HHS/IOS) <[redacted]>; Graham, Grace (FDA/OC) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Thompson, Matthew (HHS/ASL) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Spear, Stefanie (HHS/IOS) <[redacted]>
Subject: Draft deliberative

As part of today's announcement, please ensure that pregnancy is appropriately categorized on the Covid risk factor list on the CDC's website

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SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN

May 19, 2025

The Department of Health and Human Services (HHS) continually considers and evaluates available science and evidence related to the safety and effectiveness of all currently available Food and Drug Administration (FDA) approved or authorized vaccines, and any risks of severe disease, hospitalization, and death to certain populations.

By Secretarial Directive on June 18, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of Pfizer- BioNTech and the Moderna COVID-19 vaccines in the U.S. population for children ages six months through five years, consistent with the parameters of the Emergency Use Authorizations (EUAs) issued by FDA, for the Pfizer- BioNTech and the Moderna COVID-19 vaccines.[1]

By Secretarial Directive on June 24, 2022, HHS ratified the Centers of Disease Control and Prevention (CDC) recommendations concerning use of COVID-19 vaccines in the U.S. population for children ages six through 17 years, consistent with the parameters of EUAs issued by FDA.

The CDC also currently recommends the COVID-19 vaccine during pregnancy.[2]

Based on a review of the recommendation of the FDA and National Institutes of Health (NIH), I have determined that the known risks associated with use of COVID-19 vaccines in healthy U.S. children ages six months to 17 years do not outweigh the purported benefits of the vaccine. Accordingly, the HHS Secretarial Directives ratifying CDC recommendations for use of COVID-19 vaccines for children ages six months to 17 years and are rescinded.

Based on a review of the recommendation of the FDA, I have similarly determined that the lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy combined with the uncertainty of the benefits of vaccination pose potential risks to the mother and developing baby. Therefore, the CDC recommendation that pregnant women receive the COVID-19 vaccine is rescinded.

Accordingly, the CDC is directed to remove COVID-19 vaccines from the recommended Child and Adolescent Immunization Schedule by Age and recommended vaccines during pregnancy, as noted above.

Robert F. Kennedy, Jr.
Secretary

[1] The Pfizer and Moderna vaccines are currently approved by the FDA for children 12 years of age and older.
[2] https://www.cdc.gov/vaccines-pregnancy/recommended-vaccines/index.html.

Houry, Debra E. (CDC/IOD)

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Friday, June 6, 2025 6:24 PM
To: Monarez, Susan (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD)
Cc: Greco Kone, Rebecca (CDC/NCIRD/OD); Limbago, Brandi (CDC/NCIRD/OD); Houry, Debra E. (CDC/IOD); Witkofsky, Nina (CDC/IOD); Burns, Stuart (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD)
Subject: Policy document, pregnancy recommendations, slide deck
Attachments: NCIRD COVID19 schedule change data summary_6_6_25.pdf; INTERNAL USE ONLY_Policy Impacts Analysis_COVID-19_6.6.25.pdf

Categories: 4

Susan and Matt,

Following up on the request from Reyn and Tracy Beth from FDA, NCIRD put together a slide deck that summarizes our data related to COVID-19 vaccination, specifically the recent changes to the schedule. Our team also put together a policy analysis related to the same schedule changes. Both documents are attached here. Note that the slide deck is very dense; we are happy to provide briefings on any of this material. Let me know if it is ok to send the attached slide deck and policy analysis to Reyn and FDA.

Based on both the policy and the data we wanted to initiate a policy discussion with you regarding the recommendation for pregnant women.

We would like to propose an additional look at the schedule as it relates to pregnant women and for you to consider the possibility of revisiting this with the Office of the Secretary if you agree. Although covered extensively in the attached Power Point, we summarized the data below that supports the following policy proposal:

Consider a shared clinical decision-making recommendation for pregnant women

Summary of data (refer to slides 3-19 in attached slide deck for more detail)
Receiving COVID-19 vaccine during pregnancy has benefits to both the baby and the pregnant woman herself. In 2024-2025, among infants <6 months of age, hospitalization rates were similar to persons 65-74 years of age. No COVID-19 vaccine products are approved for infants ages <6 months. Any protection must come from transfer of maternal antibodies, either from vaccination during pregnancy or prior infection.
Among infants <6 months hospitalized for COVID-19 in 2024-2025, 71% had no underlying conditions, 22% were admitted to the ICU, and 3.5% had any record of maternal COVID-19 vaccination during pregnancy. It is important for pregnant women, together with their healthcare providers, to make an informed choice to receive COVID-19 vaccination to protect themselves and provide protection for infants in their first months of life.

Additionally, in 2024-2025, 28.5% of women ages 15-49 years who were hospitalized with laboratory-confirmed SARS CoV-2 infection were pregnant, of whom, 50% had one or more underlying conditions.

Pregnant women are at risk for severe COVID-19 and adverse maternal outcomes. A recent systematic review and meta-analysis showed that pregnant women with SARS CoV-2 infection were at significantly increased risk of maternal mortality and ICU admission compared with uninfected pregnant women. Neonates born to women with SARS CoV-2 infection were more likely to be admitted to a neonatal care unit after birth, be born preterm or moderately preterm, and be born low birth weight. Another systematic review and meta-analysis showed that COVID-19 vaccination during pregnancy in any trimester was associated with a lower risk of stillbirth or neonatal death.

Of note, the reason CDC did not have a separate COVID-19 vaccination recommendation for pregnant women is because they were included under the universal recommendation.

Thanks,
Demetre

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

CDC COMMENT ON CITED REFERENCE: The conclusion of this paper states that COVID-19 vaccine appears to be safe during pregnancy with no increase in the incidence of preterm labor and small for gestational age compared to unvaccinated women. The study reports there were no differences between vaccinated and non-vaccinated patients with respect to primary outcomes, with the rate of preterm birth 5.5% in the vaccinated group compared to 6.2% in the unvaccinated group ($p = 0.31$). Findings indicated during the second trimester, there was an increased risk of preterm birth compared to their unvaccinated counterparts (8.1% vs. 6.2%, $p < 0.001$). Notably, there were no preterm births within two weeks after vaccine receipt in the second trimester, and the majority of the preterm births were in the late preterm period, suggesting that unmeasured confounding may have contributed to the results. Safety of COVID-19 vaccine in pregnant women has been evaluated in multiple studies (including published CDC studies). Evidence from these studies has been reviewed by the ACIP COVID-19 Vaccine Safety Technical Work Group (VaST) from 2020-2023, which found no safety concerns for pregnancy, maternal, or infant outcomes.

8. **CLAIM:** Yet another study showed an increase in **placental blood clotting** in pregnant mothers who took the vaccine.

CITED REFERENCE: COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network (GVDN) cohort study of 99 million vaccinated individuals - ScienceDirect

CDC COMMENT ON CITED REFERENCE: This referenced paper did not include pregnant women or any maternal outcomes as part of its analysis, including placental blood clotting. Safety of COVID-19 vaccine in pregnant women has been evaluated in multiple studies (including published CDC studies). Evidence from these studies has been reviewed by the ACIP COVID-19 Vaccine Safety Technical Work Group (VaST) from 2020-2023, which found no safety concerns for pregnancy, maternal, or infant outcomes.

Thank you
Demetre

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

4. **CLAIM:** A study from the UK of over 1.7 million children between the ages of 5 and 15 revealed that **cases of myo and pericarditis were found exclusively in those that received the COVID-19 vaccine.**

CITED REFERENCE: OpenSAFELY: Effectiveness of COVID-19 vaccination in children and adolescents | medRxiv

CDC COMMENT ON CITED REFERENCE: This non peer reviewed article on medRxiv observed myocarditis and pericarditis among vaccinated children and adolescents in the U.K. The study cohort did not include over 1.7 million children, only ~1.24 million: 513,192 eligible adolescents were matched with 410,463 unvaccinated controls and 177,360 eligible children were matched with 141,711 unvaccinated controls. 410,463 adolescents (12-15 yo) received Dose 1, 220,029 adolescents that also received Dose 2, 141,711 children (5-11 yo) received Dose 1 and 66,231 children also received Dose 2. The number of events was rare. This study used records from emergency room and hospitalizations and therefore would not capture control patients that did not seek care or sought care in other locations. There were 9 cases of pericarditis and 3 cases of myocarditis among adolescents who received the first dose of COVID-19 vaccine, and in children there were 3 cases of pericarditis and no cases of myocarditis after receipt of the 2nd dose. Among those children who received the first dose of COVID-19 vaccine, there were 3 cases of pericarditis and no cases of myocarditis; no cases of pericarditis or myocarditis were observed following the second dose.

5. **CLAIM:** A study from Japan showed that COVID-19 vaccination was significantly associated with the onset of myo and pericarditis. These occurred most often in males under 30.

CITED REFERENCE: SARS-CoV-2 mRNA vaccine-related myocarditis and pericarditis: An analysis of the Japanese Adverse Drug Event Report database - ScienceDirect

CDC COMMENT ON CITED REFERENCE: These findings from Japan align with those of the COVID-19 vaccine safety monitoring systems from other countries, including CDC and FDA vaccine safety systems, and confirm the published CDC and FDA findings and support the updated CDC clinical considerations. The risk of myocarditis and pericarditis observed in these systems was highest among males under the age of 30 years and among those who received Moderna COVID-19 vaccine.

6. **CLAIM:** A number of studies in pregnant women showed higher rates of **fetal loss** if vaccination was received before 20 weeks of pregnancy.

CITED REFERENCE: Miscarriage after SARS-CoV-2 vaccination: A population-based cohort study - Velez - 2024 - BJOG: An International Journal of Obstetrics & Gynaecology - Wiley Online Library

CDC COMMENT ON CITED REFERENCE: The conclusion of this paper states that "SARS-CoV-2 vaccination was not associated with miscarriage, while accounting for the competing risk of induced abortion." These findings are consistent with prior studies (including published studies from CDC) where the risk of miscarriage following the COVID-19 vaccine was not significant.

7. **CLAIM:** Another showed statistically significant increases in preterm birth.

CITED REFERENCE: Safety of SARS-CoV-2 vaccination during pregnancy- obstetric outcomes from a large cohort study | BMC Pregnancy and Childbirth | Full Text

children (6 mos-6 yr) has been reviewed by the ACIP COVID-19 Vaccine Safety Technical Work Group (VaST) from 2020-2023, which found no safety concerns.

2. **CLAIM:** Information provided by manufacturers for the COVID-19 vaccines state, "[s]afety and efficacy in individuals younger than 12 years of age have not been established," and "[a]vailable data on [COVID-19 vaccine] administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy."

CITED REFERENCE: Package Insert and FDA Approved Patient Labeling - COMIRNATY

CDC COMMENT ON CITED REFERENCE (FOR SAFETY): Postmarketing surveillance further characterizes the safety profile of licensed products, especially for groups within the general population excluded from clinical trials (in this case pregnant women and children under 12). CDC and FDA have conducted multiple post-marketing studies and analysis of safety data in these populations, and this information has been presented to advisory committees to inform vaccine policy, clinical considerations for healthcare providers, and to the public. Evidence from these studies in pregnancy has been reviewed by the ACIP COVID-19 Vaccine Safety Technical Work Group (VaST) from 2020-2023, which found no safety concerns for pregnancy, maternal, or infant outcomes. Evidence from these studies in young children (6 mos-6 yr) has been reviewed by the ACIP COVID-19 Vaccine Safety Technical Work Group (VaST) from 2020-2023, which found no safety concerns.

3. **CLAIM:** Myocarditis reports in VAERS after COVID-19 vaccination in 2021 was **223 times higher than the average of all vaccines combined for the past 30 years** – representing a **2500% increase.**

CITED REFERENCE: Determinants of COVID-19 vaccine-induced myocarditis - Jessica Rose, Nicolas Hulscher, Peter A. McCullough, 2024

CDC COMMENT ON CITED REFERENCE:
The reference utilized public use VAERS data to analyze unverified myocarditis reports to VAERS following COVID-19 vaccines and found an average of 10.8 reports of myocarditis were filed between 1990 and 2020 and "notably" 2414 reports of myocarditis were filed in 2021 alone. The report identified 3078 reports of "COVID-19 vaccine-induced myocarditis" (0.3% of all AEs), 76% resulted in emergency care and hospitalization, while 3% suffered death. The authors report that they considered myocarditis cases could present as sudden death but the only mention is a man aged 33 years who suffered a cardiac arrest after running which was 600 days following Dose 2 Pfizer and death of a 15 year old male who died 358 days following Dose 1 Pfizer during his hospital stay for other illness. Limitations of analysis of VAERS data are well known. CDC and FDA have conducted multiple post-marketing studies of the COVID-19 vaccines and this information has been presented to advisory committees to inform vaccine policy, clinical considerations for healthcare providers, and to the public

It should be noted that the Journal Editor and Sage issued an expression of concern for this study. The Editor and the publisher were alerted to potential issues with the research methodology and conclusions, and author conflicts of interest. Sage has contacted the authors of this article on this matter, and an investigation is underway. These authors have produced multiple studies that have been retracted, discredited, or flagged for false/misinformation. The senior author, Peter McCullough, has had his medical licenses revoked and has been involved in other controversies.

Houry, Debra E. (CDC/IOD)

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Sunday, June 8, 2025 9:31 AM
To: Houry, Debra E. (CDC/IOD)
Cc: Jernigan, Daniel B. (CDC/NCEZID/OD)
Subject: HHS FAQ on COVID-19 Schedule Change by Secretary's Directive
Attachments: COVID Vax FAQ_FINAL.pdf; COVID19 Recommendation FAQs_ References.pdf

Categories: 4

Deb-

As you are aware, HHS distributed a FAQ to support the Secretary's directive to change the Child and Adolescent Schedule and the Adult Schedule. The schedule changes moved vaccination for 6m-18 year olds to shared clinical decision making and removed pregnant women from both, moving them to "no recommendation/not applicable." As a reminder, no SMEs in NCIRD or NCEZID have seen the data memos/formulations that the FDA and NIH produced for the secretary to support this decision.

On Thursday, June 5, I was made aware of a FAQ that HHS had circulated to offices of Congress that discussed this decision (Attached). To my knowledge, neither NCIRD nor NCEZID had seen this FAQ until we requested it, having heard from others that it had ben circulated. NCIRD has already conducted a thorough summary of data on children and women and have synthesized it into one document that I have forwarded to iOD for their reference that addresses the inaccuracies of the FAQ.

Dan and I requested that the Immunization Safety Office review the HHS FAQ and has provided an analysis of the safety related statements made in this document. I have also attached this as a PDF and pasted below. It is my understanding that CDCW may have also requested such an analysis, but I wanted to send this to you for additional guidance on further sharing of this review of data/references used in this FAQ.

COVID-19 Recommendation FAQ: Review of References

1. **CLAIM:** In addition, after two years on the market, the safety and efficacy of the vaccines for healthy children younger than 12 or pregnant mothers has not been established by the manufacturers.

CITED REFERENCE: Package Insert and FDA Approved Patient Labeling - SPIKEVAX

CDC COMMENT ON CITED REFERENCE (FOR SAFETY): Postmarketing surveillance further characterizes the safety profile of licensed products, especially for groups within the general population excluded from clinical trials (in this case, pregnant women and children under 12). CDC and FDA have conducted multiple post-marketing studies and analyses of safety data in these populations, and this information has been presented to advisory committees to inform vaccine policy, clinical considerations for healthcare providers, and to the public. Evidence from these studies in pregnancy has been reviewed by the ACIP COVID-19 Vaccine Safety Technical Work Group (VaST) from 2020-2023, which found no safety concerns for pregnancy, maternal, or infant outcomes. Evidence from these studies in young

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Friday, February 14, 2025 8:05 PM
To: Patterson, Sara S. (CDC/PHIC/OD); Griffis, Kevin (CDC/OD/OC); Monarez, Susan (CDC/IOD); Burns, William S. (Stuart) (CDC/IOD); Lubar, Debra (CDC/OD/OPPE); Tress, Deborah W. (CDC/OGC)
Subject: RE: Request from HHS re flu and vaccines

Sorry- late to all these emails and catching up. I know we discussed this in IOD re clarifying the ask and sharing our comms work which makes total sense. Deb L/ Deb T- can you comment re contracts and what options there are with TRO and appropriated funds? Want to make sure we know what is/isn't an option

Deb Houry, MD, MPH
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention
[redacted]

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Friday, February 14, 2025 3:58 PM
To: Griffis, Kevin (CDC/OD/OC) <[redacted]>; Monarez, Susan (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, William S. (Stuart) (CDC/IOD) <[redacted]>; Lubar, Debra (CDC/OD/OPPE) <[redacted]>; Tress, Deborah W. (CDC/OGC) <[redacted]>
Subject: RE: Request from HHS re flu and vaccines

Hi Kevin,

We just discussed in IOD meeting, and we think it would be helpful to share with HHS comms the various campaigns we run so they can help us understand how they might want them to change. We are under the impression that we would not want to stop all flu communication during a severe flu season but rather make sure informed consent is encouraged. Is there an opportunity to share our content back up with HHS for further guidance?

Thanks,
Sara

From: Griffis, Kevin (CDC/OD/OC) <[redacted]>
Sent: Friday, February 14, 2025 2:24 PM
To: Monarez, Susan (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Burns, William S. (Stuart) (CDC/IOD) <[redacted]>; Lubar, Debra (CDC/OD/OPPE) <[redacted]>; Tress, Deborah W. (CDC/OGC) <[redacted]>
Cc: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: FW: Request from HHS re flu and vaccines
Importance: High

Hello all,

I want to bring the email chain below to your attention. While we had previously been given the green light to proceed with paid communications, we have now been asked to take down paid campaigns related to the flu and vaccine promotion.

Given that this is the worst flu season in years, halting a campaign currently in the field presents significant reputational risk to the agency. There are also likely legal issues with contracts/appropriated funding.

Please see the attached spreadsheet for a rundown of existing paid media campaigns.

-kevin

From: Coffin, Nicole (CDC/PHIC/OD) <[redacted]>
Sent: Friday, February 14, 2025 2:10 PM
To: Griffis, Kevin (CDC/OD/OC) <[redacted]>
Cc: Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>
Subject: RE: Request from HHS re flu and vaccines
Importance: High

You are correct. We were given the greenlight to continue with all ad buys that were already paid for in flight, but to regroup on anything that starts in March.
This request is a change and would mean pulling out of circulation things already paid for and in flight.

Attached is the spreadsheet that includes the list of the campaign buys and cost information that I have from ADCs.
~Nicole

From: Griffis, Kevin (CDC/OD/OC) <[redacted]>
Sent: Friday, February 14, 2025 1:59 PM
To: Coffin, Nicole (CDC/PHIC/OD) <[redacted]>
Cc: Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>
Subject: RE: Request from HHS re flu and vaccines

My understanding was that we had a green light on all ads in flight. Is that wrong?

Can you send information on the cost of the campaigns?

From: Coffin, Nicole (CDC/PHIC/OD) <[redacted]>
Sent: Friday, February 14, 2025 1:50 PM
To: Griffis, Kevin (CDC/OD/OC) <[redacted]>
Cc: Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>
Subject: Request from HHS re flu and vaccines
Importance: High

Kevin,
Andrew Nixon/HHS gave me a call and asked that we pull out of circulation all campaign ad buys related to flu or anything encouraging shots or vaccinations.
He said this request came directly from the Secretary.
I noted that these have been paid for and are in flight and he acknowledged and asked that we work right away on things that are on social/online, magazines, and then will eventually need to do items that may be on bus stops or benches (if it includes those type of things).
He also mentioned that the plan is to transform to an informed consent campaign.

In looking at the campaign spend spreadsheet attached, I believe this impacts several programs. (Attaching the spreadsheet, in case helpful).

Seeking guidance on how best to proceed.

Thanks,
~Nicole

Nicole Coffin, MA
Deputy Director of Communications, *Acting/Temporary Assignment*
Centers for Disease Control and Prevention
[redacted]

Houry, Debra E. (CDC/IOD)

From: Monarez, Susan (CDC/IOD)
Sent: Monday, February 17, 2025 2:36 PM
To: Houry, Debra E. (CDC/IOD); Burns, William S. (Stuart) (CDC/IOD); Lubar, Debra (CDC/OD/OPPE)
Subject: RE: Request re flu campaigns/ad buys

Thanks Deb. Appreciate the awareness.

Please keep us posted.

Best,
Susan

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Monday, February 17, 2025 2:34 PM
To: Burns, William S. (Stuart) (CDC/IOD) <[redacted]>; Monarez, Susan (CDC/IOD) <[redacted]>; Lubar, Debra (CDC/OD/OPPE) <[redacted]>
Subject: FW: Request re flu campaigns/ad buys
Importance: High

For awareness- Stefanie and Andrew called Nicole and asked her to pull down the wild to mild campaign
I asked Nicole to confirm that this is just the media buys and not our flu information on CDC websites that has the mild to wild logo but is focused on how high risk individuals can protect themselves
It would be helpful to understand too what needs to be done differently in future as this was message tested and audiences responded well to this campaign
When Nicole sends the requested memo to Stefanie I suggested she also include info on our metrics and testing

Deb Houry, MD, MPH
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention
[redacted]
Executive Assistant: Latrisha Smith [redacted]
Special Assistant: Melissa O'Connor [redacted]

From: Coffin, Nicole (CDC/PHIC/OD) <[redacted]>
Sent: Monday, February 17, 2025 2:16 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: FW: Request re flu campaigns/ad buys
Importance: High

FYSA

From: Coffin, Nicole (CDC/PHIC/OD)
Sent: Monday, February 17, 2025 2:16 PM
To: Spear, Stefanie (HHS/IOS) <[redacted]>; Nixon, Andrew (HHS/ASPA) <[redacted]>
Cc: Griffis, Kevin (CDC/OD/OC) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>; Corry, Thomas (HHS/ASPA) <[redacted]>

Subject: RE: Request re flu campaigns/ad buys
Importance: High

Stefanie, Andrew,
Thanks for the update.

I have moved forward with letting CDC leadership know that HHS has instructed we immediately pause the Wild to Mild flu campaign but the Get My Flu Shot campaign can remain in place.
I will also connect with the program and let them know that you would like a memo describing each campaign in full, including where it ran, cost, future, and how much has yet to been paid out.

Question for clarification – does the ask include pulling down flu content on the CDC website that is branded with Wild to Mild? For example, one-page highlights who are at high risk for flu and what individuals can do to protect themselves, including treatment. Or do you mean just pause campaign items in flight like paid and high impact ad placement? I checked in with the program and learned there are only 2 days left on the Wild to Mild paid ad buys. Double-checking if you would still like it paused.

Let me know if there is anything I am missing or did not understand correctly, as I was out running errands when you called.
Thanks,
~Nicole

From: Coffin, Nicole (CDC/PHIC/OD)
Sent: Friday, February 14, 2025 10:29 PM
To: 'Nixon, Andrew (HHS/ASPA)' <[redacted]>
Cc: Griffis, Kevin (CDC/OD/OC) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>; Corry, Thomas (HHS/ASPA) <[redacted]>
Subject: RE: Request re flu campaigns/ad buys

Andrew,
Here are some of the flu campaign assets for February.

Note that there are two primary campaigns:

- Wild to Mild, which focuses on pregnant women and parents of kids
- Get My Flu Shot, which is a collaboration with the American Medical Association and the Ad Council

I have attached a few Wild to Mild assets from social media line ups.

The Ad Council assets are available here: GetMyFluShot | Homepage & Get My Flu Shot – No One Has Time for Flu

We also frequently promote graphics and prevention messages in other places as well, focusing on Health Care Providers, older adults, adults with chronic conditions, and the general public.

Let me know if you have additional questions or guidance.
Thanks,
~Nicole

From: Nixon, Andrew (HHS/ASPA) <[redacted]>
Sent: Friday, February 14, 2025 6:06 PM

To: Coffin, Nicole (CDC/PHIC/OD) <[redacted]>
Cc: Griffis, Kevin (CDC/OD/OC) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>; Corry, Thomas (HHS/ASPA) <[redacted]>
Subject: RE: Request re flu campaigns/ad buys

Happy to look over the content, but this was a direct ask from Secretary Kennedy. Can you send the content as soon as your able?

Thank you,

Andrew G. Nixon
Director of Communications
U.S. Department of Health and Human Services
[redacted]

From: Coffin, Nicole (CDC/PHIC/OD) <[redacted]>
Sent: Friday, February 14, 2025 4:58 PM
To: Nixon, Andrew (HHS/ASPA) <[redacted]>
Cc: Griffis, Kevin (CDC/OD/OC) <[redacted]>; Shockey, Caitlin E. (CDC/OD/OC) <[redacted]>
Subject: Request re flu campaigns/ad buys

Andrew,
CDC leadership discussed and thought it would be helpful to share the various campaigns we run so you all could help us understand how you might want assets changed. They are under the impression that HHS would not want CDC to stop all flu communication during a severe flu season but rather make sure informed consent is encouraged. Is there an opportunity to share our content with you for further guidance?
Thanks,
~Nicole

Nicole Coffin, MA
Deputy Director of Communications, *Acting/Temporary Assignment*
Centers for Disease Control and Prevention
[redacted]

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Thursday, May 1, 2025 9:47 AM
To: Buzzelli, Matthew J (Matt) (CDC/IOD); Burns, Stuart (CDC/IOD); Witkofsky, Nina (CDC/IOD)
Subject: if helpful- re vaccines

From discussion this morning- sharing if helpful for TPs so that information is correct for the Secretary

https://www.chop.edu/vaccine-education-center/vaccine-safety/vaccine-ingredients/fetal-tissues

Can vaccines made using fetal cells alter a person's DNA?
Even though fetal cells are used to grow vaccine viruses, vaccines do not contain these cells or pieces of DNA that are recognizable as human DNA. People can be reassured by the following:

- When viruses grow in cells, the cells are killed because in most cases the new viruses burst the cells to be released.
- Once the vaccine virus is grown, it is purified, so that cellular debris and growth reagents are removed.
- During this process of purification, any remaining cellular DNA is also broken down. To learn more about DNA and vaccine, visit the "Vaccine ingredients – DNA" page.

Do vaccines contain parts of fetuses or fetal cells?
In order to grow viruses in the lab, cells need to be made into single cell suspensions, meaning they can no longer be grouped together in the form of tissues or organs. As such, vaccines do not contain "parts of fetuses."
Vaccines also do not contain fetal cells. Once the vaccine viruses are grown in the cells, the next step in the manufacturing process is to purify the vaccine viruses away from the cells and substances used to help cells grow. If you have ever picked blueberries, you can think of this part of the process as similar. While you are picking, you might get some of the blueberry plant — stems, leaves and even branches — in your berry bucket, but to use the berries, you remove all of those things, so your pie contains only the blueberries (and any other ingredients you choose to add).
This purification part of the process is important for two reasons. The first, and perhaps most obvious, is the manufacturing reason. From a manufacturer's perspective, an efficient process that results in the purest possible product makes the final product easier to characterize. However, as consumers, the second, and more important, reason matters more. A pure product will not introduce unnecessary components that could trigger immune responses or affect us in other ways.

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Daskalakis, Demetre (CDC/NCIRD/OD)
Sent: Thursday, May 1, 2025 9:08 AM
To: Houry, Debra E. (CDC/IOD); Witkofsky, Nina (CDC/IOD)
Subject: RE:

Happy to help here. Thanks for sending

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Thursday, May 1, 2025 8:35 AM
To: Witkofsky, Nina (CDC/IOD) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: Re:

Here you for sending. Is there anyway we can help him with his talking points? This was brought up on John Stewart as well as he is off on the diabetes statistic by 100 fold in kids. Also need to clarify that these ingredients are not in thr vaccine and cdc is not doing these studies. That would be NIH

Get Outlook for iOS

From: Witkofsky, Nina (CDC/IOD) <[redacted]>
Sent: Thursday, May 1, 2025 7:49:29 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: Fw:

Secretary on Cuomo town hall last night

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https://www.youtube.com/watch?v=w4i7kGh63jo

Houry, Debra E. (CDC/IOD)

From: Burns, Stuart (CDC/IOD)
Sent: Wednesday, April 9, 2025 5:50 PM
To: Houry, Debra E. (CDC/IOD)
Subject: Re: Measles data 2010 - present

Thank you. Stuart

Get Outlook for iOS

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, April 9, 2025 4:57:34 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Subject: Re: Measles data 2010 - present

Let me see how much work it will take team. The active measles response has to take priority so I'll see what capacity they have I can have my SA do a medline search for #2

Get Outlook for iOS

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Wednesday, April 9, 2025 4:43:59 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: Re: Measles data 2010 - present

I circled back with Matt and he said it is needed by COB Friday. Can they make this deadline. Sorry to press on it. I wish next week would be early, but it is really needed sooner.

Stuart

Get Outlook for iOS

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, April 9, 2025 2:14:37 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: Measles data 2010 - present

Got it! Just sent to team- several are about to be deployed and some are on spring break- so likely won't have this until early next week

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Friday, April 4, 2025 9:23 AM
To: Viall, Abigail H. (CDC/OD/OPHDST); Buzzelli, Matthew J (Matt) (CDC/IOD)
Cc: Patterson, Sara S. (CDC/PHIC/OD); Hoffmann, Lauren (CDC/OD/OCS)
Subject: RE: Matt's Action Items

Categories: 4

Thanks Abby-
Love the format!
Sara- can we add the David Geier item to our 9a this morning? I wasn't aware of this. Given the prior research issues would be good to raise
https://quackwatch.org/cases/fdawarning/rsch/geier/
https://quackwatch.org/wp-content/uploads/sites/33/quackwatch/casewatch/board/med/geier/d_geier_charges.pdf

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Sent: Thursday, April 3, 2025 8:59 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Cc: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Hoffmann, Lauren (CDC/OD/OCS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Subject: Matt's Action Items

Hi All,

Here's what I'm tracking on.

Matt, I've added a new column to indicate if an item is for awareness of status vs. ready for a direct action by you. Also, for the ethics forms and Jordan's OF-8, I've gone ahead and attached the emails here so you don't have to go scrolling back through your inbox to locate them.

Action Items	Status	
ACIP member term extension	Email sent to Diane from on your behalf; no response yet	4/3/
Coordinated (with John Knox) emails to CDC and ASPR teams	John Knox sent email template for your review at 5:22 pm. Would like to coordinate sending in morning (proposed 8:00am)	4/4/
Jordan OF-8	Signature needed so he can start next week	4/4/

NIOSH lab closure/animal disposition memo	Deb to discuss OGC comments with Matt and then identify path forward to submit on time	4/4/
IRB member extension	Will have to you in the next hour or two	4/4/
OGE 278e financial disclosure report and updated ethics form	Emails with links/forms attached	4/4/
OARS HHS 520 for Nina	Email with links to system attached	4/4/
ASPR-CDC integration—high level picture	CDC/ORR and ASPR teams working to have something ready for Matt and John to review on weekend in advance of sharing with HHS	4/6/
Letter from Ambassador Eric Kneedler	GHC and Exec Teams working on bundled response to outreach from multiple Ambassadors	4/7/
Chamblee tour and NCIPC meeting--agenda, participants list	Draft agenda received; Abby to discuss with Matt, Stuart, and Deb	4/7/
NTE memos for HHS	Revisions received from Deb Lubar; Matt to review	4/7/
David Geier scientific ethics verification number	Flagged by Stuart in email sent 3:11pm Thursday, 4/3 –need to determine if David Geier has scientific ethics verification number and has taken required trainings to access CDC research data sets	4/7/
Review draft SOW for IOD Comms Contract	Vicki sent email with doc at 12:24pm Thursday, 4/3	4/7/
APHA attendance	Discuss next week (not urgent)	4/8/
Response to Karen Hacker	Deb Houry counseled not responding or responding using language that refers Karen to HHS HR.	4/8/
5 monthly Infectious Diseases Rapid Response Reserve Fund (IDRRRF)	OBPA signed off; Abby to review quickly for any flags	4/8/

Abigail Viall
Senior Advisor
Centers for Disease Control and Prevention
Department of Health and Human Services
[redacted]

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Sunday, June 8, 2025 9:38 AM
To: Tress, Deborah W. (CDC/OGC); Ford, Kenya S. (CDC/OGC); Haynes, Benjamin (CDC/OD/OC); Witkofsky, Nina (CDC/IOD); Faircloth, Jordan (CDC/OD/OCS)
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD); Burns, Stuart (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD)
Subject: VSD reactive talking points

Categories: 4

Hi all

Secretary Kennedy put out a statement on X yesterday about the Vaccine Safety Datalink. Given that there has been recent OGC involvement with VSD and the communication may generate media and exec sec/controlled correspondence queries for CDC, I wanted to share info that NCEZID pulled together as background if you are contacted. Thanks

Deb

Response to statements made about the VSD in https://x.com/SecKennedy/status/1931360039496712222

"In 1999, an in-house study of VSD showed an alarming and elevated rate for autism and neurological diseases among children receiving certain vaccines early in life. The CDC in-house researchers found an astronomical increased 11.35x risk in one run of the raw data and reduced that in a subsequent iteration to a still frightening 2.68x increased risk by unethically altering study protocols".

- We assumed that this statement refers to the preliminary screening analysis using automated VSD data, conducted by Epidemic Intelligence Service officer Thomas Verstraeten and presented at the 1999 EIS Conference; however, it is unclear as the relative risks presented in the abstract do not align with those in this statement.
- The final analysis showed no increased risk of autism. This analysis has undergone additional external reviews with the following conclusions:
    - IOM interpretation of study (2004):"given these strengths and limitations, and with the effect estimates, although nonsignificant, near or below 1, the study showed no association between TCVs [thimerosal-containing vaccines] and autism."
    - Re-analyses by Drs. Austin and Lally of Emory University at the RDC (2005)
        - Purpose: to resolve discrepancies between an initial unpublished report and the final publication, specifically by evaluating the impact of 6 differences in methodology used for the unpublished and final published report.
        - Conclusion: The researchers were able to duplicate the major findings of the study, and their overall conclusion was that the methodology used by CDC investigators was sound and that the findings are valid.

- Senate HELP Committee investigation (2009): investigated alleged misconduct by government agencies related to thimerosal vaccines and autism, and found that the following claims were unsubstantiated:
  - CDC did not convene the Simpsonwood Conference to cover up findings of causality
  - Dr. Thomas Verstraeten was not pressured into changing his findings
  - The CDC did not hide the Vaccine Safety Datalink from the public

- Because of the limitations of automated VSD data on assessing neurodevelopmental outcomes, two rigorous studies with primary data collection were conducted as a follow-up (neither of which showed evidence of an association between thimerosal-containing vaccines and autism or other neurodevelopmental outcomes):
  - Thompson WW, et al. Early Thimerosal exposure and neuropsychological outcomes at 7 to 10 years. *N Engl J Med.* 2007 Sept 27;357(13):1281-92
  - Price CS, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. *Pediatrics.* 2010 Oct;126(4):656-64. Epub 2010 Sep 13.

"CDC has repeatedly claimed to have lost the critical data underlying the research"

- The final, analytic database from the Verstraeten analysis was shared with HHS and NIH on March 14, 2025.
- The underlying data to the Verstraeten analysis are from the pre-2001 cycle files, which have not been lost. The existence of these archived cycle files has been repeatedly disclosed to HHS OGC as part of the investigation that was initiated on May 13, 2025.
- During interviews, HHS OGC inquired about other potential analytic datasets created by Verstraeten from the cycle files which are not the 'final' analytic dataset. For example, datasets before the exclusion criteria described in the manuscript (i.e., documentation of at least 2 polio vaccines by 1 year of age as a proxy for healthcare utilization at the HMO) were applied.
  - Extensive reviews of archived VSD files were undertaken, and there is no clearly labeled or documented dataset that appears to be *the* dataset that Verstraeten used to present preliminary findings at the 1999 Epidemic Intelligence Service Conference.
  - As described to HHS OGC lawyers, if there is interest in data that did not have these exclusion criteria applied, a new dataset would need to be constructed from the original cycle files; however, there are no guarantees that this would be an exact replicate of any earlier datasets created by Verstraeten.

"CDC has terminated the VSD data sharing program and taken draconian steps to prevent outside researchers from ever again accessing the VSD"

- The VSD data sharing program has not been terminated, as described here: Accessing and Using Data from the Vaccine Safety Datalink (VSD) | Vaccine Safety Systems | CDC.
- Two public-use datasets from VSD studies related to thimerosal-containing vaccines and neurodevelopmental outcomes are available to outside researchers and have been requested 27 times.
- In addition, external researchers may request access to VSD data from any published study for re-analysis through the NCHS Research Data Center.
- CDC is actively undertaking additional steps to make VSD data more accessible, including through creation of more public-use datasets.

"Beginning in 2001, CDC created an architecture of byzantine rules to block independent scientists from access. CDC also disaggregated the VSD data and put it under control of private corporations to further ensure that it could never be studied by external researchers"

- In 2001, the VSD implemented a Distributed Data Model (DDM) which allows VSD member healthcare organizations to assemble and maintain its computerized files on an on-site server and share analytic output and limited datasets.
- This model protects confidentiality of patient medical records at the member organizations, and allows organizations to retain ownership of their own source data.
- As described above, external researchers can request access to datasets from published VSD studies through the data sharing program.

"In 2002, the U.S. Congress Government Oversight Committee ordered CDC to allow Dr. Geier and his son to access the VSD data, which the agency maintains at enormous expense to the U.S. taxpayers. In extraordinary acts of insubordination, CDC repeatedly refused that Congressional order. When a frustrated Committee Chair, Representative Dan Burton, threatened to come personally to the CDC's Research Data Center (RDC) in Hyattsville to force the CDC to allow the Geiers to examine the data, the CDC responded that it would repel the Chairman with armed guards."

- Current ISO staff were not employed or engaged with this issue in 2002 when these hearings involving Representative Burton took place; therefore, we have no information on this purported exchange.
- We are unable to find documentation of these statements in publicly available sources.

"After two years and multiple Congressional subpoenas, CDC officials finally allowed the Geiers access. However, CDC continually obstructed the Geiers' ability to actually study the VSD. Among a long retinue of manufactured impediments, CDC assigned a pair of burly monitors to oversee the Geiers' every movement. Government officials whited out data before handing data sets to the Geiers. They forced the Geiers to review data in a windowless room heated to over 90 degrees Fahrenheit. They gave the researchers computers with no instructions on how to use them and no user interface. They wiped the Geiers' hard disks and destroyed their hard drives when the researchers temporarily left the study room. Ultimately, CDC officials sent letters to the HMOs that now controlled the data, falsely accusing the Geiers of misusing the data."

- The National Center for Health Statistics (NCHS) operates the Research Data Center (RDC) to provide access to restricted-use data from federal government agencies.
- The procedures in place through the RDC are designed to ensure that the confidentiality and privacy of medical record information of study participants are not compromised.
- The policies and procedures of the RDC are described in-depth at RDC website and apply to all researchers, and not selectively applied to certain researchers. As clearly stated on the RDC website, these include:
    - An RDC analyst supervises all visits.
    - Analytic datasets are created based only on the requested and approved variables. Therefore, data are not "whited out". Data are provided based on the approved variables.
    - RDC staff cannot assist the researcher with their analysis
    - Researchers cannot bring in any electronic communication devices.
    - As per RDC policies and procedures, no output will leave an RDC facility without review by an analyst. Any output must match the research questions in the approved application. In addition, researchers may only use their output and statistics in a way that does not pose any additional disclosure risks to participants.
- The RDC facilities (including the Hyattsville location) are all federal buildings, and therefore must comply with any federal standards related to building security, maintenance, and upkeep.
- In February 2004, CDC sent a letter (internal draft found in ISO archives) to the IRB Administrator for Northern California Kaiser Permanente informing her of concerns related to Dr. Geier's analyses at the Research Data Center in October 2003 and January 2004: potential breaches in confidentiality, execution

of unauthorized analyses, and renaming of files which would have allowed the researchers to leave the RDC with unauthorized files. These breaches risked violation of patient privacy that the Geiers had agreed to comply with.

"In 2005, the Institute of Medicine took testimony regarding the Geiers' ordeal and issued a scathing 140-page report with 27 recommendations for CDC to guarantee public access to the VSD. The CDC implemented none of these recommendations and continued to fight to keep the Geiers out of the VSD."

- The 2005 report "Vaccine Safety Research, Data Access, and Public Trust" is not a scathing review of the VSD; the report is balanced in describing the strengths and limitations of the VSD and data access.
- Many of the committee recommendations are now standard parts of the VSD data sharing program, including through the NCHS Research Data program. For example, the websites for these programs describe what data are available and the criteria for evaluation of proposals. Other recommendations related to archival of VSD study protocols, datasets, and outputs are currently in-place. Other recommendations related to making VSD data findings available to the public are also the current standard, as VSD data are routinely shared at public federal advisory committee meetings (ACIP, VRBPAC), and published in peer-reviewed literature.
- CDC continues to work to enhance access to VSD data. Efforts are ongoing to make de-identified datasets available from VSD studies, in addition to continued access to VSD data through the RDC.

As a result of CDC's efforts, David Geier is the only living independent researcher to have had access to the VSD.

- This is not accurate. For the two public-use datasets, 27 requests for these data have been made. Multiple secondary or re-analyses have been published for the 3 thimerosal-related studies from VSD:
    - Verstraeten, et al. Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases | Pediatrics | American Academy of Pediatrics. *Pediatrics.* 2003 Nov; 112(5):1039-1048.
        - Re-analysis by Dr. Harland Austin and Ms. Cathy Lally of Emory University at the RDC (not published but report available). In response to a Discover Order issued by the US Court of Federal Claims, the final dataset was made available to these researchers, who were able to duplicate the major findings of the study. The researchers concluded that the methodology used by CDC investigators was sound and that the findings were valid.
    - Thompson WW, et al. Early Thimerosal exposure and neuropsychological outcomes at 7 to 10 years. *N Engl J Med.* 2007 Sept 27;357(13):1281-92.
        - Smith MJ (University of Louisville), et al. On-time Vaccine Receipt in the First Year Does Not Adversely Affect Neuropsychological Outcomes | Pediatrics | American Academy of Pediatrics
        - Barile JP (Georgia State University), et al. Thimerosal Exposure in Early Life and Neuropsychological Outcomes 7–10 Years Later | Journal of Pediatric Psychology | Oxford Academic
    - Price CS, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. *Pediatrics.* 2010 Oct;126(4):656-64. Epub 2010 Sep 13.

DeSoto (University of Northern Iowa): Synthetic folic acid supplementation during pregnancy may increase the risk of developing autism - IOS Press

Houry, Debra E. (CDC/IOD)

From: Jernigan, Daniel B. (CDC/NCEZID/OD)
Sent: Friday, March 14, 2025 5:58 PM
To: Memoli, Matthew (NIH/OD) [E]; Powers, John (NIH) [C]
Cc: Monarez, Susan (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD); Houry, Debra E. (CDC/IOD)
Subject: VSD and Birth Defects Datasets
Attachments: PubUse_Aut_Introduction_09_02_2010.pdf; PubUse_Introduction_09_27_2007.pdf; Autism MMR Data Documentation.pdf; Verstraeten Pediatrics Study Data Documentation.pdf

Matt and John:
Thank you for your interest in CDC's available data related to vaccines and outcomes including autism spectrum disorder. As previously discussed, we are providing two de-identified, public use datasets to you. Here below are the publications which used those data:

- Price CS, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. *Pediatrics*. 2010 Oct;126(4):656-64. Epub 2010 Sep 13.
- Thompson WW, et al. Early Thimerosal exposure and neuropsychological outcomes at 7 to 10 years. *N Engl J Med*. 2007 Sept 27;357(13):1281-92.

In addition, we are also providing two additional datasets related to vaccines and autism spectrum disorder – one from VSD and one from what is now called the National Center on Birth Defects and Developmental Disabilities. These two additional datasets have not yet been fully de-identified and may contain direct or indirect identifiers that should be treated with caution to assure protection of privacy and confidentiality. Here below are the publications which used those data:

- Verstraeten, et al. Safety of Thimerosal-Containing Vaccines: A Two-Phased Study of Computerized Health Maintenance Organization Databases | Pediatrics | American Academy of Pediatrics. *Pediatrics*. 2003 Nov; 112(5):1039-1048.
- DeStefano, et al. Age at First Measles-Mumps-Rubella Vaccination in Children With Autism and School-Matched Control Subjects: A Population-Based Study in Metropolitan Atlanta | Pediatrics | American Academy of Pediatrics. *Pediatrics*. 2004 Feb; 113(2):259-266.

Below are the instructions to download these 4 datasets and other necessary documentation:

- [redacted]
- [redacted]

We are also attaching PDFs that provide additional information for each of the 4 datasets. Staff of CDC's Immunization Safety Office are available for any support needed.

The HHS Office of General Counsel has advised that CDC is legally required to maintain the confidentiality of personally identifiable information and other data points that could indirectly identify an individual. In order to assure compliance, any HHS employees, or other federal staff, who access these data must not re-release, share, provide access to, or otherwise make these data available to unauthorized users. Users of these data should also undertake the necessary security procedures to avoid inadvertent data breaches. If a need is identified to make these data available to external researchers, please notify us so that we can provide the necessary data use

agreements for external researchers, as indicated by the HHS Office of General Counsel in the memo dated March 13, 2025.

Applicable federal laws and regulations pertaining to these data include, but are not limited to:

a. Human subjects Common Rule 45 CFR Part 46
b. Assurance of Confidentiality, Section 308(d) of the Public Health Service Act (42 U.S.C. § 242m(d))
c. Privacy Act of 1974 (5 U.S.C. § 552a); and HHS Privacy Act regulations (45 C.F.R. Part 5b)
d. HIPAA Privacy Rule, 45 C.F.R. Parts 160 and 164

Thanks,
Dan

Houry, Debra E. (CDC/IOD)

From: Monarez, Susan (CDC/IOD)
Sent: Friday, March 14, 2025 5:44 AM
To: Jernigan, Daniel B. (CDC/NCEZID/OD)
Cc: Houry, Debra E. (CDC/IOD)
Subject: Re: VSD data

Thanks Dan.

I'll give you a call this morning.

I appreciate all your support.

Best,
Susan

From: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>
Sent: Thursday, March 13, 2025 9:22 PM
To: Monarez, Susan (CDC/IOD) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: RE: VSD data

Thanks. Received. I would have been happy to have just had a follow up call with John and Matt. Let me know how we can help here.
Dan.

From: Monarez, Susan (CDC/IOD) <[redacted]>
Sent: Thursday, March 13, 2025 7:45 PM
To: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: VSD data

Good evening Dan -

Please see direction from HHS.

Please let me know if you have any questions.

Best,
Susan

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Friday, March 14, 2025 11:17 AM
To: Remley, Karen (CDC/NCBDDD/OD); Houlihan, Catherine (CDC/NCIRD/OD) (CTR); Meyer, Sarah (CDC/NCEZID/DHQP/ISO); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Chaney, Sascha (CDC/NCBDDD/OD); Maenner, Matthew J. (CDC/NCBDDD/DHDD); Tinker, Sarah (CDC/NCBDDD/DHDD); Meaney Delman, Dana M. (CDC/NCBDDD/OD); Rattay, Karyl (CDC/NCBDDD/DHDD)
Cc: Boehmer, Tegan K. (CDC/OD/OPHDST); Viall, Abigail H. (CDC/OD/OPHDST); Small, Plezie (CDC/NCBDDD/DHDD) (CTR); Abercrombie, Julia (CDC/NCBDDD/DHDD)
Subject: RE: ISO-NCBDDD coordination

Thanks Karen
I don't think we should pursue a narrow focus on vaccines and autism- open to learning more about all of NIH's portfolio on autism if we are asked to do work on larger questions around autism, which are certainly important like environmental exposure and epigenetics, to understand what is driving increases

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Remley, Karen (CDC/NCBDDD/OD) <[redacted]>
Sent: Friday, March 14, 2025 10:23 AM
To: Houlihan, Catherine (CDC/NCIRD/OD) (CTR) <[redacted]>; Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <[redacted]>; Gee, Julianne (CDC/NCEZID/DHQP/ISO) <[redacted]>; Chaney, Sascha (CDC/NCBDDD/OD) <[redacted]>; Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>; Meaney Delman, Dana M. (CDC/NCBDDD/OD) <[redacted]>; Rattay, Karyl (CDC/NCBDDD/DHDD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Boehmer, Tegan K. (CDC/OD/OPHDST) <[redacted]>; Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>; Small, Plezie (CDC/NCBDDD/DHDD) (CTR) <[redacted]>; Abercrombie, Julia (CDC/NCBDDD/DHDD) <[redacted]>
Subject: RE: ISO-NCBDDD coordination

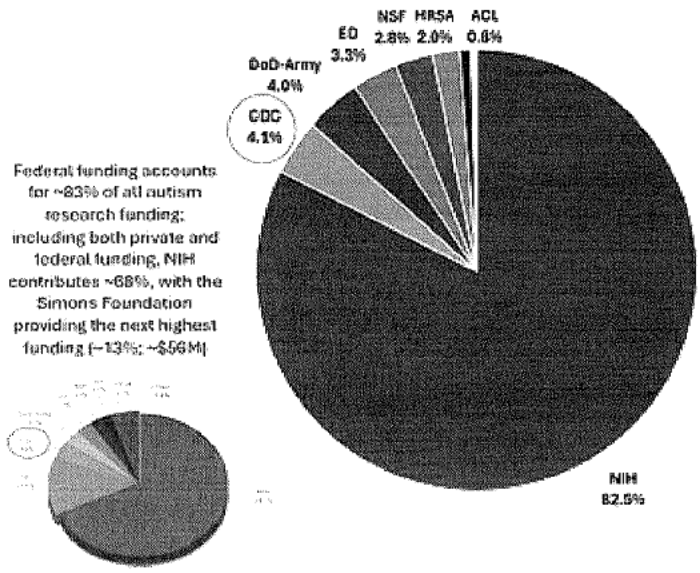
Dear all,
As we look into how best to respond to questions about vaccine safety and autism, our group was looking at data from the Interagency Autism Coordinating Committee – as you can see NIH has the vast majority of funding and projects- it may be worth a meeting to understand what data elements they are collecting around vaccination as they have many large registries etc.

Best
Karen

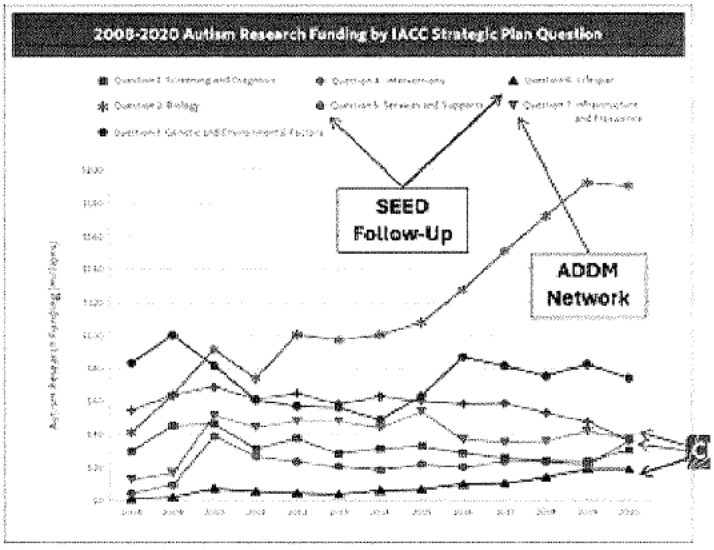
CDC's Contribution to Federal Autism Research* Activities

Informed by the 2019-2020** Portfolio Analysis [LINK]
Conducted by the HHS Interagency Autism Coordinating Committee (IACC)

NIH funds 82.5% of federal autism research (~$285.5M)



Federal funding accounts for ~83% of all autism research funding; including both private and federal funding, NIH contributes ~68%, with the Simons Foundation providing the next highest funding (~13%; ~$56M)



- *The Autism and Developmental Disabilities Monitoring (ADDM) Network funds ~$9M to 15 grantees to better understand autism prevalence*
- *The Study to Explore Early Development (SEED) funds ~$5M to 5 grantees address services and supports and lifespan issues*

*CDC considers ADDM, and moving forward possibly SEED Follow-Up, to be Public Health Surveillance activities rather than research
**Most recent data available from IACC

Karen Remley, MD, MBA, MPH, FAAP
Director, National Center on Birth Defects and Developmental Disabilities
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS S106-4
Atlanta, GA 30329-4018
[redacted]

-----Original Appointment-----
From: Houlihan, Catherine (CDC/NCIRD/OD) (CTR) <[redacted]>
Sent: Thursday, March 6, 2025 10:42 AM
To: Houlihan, Catherine (CDC/NCIRD/OD) (CTR); Meyer, Sarah (CDC/NCEZID/DHQP/ISO); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Chaney, Sascha (CDC/NCBDDD/OD); Maenner, Matthew J. (CDC/NCBDDD/DHDD); Tinker, Sarah (CDC/NCBDDD/DHDD); Meaney Delman, Dana M. (CDC/NCBDDD/OD); Rattay, Karyl (CDC/NCBDDD/DHDD)
Cc: Remley, Karen (CDC/NCBDDD/OD); Boehmer, Tegan K. (CDC/IOD/OPHDST); Viall, Abigail H. (CDC/OD/OPHDST); Small, Plezie (CDC/NCBDDD/DHDD) (CTR); Abercrombie, Julia (CDC/NCBDDD/DHDD)
Subject: ISO-NCBDDD coordination
When: Friday, March 7, 2025 10:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

-----Original Appointment-----
From: Houlihan, Catherine (CDC/NCIRD/OD) (CTR) <[redacted]>
Sent: Thursday, March 6, 2025 10:38 AM
To: Houlihan, Catherine (CDC/NCIRD/OD) (CTR); Meyer, Sarah (CDC/NCEZID/DHQP/ISO); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Gee, Julianne (CDC/NCEZID/DHQP/ISO); Chaney, Sascha (CDC/NCBDDD/OD); Maenner, Matthew J. (CDC/NCBDDD/DHDD); Tinker, Sandra J. (CDC/NCCDPHP/DNPAO); Meaney Delman, Dana M. (CDC/NCBDDD/OD); Rattay, Karyl (CDC/NCBDDD/DHDD)
Subject: ISO-NCBDDD coordination
When: Friday, March 7, 2025 10:30 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

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Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Sunday, March 23, 2025 8:12 AM
To: Buzzelli, Matthew J (Matt) (CDC/IOD); Monarez, Susan (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD)
Subject: update on VSD

Just wanted to send a quick update as I'm catching up on things from the weekend

- ***Briefing for Matt B***- Matt, Jen said you called with ?s about VSD on Friday; she and Dan will set up a briefing for you on Monday to do a deeper dive; the FAQ document I sent you and Susan I think is also a helpful resource. I've read it a few times and now get what the data can and can't do
- ***VSD dataset initial request***- 4 datasets were sent to NIH last week as requested. When we first met two weeks ago (CDC, NIH, HHS) the proposed plan was to have this competed for a third party independent group for analyses- I haven't heard anything further re this- didn't know if either of you had. From the most recent discussion Dan had with John Powers, I think John and potentially other contractors at NIH will be doing the analyses. Our CDC team is available if there are further ?s from NIH on the datasets.
- ***New requests for prospective VSD data***- Dan and team met and worked through options and he will follow up with NIH on Monday. As I mentioned on Friday, this would likely need IRB approval and a study question given how these sites and data systems are set up. I think there is a misperception that there is a cache of EHRs sitting in the data hub vs it being a passthrough for studies. CDC team has found workable option for NIH to move forward (ie developing study question and protocol)- this is what protocol and path CDC follows when we are looking at studies.
- ***NIH autism datasets***- CDC NCBDDD and vaccine scientists met with NIH national autism coordinator and NIMH scientists Friday to discuss coordination around recent autism requests at CDC including 1) NIH review of previously published CDC datasets, and 2) determining if NIH (or IACC) is aware of any ongoing NIH cohorts studies examining the etiology of autism. The NIH autism scientists were not aware of NIH leadership requests to CDC and had not been engaged in any discussions re autism with their leaders. They indicated most of their NIH data would be >10 years old as they aren't looking at vaccines in these datasets given the science base developed over the past 20 years. We were unable to get additional information during the call as the NIH autism scientists said they needed to talk to Dr. Memolli before they would engage in any technical discussions with CDC about NIH datasets that are available or other collaborations re autism.

Sorry for long email- trying to synthesize a few different trails and pursuits. Happy to discuss more at our check in tomorrow too
Deb

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Meaney Delman, Dana M. (CDC/NCBDDD/OD)
Sent: Saturday, March 22, 2025 6:59 PM
To: Houry, Debra E. (CDC/IOD)
Cc: Jernigan, Daniel B. (CDC/NCEZID/OD); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Rattay, Karyl (CDC/NCBDDD/DHDD); Meyer, Sarah (CDC/NCEZID/DHQP/ISO); Remley, Karen (CDC/NCBDDD/OD)
Subject: Call with NIH Friday

Deb,

ISO and NCBDDD met with Susan Daniels, the National Autism Coordinator, and several others within NIH's NIMH on Friday 3/21/3025 for a short call.

The purpose of the meeting was to discuss coordination around recent autism requests at CDC including 1) NIH review of previously published CDC datasets, and 2) determining if NIH (or IACC) is aware of any ongoing cohorts studies examining the etiology of autism. NIMH indicated they were not aware of any of the data review requests and would need to get back to CDC for a technical discussion at a later date, as this was not something they had discussed with their Acting Director.

Please let us know if you have questions- it was a short call.

Best,
Dana

Dana Meaney-Delman MD MPH
Principal Deputy Director
NCBDDD
CDC
[redacted]

Houry, Debra E. (CDC/IOD)

From: Jernigan, Daniel B. (CDC/NCEZID/OD)
Sent: Tuesday, March 18, 2025 12:21 PM
To: Houry, Debra E. (CDC/IOD)
Subject: Fw: Connecting re VSD

FYI.
Dan

Dan Jernigan, MD MPH
Director, NCEZID, CDC [redacted]

From: Geier, David (HHS/ASFR) (CTR) <[redacted]>
Sent: Tuesday, March 18, 2025 12:05 PM
To: Monarez, Susan (CDC/IOD) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>
Subject: Re: Connecting re VSD

Hi Dan,

It a pleasure to be connected with you.

Please, let me know that next steps to facilitate the process of accessing the VSD data.

Thanks,
David

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From: Monarez, Susan (CDC/IOD) <[redacted]>
Sent: Tuesday, March 18, 2025 12:00 PM
To: Geier, David (HHS/ASFR) (CTR) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>
Subject: Connecting re VSD

David/Dan -

Making sure you are connected.

Dan - David needs access to the VSD data. Please have the team support.

Best,
Susan

Houry, Debra E. (CDC/IOD)

From: Jernigan, Daniel B. (CDC/NCEZID/OD)
Sent: Monday, July 14, 2025 7:32 AM
To: Burns, Stuart (CDC/IOD); Houry, Debra E. (CDC/IOD); Anderson, Hannah (HHS/IOS)
Cc: Braden, Chris (CDC/NCEZID/OD); Meyer, Sarah (CDC/NCEZID/DHQP/ISO)
Subject: RE: Prep for Visitor

Hannah, Stuart:
As we prepare for David's access to the VSD files, I wanted to get your thoughts on a couple of issues I feel would help protect the Secretary and lead to an overall more successful evaluation of the data.

The first is regarding study ethics. I'm concerned that David will not be signing an assurance of confidentiality. While I recognize that OGC has determined that David, acting as the direct agent of the Secretary, is not legally bound to sign the assurance, there is still an ethical best practice that signing the assurance would help meet, and would help protect the Department. In particular, the VSD files being provided to David are not de-identified and contain over 100 million records with personally identifiable patient information of clinical encounters, diagnoses, and treatments. I see a problem here that we are allowing less assurance than is currently in place, given that all CDC staff and VSD investigators accessing the data have signed the statement of confidentiality. Additionally, the assurance of confidentiality has supported a longstanding trusted engagement with the data providers and co-investigators. The assurance assumes that partners are informed of studies being conducted by any site across the network. Failing to maintain that trusted relationship introduces risk for the department if VSD partners withdraw from the network, ending an extremely valuable tool for evaluating vaccine adverse events which is critically important for achieving the Secretary's priorities.

A second issue is regarding scientific practice. Over the many years of the VSD, a strength of the effort has been the shared scientific exploration and adherence to gold standard scientific methods. Best practices being implemented in VSD have required investigators to develop a study question and a proposed protocol which is presented to the network for discussion. This process helps refine the approach to data collection and analysis so that the work is optimized to answer the vaccine safety question. For this current effort, we do not have clarity on the study question, the analytic plan, the study endpoint, the timeline for completion, the use of parallel work to demonstrate replicability of findings, collaborators, review/clearance, or publication product. Some greater transparency on the study would help me to understand how the process adheres to the current scientific practice of the VSD, and the practices used by CDC investigators. Deviation from this process poses a reputational risk to HHS and CDC. Following current expected scientific practices for the VSD evaluation would strengthen the analysis and findings, helping to meet the Secretary's objectives.

Look forward to discussing.
Thanks
Dan.

From: Jernigan, Daniel B. (CDC/NCEZID/OD)
Sent: Friday, July 11, 2025 4:48 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Anderson, Hannah (HHS/IOS) <[redacted]>
Cc: Braden, Chris (CDC/DDID/NCEZID/OD) <[redacted]>; Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>
Subject: Prep for Visitor

Hannah, Stuart, Deb H:

I understand that the laptop, workstation, office, share drive and cycle file prep are completed. Let us know when David will be arriving.
Thanks
Dan.

Daniel B. Jernigan
Director, National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention
Department of Health and Human Services

Houry, Debra E. (CDC/IOD)

From: Archer, William (HHS/IOS) <[redacted]>
Sent: Sunday, July 27, 2025 2:01 PM
To: Houry, Debra E. (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD); Thompson, Matthew (HHS/ASL)
Subject: Re: VSD next steps

Matt you and I need a brief call as soon as we can in Monday.

Matt T can arrange.

Thanks
Reyn

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From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Sunday, July 27, 2025 1:55:16 PM
To: Archer, William (HHS/IOS) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Subject: RE: VSD next steps

Hi Reyn
Thanks so much for looping me and Nina in. I had checked in with Stuart and Dan earlier last week and they had indicated things were progressing and hadn't flagged anything other than Stuart didn't think the pre 2001 data were that useful (even with the PII). Unfortunately I will miss you on Thursday- I am out on leave Thursday/ Friday for a last quick vacation before school starts. Happy to hop on a call earlier this week with you to see where I can help; or we can debrief after your Thursday meeting so I can learn of next steps and what is needed. A few quick thoughts based on your email below

- Secretary buying the VSD data- does this mean pre 2002; pre 2025; or system going forward? Has OGC and office of science weighed in on what can/ can't be done and any contract modifications? I can add them to the Thursday meeting if helpful.
- Accelerating research- we are always interested in supporting new queries and explorations. Look forward to hearing the outcome of the meeting. I remember from the meeting we had with Hannah these site studies can take some time to stand up, but likely more helpful as data can be collected prospectively on outcomes of interest.
- Re technology and data- we have two offices, OCIO and OPDHST. OCIO is more the back house and does support technology; OPDHST is more the work with states and programs. With the IHS reassignments, the chief information officer, chief data officer, and forecasting lead were all placed on administrative leave and with RIFs we did lose some of the IT team with the planned HHS centralization and shared services. We have put actings in these leadership roles and are prioritizing laterals and details where we can too. OCIO reports to the COO (who is also acting) and OPDHST had been working directly with Susan (and Mandy before that) on many of these items given her interest and expertise. Having Susan on board will be great as I know she will want a human capital needs assessment done (and Christa our acting COO has starting looking at this) and will have thoughts re data and AI for the agency. Re the budget, Christa and Rachel have

focused on the SBC presentation and worked on the proposed initiatives; my understanding was the data budget briefing was more focused on some of the prior expenditures and a detailed breakdown of the line so I think the priority was on the SBC and FY 27 budget for this week. I haven't seen the requests to Jen/ OPDHST as I think these are going directly to her and she's been working with you and Matt VP but I can check in with her re status.

We look forward to having you meet with Susan in the next few weeks as we learn more about her priorities too so our team can focus on HHS and CDC Director initiatives.

From: Archer, William (HHS/IOS) <[redacted]>
Sent: Saturday, July 26, 2025 1:48 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Subject: VSD next steps

Dear Deb and Nina:

I spoke with Dan Jernigan yesterday about a next step related to the VSD databases stage 1 and 2.

After a lot of work with the team at CDC we finally were able to share David Geier's program files and connect him with the database from home.
We also learned that the 13 PIs have large data sets in petabytes of data which CDC cannot host or fully analyze. The Sec would like to understand a plan to modernize how the IT systems work (4 days to connect David) and know what is needed to up date the storage and analytics capacity. The goal is to bring past data sets into CDC and move to allow them to be public once the original studies are done. This is a requirement of the EO. Dan agrees in principle with caveats to assure we remove PII. This is also a deficiency. We don't have a rapid way to do that and we were initially told the pre2002 data might take months. Then we were told that it might take weeks. We are two weeks in and I don't think it has started. This is not a criticism of the teams it's a question of how we build that functionality. This needs to be clearly defined and added to the budget. We have one day. Also the Secretary wants to buy all the VSD data and put it in the office of the Secretary. This may be a leap but there are other ways to achieve this but today CDC is not ready to take big leaps. I am being told we must find a way to take big leaps. I need your help on this.

We also need to see all this in the budget process and I will be making sure that we discuss it next week. But the budget is moving and we need decide. If the centers can't do this quickly, OMB has given the director 5% budget moving authority. We will use this process instead.

A second point is that the Secretary is committed to accelerating the process of working with the VSD team and doing more research. I suggested to Dan that he think about how to expand staff and budget at VSD to answer key questions the Secretary wants. As a first step of this work, Dan agreed to host me, Stuart, David, and Lyn and his team on Thursday. I'll fly early AM and we will meet around 10:00am for a couple hours. Dan wanted to make sure you and Nina are aware of this.

We still are struggling to get OPHDST information to present to the Dep Sec. Matt VP has been working to refine it. It still needs work. The team must perform at a higher level. Three requests are out. One to survey each state and another to share the budget to know what is funded and what resources can still be programmed. The third is the 5 slide presentation to S2. Finally we are being told of loss of staff yet staff I understand are being brought in from other parts of CDC. We need to do a through review of the

health IT mission and determine what staff we need. Some may not be fit for purpose. We need to strengthen capabilities with outside contractors including for AI. Days not weeks, weeks not months. The leaders doing data sharing at Dep Sec are waiting on us to show up fully. The train has left the station and soon it will be challenging to sustain the narrative that CDC can help set up health data across AHA and CDC. IOS is open to CDC leading and Susan wants it. Right now we are getting feedback from the Deb Secs team that CDC is not keeping up. The team it seems is just not able to keep to the expected pace. Who is accountable for assessing the tech needs across the agency? What is the process of updating systems? How are these needs moved through a process to the budget? Who oversees performance of this team? This needs to be refined Monday as we have budget meetings on Tuesday and Wednesday. It's disappointing these three requests with the office mentioned above are lingering weeks and months.

I'd like to have lunch with you and Matt to go over a few other things as well.

I also want to make sure we have budget to restore the Journal of EID. Susan also wants this.

Thanks and looking forward to having Susan soon.

Reyn

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Houry, Debra E. (CDC/IOD)

From: Viall, Abigail H. (CDC/OD/OPHDST)
Sent: Monday, March 10, 2025 5:51 PM
To: Remley, Karen (CDC/NCBDDD/OD); Meaney Delman, Dana M. (CDC/NCBDDD/OD); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Meyer, Sarah (CDC/NCEZID/DHQP/ISO); Jernigan, Daniel B. (CDC/NCEZID/OD); Layden, Jennifer (CDC/OD/OPHDST); Houry, Debra E. (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD)
Cc: Monarez, Susan (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD); Viall, Abigail H. (CDC/OD/OPHDST); Lubar, Debra (CDC/OD/OPPE); Mahmood, Aisha (CDC/NCIPC/OD)
Subject: Follow up on ASD Briefing Document
Attachments: Autism Study Action Plan_revised_3-10-25_5pm.docx

Good Evening,

First, I want to thank you for the way you came together last night and this morning to help inform the Increasing Transparency in Autism Action Plan proposal for HHS—and for answering all my questions as we pulled together the final version.

I'm attaching a clean version of the final document for your records.

For now, the immediate focus for next steps is on Actions 1 and 2. Specifically:

1. CDC will take action to make de-identified VSD data sets openly available
2. CDC and NIH will develop a study protocol for re-examining VSD data for an association between vaccine administration and ASD, and then the two agencies will convene a study group to execute that study protocol

Matt Buzzelli will oversee CDC's involvement, and CDC and NIH will identify agency leads for study protocol development.

Please don't hesitate to reach out if you have any questions.

Thanks
Abby

Abigail Viall, ScD, MA
Data Policy and Standards Division
Office of Public Health Data, Surveillance, and Technology
Centers for Disease Control and Prevention
[redacted]

"It's a riddle wrapped in a mystery inside an enigma."
~Winston Churchill

Increasing Transparency in Autism – Action Plan

OVERVIEW

Autism spectrum disorder (ASD) rates in the United States have increased substantially since the 1980s. Like ASD itself, the specific mix of biological, social, and environmental factors driving this rise are complex and not well understood. Greater awareness has contributed to observed increases in ASD rates, but it does not fully explain them. Some have posited a link between vaccines and ASD; however, repeated reviews by the IOM and others have found no evidence of a link between the two[1].. Nonetheless, concerns about vaccines and autism persist, and these affect public acceptance of vaccines.

As part of its *Executive Order, Establishing the President's Make America Healthy Again Commission*, the Administration has charged HHS to chair a USG-wide Commission charged with making recommendations to the President. The initial mission of the Commission shall be to advise and assist the President on how best to exercise his authority to address the childhood chronic disease crisis—including increasing rates of ASD.

To support this broader initiative, HHS--in partnership with CDC, NIH and FDA--will implement the following actions

1. identify an independent study group to re-examine any scientific evidence for an association between vaccine administration and ASD;
2. make existing data from VSD available to the study group and the broader public;
3. identify a second study group to examine a more complete set of factors associated with ASD—including, but not limited to, administration of vaccines--using additional available datasets; and
4. launch a new, prospective study to examine any possible associations between prenatal and postnatal exposures, including on-going vaccine administration, environmental exposures, infections, epigenetics, and autism and related neurodevelopmental outcomes.

Actions 1 and 2 are narrowly scoped to address remaining public questions around vaccine safety and links between vaccine administration and ASD. Actions 3 and 4 build on that initial work to fill high-priority knowledge gaps to evaluate how much potential ASD risk factors contribute to increased ASD prevalence in the United States.

These proposed actions will better ensure HHS resources are used to comprehensively detect and address what is contributing to the increasing rates of autism, as well as maximize access to developmental services.

BACKGROUND

Action 1: Identify independent study group to reexamine VSD data

[1] The Institute of Medicine reviewed over 200 studies in 2004 and more than 1,000 studies in 2011. A systematic review of 67 studies and a meta-analysis of 10 studies have also arrived at the same conclusion.

CDC will identify two or more study groups of nationally recognized vaccine and ASD experts that can scientifically and objectively evaluate potential associations between vaccines and autism and neurodevelopmental outcomes. CDC and other HHS operating divisions will identify appropriate contracting mechanisms to implement the studies, and where funds may be available for supporting this work.

Action 2: Make existing VSD data available

CDC will make available immediately, to the independent study groups, existing datasets prepared to address the possible association of ASD with vaccines. VSD has previously collected data related to vaccines and neurodevelopmental outcomes (including autism spectrum disorder). These datasets along with codebooks and other necessary documentation from these studies can be made available upon request to external researchers for re-analysis.

Action 3: Identify a second independent study group to evaluate a more complete set of factors associated with ASD using secondary data

HHS, in partnership with CDC, NIH, FDA, and other agencies as applicable, will identify additional expert study groups to conduct retrospective (Action 3) and prospective (Action 4) studies of possible associations between prenatal and postnatal exposures, including on-going vaccine administration, environmental exposures, infections, epigenetics, and autism and related neurodevelopmental outcomes. CDC, NIH and FDA have funded research and collected data related to potential drivers of ASD, and the agencies will identify and make relevant datasets available to the study group for analysis. Similarly, the agencies will support the study group as it seeks to identify other potential data sets that could be used to evaluate associations between ASD and vaccination and other environmental factors, correlation with genetic, proteomic, metabolomic, and other biophysiological data, geographic variability in prevalence, and other critical variables.

Action 4: Conduct a new, prospective study

HHS will launch a new study to evaluate the underlying etiology of ASD and related disorders through NIH and CDC. NIH could focus on epigenetics, neuroanatomy, clinical aspects, and cohort enrollment and CDC could collect population level and prenatal and postnatal exposure data. The study will collect primary, prospective data including vaccination and other environmental factors, correlation with genetic, proteomic, and other biophysiological data, geographic variability in prevalence, and other critical variables. To ensure transparency and credibility of the study, an external study oversight committee would be formed, to include nationally recognized scientific experts as well as community members and other stakeholders. Committee review of study protocol would ensure transparency and buy-in for any scientific results.

IMPLEMENTATION:

Action 1

CDC will identify two or more independent study groups to re-analyze existing datasets from VSD assessing thimerosal-containing vaccines and autism and neurodevelopmental outcomes. Existing contracts and grants will be leveraged to ensure that the study group can be formed expeditiously (likely within a few months), and that the re-analysis can be completed in a timely manner. Potential options (pending additional discussion) include:

- The Clinical Immunization Safety Assessment (CISA) Project, a network of vaccine safety experts from 8 medical research centers, through an existing IDIQ contract (the most rapid option).
- Commissioned reanalysis through the Global Vaccine Data Network, a multinational, investigator-led research network, through an existing grant.
- Commissioned reanalysis through analytical research groups; possible existing or new CDC mechanisms and timelines would need to be identified.

Action 2

CDC currently provides access to de-identified datasets from VSD studies on autism and neurodevelopmental to external researchers through a formal request process detailed on the VSD data sharing program website. Approximately 20 requests for use of the de-identified VSD datasets have been made by external researchers. Documentation such as codebooks and technical reports are also available on the VSD website.

Available datasets include those described in the following publications:

- Price CS, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. *Pediatrics.* 2010 Oct;126(4):656-64. Epub 2010 Sep 13.
- Thompson WW, et al. Early Thimerosal exposure and neuropsychological outcomes at 7 to 10 years. *N Engl J Med.* 2007 Sept 27;357(13):1281-92

CDC will work with the study group convened under Action 1 to access these data sets and provide interpretive support as needed.

Currently, CDC's data use agreements (DUAs) with VSB sites require IRB review and approval and a signed use form by proposed researchers. These requirements are intended to support transparent use of VSD data in a research study while meeting CDC's obligations to protect patient confidentiality. However, they also serve as checks on open data access and analysis of VSD and ASD associations.

CDC will work with HHS and OGC to revisit its DUAs with VSD sites to assess how to expand the availability of these de-identified data to interested users through public websites.

Action 3

HHS, in partnership with CDC, NIH, FDA, and other agencies as applicable, will identify and fund a second expert study group to examine links between ASD and a range of potential

exposures and risk factors, including, but not limited to, vaccine administration. With input from programmatic subject matter experts and data acquisition experts, the study group will identify other potential datasets and data assets of interest to support their work, as well as mechanisms to secure those data sets. In the case of data sets accessible through existing HHS contracting or similar mechanisms, a contract modification may be sufficient. If a new mechanism (e.g., a BAA) is considered, additional time may be necessary to set up the study group, define and secure data assets, and conduct analyses.

Depending on the scope of the work, CDC estimates total costs for data acquisition/contracts could range from $1M to $10M. Data storage and compute costs would range between $250,000 to $2M depending on number of data sources, hosting parameters, and other factors.

Ultimately, there are significant limitations to the secondary use of healthcare data assets and acquisitions not designed to examine associations, and thus need to determine which datasets, as well as what study questions could be meaningfully examined with such datasets and sources. Potentially could do updates similar to Vaccines are not associated with autism: An evidence-based meta-analysis of case-control and cohort studies – ScienceDirect and Safety of Vaccines Used for Routine Immunization of US Children: A Systematic Review | Pediatrics | American Academy of Pediatrics.

Additional activities, as described under Action 4, could address these limitations.

Action 4

To best assess the etiology of ASD, prospective studies from large, multi-site cohorts with primary data collection on a variety of potential environmental exposures using comprehensive ASD and developmental assessments, as well as biologic specimens, would be needed. Possible approaches include NIH leading clinical studies and supporting collaboration across HHS, given their strong infrastructure for ASD research, leveraging existing CDC partnerships (e.g., Autism and Developmental Disabilities Monitoring [ADDM], VSD) or competitive extramural research grants through NIH for external researchers. The timeline and budget for a comprehensive, prospective study would need to be developed based on final study objectives, but it is anticipated to cost several million dollars to implement.

Potential design approaches include:

- **Large, multi-site population-based cohort study** that begins following mothers from early pregnancy through childhood and in numerous geographic communities. Existing CDC contract mechanisms that could be leveraged still need to be explored.
- **US government-funded autism studies and surveillance networks:** These data sources currently do not collect vaccination history, and it is unlikely that detailed vaccination history of sufficient completeness or quality can be retrospectively collected and linked to enrolled participants. However, going forward, inclusion of vaccination history could be explored.
    - CDC: Autism and Developmental Disabilities Monitoring (ADDM) Network or Study to Explore Early Development (SEED), through existing CDC mechanisms.
    - CDC will explore other potential options with other federal agencies (e.g., NIH), with potentials for interagency agreements.

- **Electronic health record (EHR)-based systems to identify a cohort:** These systems would serve as a base population from which to recruit a cohort for standardized neurodevelopmental testing and additional data collection on potential exposures, early intervention services and educational records. Options potentially include:
    - **Vaccine Safety Datalink:** through existing IDIQ contract
    - **Other EHR-based systems with CDC relationships (e.g. COSMOS, United Health-Optum Labs, Health Verity, Truveta)** will be explored but are likely not viable options given that systems are de-identified, with limited ability to collect additional data, conduct neurodevelopmental testing, or collect specimens on patients.

Houry, Debra E. (CDC/IOD)

From:	Monarez, Susan (CDC/IOD)
Sent:	Sunday, March 9, 2025 5:37 PM
To:	Jernigan, Daniel B. (CDC/NCEZID/OD); Meaney Delman, Dana M. (CDC/NCBDDD/OD); Layden, Jennifer (CDC/OD/OPHDST)
Cc:	Houry, Debra E. (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD); Viall, Abigail H. (CDC/OD/OPHDST); Buzzelli, Matthew J (Matt) (CDC/IOD)
Subject:	CDC Autism Study Action Plan
Attachments:	Autism Study Action Plan_09Mar2025.docx
Importance:	High

Dan, Dana, Jen –

We need to provide HHS with an Autism Study Action Plan tomorrow AM.

I have used our previous inputs and expanded based on some additional feedback.

Could you please review the document and provide input on all – I have highlighted areas I need help with to complete before our HHS meeting tomorrow at 11 am.

If you could please send all your inputs to Abby, Sara, and Deb **no later than 9 am tomorrow**, we can integrate and be prepared to brief HHS at 11 am.

I am available this evening and tomorrow morning should you have any questions. [redacted]

Please don't hesitate to call – no question is too small.

Thank you!!

Susan

Increasing Transparency in Autism – Action Plan

OVERVIEW

CDC recommends initiating four immediate actions to increasing transparency and scientific evidence related to possible associations between childhood vaccines and autism spectrum disorder (ASD). CDC, in partnership with NIH and FDA, could immediately implement the follow actions 1) identify independent study group to examine any potential scientific linkage between vaccine administration and autism; 2) immediately make available to study group existing data from VSD; 3) identify and make available to the study group additional datasets at CDC, NIH, FDA, and other sources that can provide increased scientific data to inform examination of potential linkage; and 4) launch an new, prospective study to examine any potential linkages between on-going vaccine administration and autism.

BACKGROUND

Action 1: Identify independent study groups

CDC will identify two or more study groups who can examine existing data related to ASD, including vaccination and other potential influencing factors. CDC will the appropriate contracting actions to be taken and from where the funds will be drawn.

Action 2: Use existing VSD data

CDC will make available immediately to the VSD study group datasets related to vaccines and ASD. VSD has previously collected data related to vaccines and neurodevelopmental outcomes (including autism spectrum disorder). These datasets along with codebooks and other necessary documentation from these studies can be made available upon request to external researchers for re-analysis.

Action 3: Identify additional existing datasets and perform meta-analysis to identify any other potential drivers of autism

In additional to CDC, NIH and FDA have funded research and collected data related to potential drivers of ASD. The agencies will work together to identify relevant datasets and facilitate access to the study group. CDC will fund an additional study group under the agency's data analytics group to aggregate as appropriate and perform a meta-analysis of existing, relevant data that could provide critical information related to the causes of autism. Data could include vaccination and other environmental factors, correlation with genetic, proteomic, metabolomic, and other biophysiological data, geographic variability in prevalence, and other critical variables

Action 4: Conduct new prospective study

CDC will launch a new study to evaluate the underlying etiology of ASD and related disorders. The study will collect primary, prospective data including vaccination and other environmental factors, correlation with genetic, proteomic, and other biophysiological data, geographic variability in prevalence, and other critical variables. To ensure transparency and credibility of the study, an external study oversight committee would be formed, to include nationally recognized scientific experts as well as community members and other stakeholders. Committee review of study protocol would ensure transparency and buy-in for any scientific results.

IMPLEMENTATION:

Action 1.
Dan/Mike/Sara:

- Please describe how you would establish a team to use the VSD data. Can we establish more than one study group to ensure independence and transparency?
- Please provide an estimate for when the study group will be established
- Please provide any necessary HHS actions needed to launch the study in a timely manner

Action 2.
VSD is a collaborative project between CDC and 13 healthcare organizations currently covering approximately 13.5 million people. VSD uses electronic health record (EHR) data from member sites to monitor safety of new vaccines and detect adverse events in near-real time, as well conduct rigorous epidemiologic studies on vaccine safety topics.

Available Data from VSD on Neurodevelopmental Outcomes
De-identified datasets from VSD studies on autism and neuropsychological outcomes can be obtained by external researchers. Documentation such as codebooks and technical reports are provided on the VSD data sharing program website.

Available datasets: Why can't we make the public use files from these two previous studies available on our website? Let's try to get to yes with any of the appropriate safeguards in place.

- Price CS, et al. Prenatal and infant exposure to thimerosal from vaccines and immunoglobulins and risk of autism. *Pediatrics.* 2010 Oct;126(4):656-64. Epub 2010 Sep 13.
- Thompson WW, et al. Early Thimerosal exposure and neuropsychological outcomes at 7 to 10 years. *N Engl J Med.* 2007 Sept 27;357(13):1281-92

CDC staff are available to assist with interpretation and access as needed.

Are Any Other VSD Data on Neurodevelopmental Outcomes Available?
Since its completion of the studies referenced above, VSD has not conducted any new prospective studies on the association between vaccines and neurodevelopmental outcomes, including autism spectrum disorder. All other subsequent studies from VSD (e.g., Barile, et al., Iqbal, et al., DeStefano, et al.) utilized the aforementioned de-identified datasets. However, VSD

investigators have identified learning, communication, or developmental disorders as potential outcomes of interest for studying the safety of the childhood immunization schedule.

Process to Access Data:
Investigators accessing these data are required to sign a Data Sharing and Use Agreement (DSUA). Signed agreements are received at publicdataset@cdc.gov, whereupon the data are securely transferred to the user. CDC staff are available for any needed assistance.

Action 3:

Jen (with support from Dan/Dana and teams):

- Please provide a contracting approach to fund a data analytics project out of your shop – I think you can probably sub-contract from an existing contract. I can help scope the SOW.
- Please add other datasets that we think useful beyond VSD (e.g., VAERS, UK Biobank, public and private sector claims data, other private sector data.etc) – the sub-contractor(s) will add more
- Please provide a timeline for when we can get the contract in place
- Please provide a timeline for when we think we can get the work started

Action 4:

Dan/Dana

- Please provide information on how we would launch this study
- Would we include NIH and FDA?
- Would we wait for the results of Actions 2 and 3? (I think yes, but please correct me)

Houry, Debra E. (CDC/IOD)

From: Archer, William (HHS/IOS) <[redacted]>
Sent: Thursday, July 10, 2025 7:31 AM
To: Jernigan, Daniel B. (CDC/NCEZID/OD); Anderson, Hannah (HHS/IOS); Houry, Debra E. (CDC/IOD); Grant, Althea M. (CDC/OD/OS)
Cc: Burns, Stuart (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD); Yueh, Lena (HHS/OGC); Braden, Chris (CDC/NCEZID/OD); Meyer, Sarah (CDC/NCEZID/DHQP/ISO); Bell, Michael MD (CDC/NCEZID/DHQP/OD); Hulkower, Rachel (CDC/OD/OS)
Subject: Re: contract

Dan I appreciate you all. Our job is to not prejudge the outcome but to face what might be true together.

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From: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>
Sent: Wednesday, July 9, 2025 11:44:40 PM
To: Anderson, Hannah (HHS/IOS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Meyer, Sarah (CDC/NCEZID/DHQP/ISO) <[redacted]>; Bell, Michael MD (CDC/NCEZID/DHQP/OD) <[redacted]>; Hulkower, Rachel (CDC/OD/OS) <[redacted]>
Subject: RE: contract

Thanks. Attached is a collection of the due outs from our discussions today, some of which have already been completed. Really appreciate the good dialogue as we work to achieve the Secretary's intent. Also really appreciate Deb H's team in setting up a meeting at 10AM tomorrow to keep us moving forward.
Thanks
Dan.

From: Anderson, Hannah (HHS/IOS) <[redacted]>
Sent: Wednesday, July 9, 2025 3:13 PM
To: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>
Subject: RE: contract

Ok so some responses here--

- Verify that this activity is covered under the scope of work for David's contract – yes covered
- Confirm that the contracting company is aware of this activity – yes confirmed
- Confirm who the COR for David's work is (i.e., who is the FTE with oversight over this activity))—I will handle all administrative actions of the contract with the COR. You can view me as the Project Manager for OS.

From: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>
Sent: Wednesday, July 9, 2025 3:04 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Anderson, Hannah (HHS/IOS) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>
Subject: RE: contract

Thanks. So, since this is not a personal services contract, having someone verify the scope of the contract to show that it covers the work would be great. I think we can assume that the contracting company is aware. Regarding the question on the COR, the question was really who is the lead FTE for this effort at HHS?
Thanks
Dan.

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, July 9, 2025 2:32 PM
To: Anderson, Hannah (HHS/IOS) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>
Subject: RE: contract

Team working now on summary of contract, science, logistics, etc for follow up
Pulling from that document looks like for contract :

- Verify that this activity is covered under the scope of work for David's contract
- Confirm that the contracting company is aware of this activity
- Confirm who the COR for David's work is (i.e., who is the FTE with oversight over this activity)

Dan may have additional thoughts too that I missed

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Anderson, Hannah (HHS/IOS) <[redacted]>
Sent: Wednesday, July 9, 2025 2:26 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>
Subject: contract

It's a professional services contract – let me know what questions you have from here that I can run down. I know Lena is working with the team to understand how it implicates the AOC

Hannah

Houry, Debra E. (CDC/IOD)

From: Archer, William (HHS/IOS) <[redacted]>
Sent: Thursday, July 10, 2025 7:33 AM
To: Jernigan, Daniel B. (CDC/NCEZID/OD); Houry, Debra E. (CDC/IOD); Anderson, Hannah (HHS/IOS); Grant, Althea M. (CDC/OD/OS)
Cc: Burns, Stuart (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD); Yueh, Lena (HHS/OGC); Braden, Chris (CDC/NCEZID/OD)
Subject: Re: contract

Good.

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From: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>
Sent: Wednesday, July 9, 2025 10:52:30 PM
To: Archer, William (HHS/IOS) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Anderson, Hannah (HHS/IOS) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>
Subject: RE: contract

Thanks for the question. Hannah has determined that the contractor (ITSC) engagement is addressed.
Dan.

From: Archer, William (HHS/IOS) <[redacted]>
Sent: Wednesday, July 9, 2025 6:36 PM
To: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Anderson, Hannah (HHS/IOS) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>
Subject: RE: contract

Are there any risks in assuming the contracting company is aware?

From: Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>
Sent: Wednesday, July 9, 2025 3:04 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Anderson, Hannah (HHS/IOS) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>; Braden, Chris (CDC/NCEZID/OD) <[redacted]>
Subject: RE: contract

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Thanks
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From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, July 9, 2025 2:32 PM
To: Anderson, Hannah (HHS/IOS) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>
Subject: RE: contract

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- Confirm that the contracting company is aware of this activity
- Confirm who the COR for David's work is (i.e., who is the FTE with oversight over this activity)

Dan may have additional thoughts too that I missed

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Anderson, Hannah (HHS/IOS) <[redacted]>
Sent: Wednesday, July 9, 2025 2:26 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Jernigan, Daniel B. (CDC/NCEZID/OD) <[redacted]>; Grant, Althea M. (CDC/OD/OS) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Yueh, Lena (HHS/OGC) <[redacted]>
Subject: contract

It's a professional services contract – let me know what questions you have from here that I can run down. I know Lena is working with the team to understand how it implicates the AOC

Hannah

Hannah Anderson
Deputy Chief of Staff, Policy
U.S. Department of Health and Human Services (HHS)

Houry, Debra E. (CDC/IOD)

From: Shirley, Malia (HHS/IOS) <[redacted]>
Sent: Wednesday, July 30, 2025 1:52 PM
To: Houry, Debra E. (CDC/IOD)
Subject: RE: SES Performance Review

Hi Deb!

Sorry for the confusion – I just verified with Matt and he said he does **not** need to meet with you. He said Susan can conduct your review when she is available.

Thank you!

Best,
Malia

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, July 30, 2025 10:22 AM
To: Shirley, Malia (HHS/IOS) <[redacted]>
Cc: Capozzola, Christa (CDC/GHC/OD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Monarez, Susan (CDC/IOD) <[redacted]>
Subject: RE: SES Performance Review

Hi Malia
I talked with our CDC leadership team and my performance progress review was already done last month. Delighted to meet with Matt Buckham as I haven't worked with him yet, but a few clarifications that may be helpful:

- I was the acting CDC Director the week of Jan 20th per COOP and delegation of authorities by Dr. Cohen until Dr. Monarez was named acting. After that, I was not named acting CDC Director. Susan was acting CDC Director from late Jan to late March and then Matt Buzzelli attended HHS meetings for Susan (and the Secretary mentioned this at a hearing) and the Secretary signed policy memos such as ACIP in the absence of an acting CDC Director.

Adding CDC team back- **Matt Buzzelli can weigh in as well**
Thanks all, just let me know how you wish to proceed. Apologies if I've made this more complicated than intended
Deb

From: Shirley, Malia (HHS/IOS) <[redacted]>
Sent: Wednesday, July 30, 2025 8:42 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: RE: SES Performance Review

Hi Debra!

Sorry for the confusion – you were on the list Matt forwarded to me so we will go ahead and get you scheduled! Those two times are currently unavailable. The earliest we can do is 10:30am on Aug 5. Does that work for you?

Thank you!

Best,
Malia

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Tuesday, July 29, 2025 8:14 PM
To: Shirley, Malia (HHS/IOS) <[redacted]>
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Monarez, Susan (CDC/IOD) <[redacted]>
Subject: RE: SES Performance Review

Hi
I'm not sure if this is meant for me as I'm a T42 and not SES and report to Dr. Monarez. Tuesday Aug 5th 945a is 1st preference and 10a would be second preference.

From: Shirley, Malia (HHS/IOS) <[redacted]>
Sent: Tuesday, July 29, 2025 6:42 PM
To: Gradison, Andrew (ACF) <[redacted]>; Lazare, Mary (ACL) <[redacted]>; Klein, Roger (AHRQ/OD) <[redacted]>; Weir, Shana (OS/ASA) <[redacted]>; Knox, John (ASPR/IO) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Engels, Thomas (HRSA) <[redacted]>; Smith, Benjamin P. (IHS/HQ) <[redacted]>; Kevenev, Sean (HHS/OGC) <[redacted]>; Kleinschmidt, Arthur (SAMHSA/OAS) <[redacted]>; Cutler, Diane (HHS/IOS) <[redacted]>; LeFevre, Julie (HHS/IOS) <[redacted]>; Rice, Garey (OS/IOS) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Tignor, Beth (HHS/IOS) <[redacted]>
Subject: SES Performance Review

Good Evening,

Performance progress reviews for SES employees must take place between August 1 and August 8, 2025. Matt has requested that we schedule them while Secretary Kennedy is in Alaska. The meeting should only take about 15 minutes. The following time slots are available and will be scheduled on a first come, first serve basis. Please respond to this email with your first **and** second time slot choice. I will send you an email calendar invite as a confirmation of your meeting time.

- Tuesday, August 5th
  - 9:45am
  - 10:00am
  - 10:15am
  - 10:30am
  - 10:45am
  - 11:00am
  - 11:15am
  - 11:30am
  - 2:30pm
  - 2:45pm
  - 3:00pm
- Thursday, August 7th
  - 10:00am
  - 10:15am
  - 10:30am
  - 10:45am

- 1:30pm
- 1:45pm
- 2:00pm
- 2:15pm
- 2:30pm
- 3:00pm
- 3:15pm
- 3:30pm

Please let me know if you have any questions!
Thank you.

Best,

Malia Shirley
Office of the White House Liaison
Department of Health & Human Services
Office of the Secretary

[redacted]

Houry, Debra E. (CDC/IOD)

From: Bell, Lynna (CDC/OCOO/OHR)
Sent: Wednesday, July 30, 2025 7:50 AM
To: Houry, Debra E. (CDC/IOD); Wells, Nathan (CDC/OCOO/OHR)
Subject: Re: Please advise re SES Performance Review

Hi Dr. Houry,

HHS is under the impression that you were the acting CDC Director prior to Dr. Monarez's confirmation. This is why you received the request.

HHS response:

The IOS front office contacted Dr. Houry because she was in the acting role as Director of CDC initially. All OpDiv/StaffDiv heads performance plans were being handled by the IOS front office. Since Dr. Monarez was just confirmed, it is best that the IOS conduct the progress review for Dr. Houry and Dr. Monarez can conduct her closeout.

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From: Bell, Lynna (CDC/OCOO/OHR) <[redacted]>
Sent: Wednesday, July 30, 2025 6:54:00 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Wells, Nathan (CDC/OCOO/OHR) <[redacted]>
Subject: Re: Please advise re SES Performance Review

Good morning Dr. Houry,

I will check and will provide a response shortly. R,

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From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Tuesday, July 29, 2025 8:15:47 PM
To: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Bell, Lynna (CDC/OCOO/OHR) <[redacted]>
Subject: Please advise re SES Performance Review

Can you all check on this? I have never met with Matt Buckham previously, HHS acting chief of staff, nor with the prior HHS COS, so not sure if this is who would do my performance review. I did work with Susan when she was acting and she is now confirmed. Please advise

From: Houry, Debra E. (CDC/IOD)
Sent: Tuesday, July 29, 2025 8:14 PM
To: 'Shirley, Malia (HHS/IOS)' <[redacted]>
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Monarez, Susan (CDC/IOD) <[redacted]>
Subject: RE: SES Performance Review

Hi
I'm not sure if this is meant for me as I'm a T42 and not SES and report to Dr. Monarez. Tuesday Aug 5th 945a is 1st preference and 10a would be second preference.

From: Shirley, Malia (HHS/IOS) <[redacted]>
Sent: Tuesday, July 29, 2025 6:42 PM
To: Gradison, Andrew (ACF) <[redacted]>; Lazare, Mary (ACL) <[redacted]>; Klein, Roger (AHRQ/OD) <[redacted]>; Weir, Shana (OS/ASA) <[redacted]>; Knox, John (ASPR/IO) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Engels, Thomas (HRSA) <[redacted]>; Smith, Benjamin P. (IHS/HQ) <[redacted]>; Keveney, Sean (HHS/OGC) <[redacted]>; Kleinschmidt, Arthur (SAMHSA/OAS) <[redacted]>; Cutler, Diane (HHS/IOS) <[redacted]>; LeFevre, Julie (HHS/IOS) <[redacted]>; Rice, Garey (OS/IOS) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Tignor, Beth (HHS/IOS) <[redacted]>
Subject: SES Performance Review

Good Evening,

Performance progress reviews for SES employees must take place between August 1 and August 8, 2025. Matt has requested that we schedule them while Secretary Kennedy is in Alaska. The meeting should only take about 15 minutes. The following time slots are available and will be scheduled on a first come, first serve basis. Please respond to this email with your first **and** second time slot choice. I will send you an email calendar invite as a confirmation of your meeting time.

- Tuesday, August 5th
  - 9:45am
  - 10:00am
  - 10:15am
  - 10:30am
  - 10:45am
  - 11:00am
  - 11:15am
  - 11:30am
  - 2:30pm
  - 2:45pm
  - 3:00pm
- Thursday, August 7th
  - 10:00am
  - 10:15am
  - 10:30am
  - 10:45am
  - 1:30pm
  - 1:45pm
  - 2:00pm
  - 2:15pm
  - 2:30pm
  - 3:00pm
  - 3:15pm
  - 3:30pm

Please let me know if you have any questions!
Thank you.

Best,

Malia Shirley
Office of the White House Liaison
Department of Health & Human Services
Office of the Secretary

c: [redacted] | e: [redacted]

Houry, Debra E. (CDC/IOD)

From: Monarez, Susan (CDC/IOD)
Sent: Tuesday, August 19, 2025 4:18 PM
To: Houry, Debra E. (CDC/IOD)
Subject: Fw: Policy Approval Process

From: Buckham, Matthew (HHS/IOS) <[redacted]>
Sent: Tuesday, August 19, 2025 3:57 PM
To: Monarez, Susan (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Callahan, Kenneth (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; McLean, Christopher L (CDC/IOD) <[redacted]>; Cuthbert, West (HHS/IOS) <[redacted]>; Boothby, William (OS/IOS) <[redacted]>; Spear, Stefanie (HHS/IOS) <[redacted]>; Faircloth, Jordan (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/OD/OCS) <[redacted]>
Subject: Policy Approval Process

Susan,

Let's get on a call this week to discuss in depth, but until we can connect directly, I wanted to elevate the absolute need for political review of major policy decisions at CDC. As you are aware, there are key priorities of the White House and the Secretary underway with your team at CDC and we want to ensure that IOS and CDC political leadership all have eyes on the decisions for approval/changes before they go into effect.

Please alert your staff that our IOS Counselor Dr. Reyn Archer and your Chief of Staff/Deputy Chief of Staff both need to review any major policy decision coming out of CDC before changes occur. I'll let Dr. Archer provide guidance on what constitutes "major", but until then please err on the side of caution. When it comes to the personnel changes of senior leadership or policy sensitive positions, the White House Liaison office should also be included.

Appreciate all you do to serve in your role and help facilitate this process. We will talk soon.

Make America Great!

Matt

Houry, Debra E. (CDC/IOD)

From: Maenner, Matthew J. (CDC/NCBDDD/DHDD)
Sent: Tuesday, August 26, 2025 12:17 PM
To: Burns, Stuart (CDC/OD/OCS); Weintraub, Eric (CDC/NCEZID/DHQP/ISO)
Cc: Braden, Chris (CDC/NCEZID/OD); Gilboa, Suzanne (CDC/NCBDDD/DBDID); Archer, William (HHS/IOS); Faircloth, Jordan (CDC/IOD); Houry, Debra E. (CDC/IOD)
Subject: RE: request from Stuart

Stuart,

We met with Sudevi Ghosh (OGC) and she is assisting with creating a straightforward DUA to share the restricted access dataset for the Age at First MMR Vaccination and Autism study. As soon as the DUA is ready, it should be able to go to Mr. O'Connor & team. We will share an estimated timeline as soon as we have it.

So far, we have identified the data and associated documentation and they appear to be compiled by the original research team in 2004. This is the data set referenced in your first request, but it is actually not a "public use" dataset. Although this dataset does not include identifiers like dates, names, or locations, it does include information on uncommon health conditions. Office of Science confirmed these data are protected by an Assurance of Confidentiality, so the DUA needs to comply with the parameters of the AOC. The historical DUA for these data (from 2004) involves submission of a research proposal for CDC review and included outdated language and terms that would seem onerous today. Sudevi suggested developing a basic updated DUA would be most practical and we agree.

Sincerely,
Matt

From: Burns, Stuart (CDC/OD/OCS) <[redacted]>
Sent: Monday, August 25, 2025 9:10 PM
To: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Weintraub, Eric (CDC/NCEZID/DHQP/ISO) <[redacted]>
Cc: Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Faircloth, Jordan (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: Re: request from Stuart

Matt and Eric, I'm circling back in this request from last week to see what the next steps might be on getting this data to this research team.

Stuart

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From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Tuesday, August 19, 2025 11:09 AM
To: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Weintraub, Eric (CDC/NCEZID/DHQP/ISO) <[redacted]>
Cc: Braden, Chris (CDC/NCEZID/OD) <[redacted]>; Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>; Archer, William (HHS/IOS) <[redacted]>; Burns, Stuart (CDC/OD/OCS)

[redacted]; Faircloth, Jordan (CDC/IOD) [redacted]
Subject: request from Stuart

Hi all- please see below for request from Stuart:

Matt and Eric,

There is a researcher that HHS (Dr. Reyn Archer) has asked us to assist in getting access to the data that was used for the DeStefano et al (2004) study related to MMR and Autism. The researcher is Daniel O'Connor ([redacted]

Would you please provide Daniel with the public use dataset? I understand that this can be provided relatively quickly and if so, would you be able to communicate directly with Daniel to share the process/data with him?

A second request is whether the original datasets that the study data originated from are available for access? If so, please share the process for accessing that data with me, Dr. Archer and Daniel.

Thank you for your help on this.

Stuart

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Burns, Stuart (CDC/IOD)
Sent: Wednesday, April 9, 2025 11:31 AM
To: Houry, Debra E. (CDC/IOD)
Cc: Mahmood, Aisha (CDC/NCIPC/OD); O'Connor, Melissa (CDC/OD/OCS)
Subject: Re: Authorization Letters for purchase of COVID-19 Vaccines Moderna, Pfizer and J&J

Not sure if one or the other, perhaps both?

Stuart

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From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, April 9, 2025 11:30:18 AM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; O'Connor, Melissa (CDC/OD/OCS) <[redacted]>
Subject: RE: Authorization Letters for purchase of COVID-19 Vaccines Moderna, Pfizer and J&J

Way before my time in IOD, but I can track this down! I'll reach out to NCIRD and see what they can find- do you know if this was for the Vaccines for Children, Operation Warp Speed, etc?

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
Office: [redacted] | Cell: [redacted]

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Wednesday, April 9, 2025 10:59 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; O'Connor, Melissa (CDC/OD/OCS) <[redacted]>
Subject: Authorization Letters for purchase of COVID-19 Vaccines Moderna, Pfizer and J&J

Deb,

Would you be able to provide me with (or direction on getting) the authorization letters that permitted purchase of Moderna, J&J and Pfizer vaccines. Not the EUAs, but the permanent authorization letters.

Thanks,

Stuart

Houry, Debra E. (CDC/IOD)

From: Anderson, Hannah (HHS/IOS) <[redacted]>
Sent: Monday, April 28, 2025 5:53 AM
To: Houry, Debra E. (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD); Witkofsky, Nina (CDC/IOD); Burns, Stuart (CDC/IOD)
Cc: Archer, William (HHS/IOS); Patterson, Sara S. (CDC/PHIC/OD)
Subject: Re: COOP - NIOSH

Thank you. Please let me know this morning what the COOP is here.

Hannah Anderson
Deputy Chief of Staff, Policy

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Saturday, April 26, 2025 3:50:50 PM
To: Anderson, Hannah (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: COOP - NIOSH

Currently due to all the staff members on this program being RIF'd and large #s across NIOSH impacted, the program is not enrolling any new firefighters into the cancer registry.
https://www.cdc.gov/niosh/firefighters/registry/index.html

I will reach out to NIOSH to see what options there may be.
Matt and I just connected now and we will think through best opportunities to handle balanced with other NIOSH and other CIO programs that we have been getting requests on.

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Anderson, Hannah (HHS/IOS) <[redacted]>
Sent: Saturday, April 26, 2025 3:45 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: Re: COOP - NIOSH

Thank you very much. Can you pull the plans specifically for the firefighter programs

Hannah Anderson
Deputy Chief of Staff, Policy

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Saturday, April 26, 2025 3:14:48 PM
To: Anderson, Hannah (HHS/IOS) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: COOP - NIOSH

Hi Hannah
Attached are two documents related to NIOSH COOP post reductions in force
I can reach out to our security/facilities and NIOSH leader to see if there is a specific NIOSH COOP too with names if that is helpful similar to what we have for the overall agency COOP
Deb

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
Office: [redacted] | Cell: [redacted]

From: Anderson, Hannah (HHS/IOS) <[redacted]>
Sent: Saturday, April 26, 2025 2:59 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Archer, William (HHS/IOS) <[redacted]>
Subject: COOP - NIOSH
Importance: High

Team- sent a couple of you separate notes but can you look into COOP plans for NIOSH, ASAP? Seems to be consistent across NIOSH ops and I'd like to ensure that they are taken care of.

Hannah

Hannah Anderson
Deputy Chief of Staff, Policy
U.S. Department of Health and Human Services (HHS)

Houry, Debra E. (CDC/IOD)

From: Patterson, Sara S. (CDC/PHIC/OD)
Sent: Monday, April 28, 2025 11:12 AM
To: Wells, Nathan (CDC/OCOO/OHR); Durst, Kelley (CDC/NIOSH/OD/ODDM); Blackshear, Louis (CDC/OCOO/OHR)
Cc: Holloway, Rachel (CDC/OD/OBPA); Houry, Debra E. (CDC/IOD)
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

Hi all,

We just talked with HHS about these issues. Here is what I know and what we are being asked to do.

- John Howard – HHS OGC is working through an options paper about what the options are for bringing him back. The ball is in HHS OGC's court about this.
- RIFs – We are being asked to bring all NIOSH staff in "critical functions" until their RIF end date (either June 2 or June 30, depending on what a RIF notice stated). Kelley, what is the best way to determine what are considered critical functions? We know the firefighters, mining, and lab folks are considered critical. What do we need to do to ask these folks to come back? From a business standpoint, I imagine OCIO and OSSAM will also need to be involved but I want to make sure I understand how it works from a programmatic and HR standpoint first. Kelley, HHS is also asking that all stop work on studies, projects, etc. be reversed. What needs to happen to make this possible? Hannah Anderson is asking for this to be done today (the directive given, the process started, etc.).

Longer term (not for today). Other questions that came up and actions we need to take are:

- Staff support – Reyn (our HHS counselor) wants a list of all divisions, staff, and functions within NIOSH to help determine what functions are critical and how to navigate them. I'm thinking we could use the Morgantown description along with a staffing list as a model, but let me know if you already have something you'd recommend using. I think the staffing list could be separate and we may want to think about the specific fields we'd want included. I'm thinking something that gets to expertise/function will be important for that staffing list.
- For all of the functions that have been eliminated through the RIFs, do we know of other parts of the agency or other parts of government that can do this work longer term? Could any of it be done through consultancy or contracts? This is a longer term question, not a today question.
- Does the firefighter investigation program include looking at cyanide exposures? Does that work sit in Cincinnati?
- For the laboratories, are our lab folks actually doing the lab work or do they reference/contract it out?
    - What can be joined up with other labs elsewhere in the longer term (like agriculture, etc)?
- Reyn also wants to get input from the firefighters, coal miners, and governors in various states that are most relevant to these activities about what they'd like to see done differently? He wants to be sure we are working holistically to solving actual problems, not assume we are doing what's needed without engagement.

Would it be helpful to talk as a group about how to navigate this?

Thanks,

Sara

From: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>
Sent: Monday, April 28, 2025 10:57 AM
To: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Cc: Holloway, Rachel (CDC/OD/OBPA) <[redacted]>; Blackshear, Louis (CDC/OCOO/OHR) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

Happy to discuss

+ Louis Blackshear

Nathan Wells
Director (Acting), Office of Human Resources (OHR)
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Sent: Monday, April 28, 2025 9:39 AM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Cc: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Holloway, Rachel (CDC/OD/OBPA) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

It might be good to chat if you have a few minutes.

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Monday, April 28, 2025 9:19 AM
To: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Cc: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Holloway, Rachel (CDC/OD/OBPA) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

Hi Kelley,

I just talked with Matt, and he said that we can't bring back all of the staff we're requesting but there is a strong desire to bring back the WV staff. Also, are all WV staff needed or would there be a way to consolidate? I think the next step is to look at 1) did the RIF get run in a way that would allow us to bring back Morgantown staff only (copying Nate to see what he thinks), 2) what would we lose in the other sites if we don't bring back all of the mining program, and 3) knowing that the RIF was run with full admin codes and this might not be allowed, is there any way to bring back a smaller group of folks in WV? Are there critical functions (not considering admin code) that could be brought back that would allow us to do the critical mining work in Morgantown without bringing back everyone?

Please let me know if you want to discuss.

Thanks so much,
Sara

From: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Sent: Sunday, April 27, 2025 3:38 PM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

Hi Sara. The attached spreadsheet has tabs at the bottom labeling the organizational components. This is quick and necessarily pretty. I hope it will serve the need at hand.
Thanks for all of your help today.
Kelley

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Sunday, April 27, 2025 1:46 PM
To: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

Thank you!!!

From: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Sent: Sunday, April 27, 2025 1:42 PM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

I'm done with the narrative.

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Sunday, April 27, 2025 1:38 PM
To: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

I'm not sure how "critical" respirator certification and research are to this audience. Maybe break them out and describe in case they want them included? I'm having trouble piecing together what's considered "essential" so let's just add more and let them decide. Sound okay?

From: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Sent: Sunday, April 27, 2025 1:35 PM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

The numbers in the document I provided to Rachel included respirator certification and research—it has a time to mining? You didn't ask for respirator related info—should I include or omit. If I omit, I need to adjust the numbers in the narrative you we worked on earlier.

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Sunday, April 27, 2025 1:01 PM

To: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Subject: Re: Firefighter Program Issues At NIOSH--Two Programs Affected

That would be perfect if you can.

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From: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Sent: Sunday, April 27, 2025 12:54:28 PM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

How do you want the staffing lists? This will be a lot of people.
EEOICPA
WTHCP
Spokane Mining
Pittsburgh Mining
Mining in Morgantown—do you want all of Morgantown—that is what was in write up I gave Rachel)?
Firefighters—that overlaps with some in Morgantown +staff in Cincinnati
NIOSH OD –should I provide all of it and highlight key staff?

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Sunday, April 27, 2025 12:29 PM
To: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>; Protzel Berman, Pamela (CDC/NCEH/OD) <[redacted]>; Holloway, Rachel (CDC/OD/OBPA) <[redacted]>; Wells, Nathan (CDC/OCOO/OHR) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

I just added a note in the doc. Great minds think alike! Please add!
Thanks!

From: Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Sent: Sunday, April 27, 2025 12:28 PM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Protzel Berman, Pamela (CDC/NCEH/OD) <[redacted]>; Holloway, Rachel (CDC/OD/OBPA) <[redacted]>; Wells, Nathan (CDC/OCOO/OHR) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

Sarah: I'm not seeing anything about the radiation compensation program (EEOICPA). It's a statutory program based out of Cincinnati and 18 people were Rifed including the Director of the program? Is that on the table. Also, it receives mandatory funding.

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Sunday, April 27, 2025 12:08 PM
To: Protzel Berman, Pamela (CDC/NCEH/OD) <[redacted]>; Holloway, Rachel (CDC/OD/OBPA) <[redacted]>; Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

Hi all,

Here is what I've pulled together using recent docs. Please see what might be missing and add/edit as you see fit. Also, let me know if you think I got any numbers wrong. See if you think what I'm proposing for

admin functions works and if you'd add anything else. Kelley, I'm thinking we could try to bring back any functions in the NIOSH OD that are critical for these programs and don't exist in NCEH. Pam, I'm hoping you can add some program and expertise info in alignment with what we have for NIOSH. Your edits and feedback are very much welcome and appreciated. I've turned on tracked changes just so we can all follow edits. Thank you!!!

Sara

NIOSH and NCEH Essential Functions Options.docx

From: Protzel Berman, Pamela (CDC/NCEH/OD) <[redacted]>
Sent: Sunday, April 27, 2025 11:21 AM
To: Holloway, Rachel (CDC/OD/OBPA) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Cc: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Subject: Re: Firefighter Program Issues At NIOSH--Two Programs Affected

Yes, will do.

Pamela Protzel Berman
Deputy Director, National Center for Environmental Health & ATSDR
Centers for Disease Control & Prevention
Department of Health and Human Services
[redacted]

From: Holloway, Rachel (CDC/OD/OBPA) <[redacted]>
Sent: Sunday, April 27, 2025 11:12 AM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Protzel Berman, Pamela (CDC/NCEH/OD) <[redacted]>
Cc: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

Pam - can you include both the childhood lead prevention group and the lead exposure registry?

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Sunday, April 27, 2025 11:11 AM
To: Protzel Berman, Pamela (CDC/NCEH/OD) <[redacted]>
Cc: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Durst, Kelley (CDC/NIOSH/OD/ODDM) <[redacted]>; Holloway, Rachel (CDC/OD/OBPA) <[redacted]>
Subject: Fw: Firefighter Program Issues At NIOSH--Two Programs Affected

Hi Pam! Looping you in on this to see if you can help with lead. Thanks!

Sara

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From: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Sent: Sunday, April 27, 2025 10:54 AM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]; Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Holloway, Rachel (CDC/OD/OBPA) <[redacted]>
Subject: Re: Firefighter Program Issues At NIOSH--Two Programs Affected

Sara and Rachel, I need a list of our programs (like the one above) that covers all firefighter programs, all miner programs (black lung) and whatever program we administer that involves Lead. I need to know how many FTE's and whether they were RIF'd, including the WTC program. The goal is to consolidate the programs administratively (if possible). We need to identify the key employees to operate these functions. Can they be consolidated? Is the above list exhaustive of our programs that involve Firefighters and Miners? Stefanie will be calling me this afternoon to discuss. Sorry to bother you on a Sunday.

Matt

Matt Buzzelli
Chief of Staff
Centers for Disease Control and Prevention
U.S. Department of Health and Human Services
C:[redacted]

U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Saturday, April 26, 2025 5:13:56 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Holloway, Rachel (CDC/OD/OBPA) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

Here is what was sent to the Hill on mining and firefighters. The mining program is eliminated in Passback. The firefighter cancer registry is still funded in the passback, but the staff were all riffed. I'm copying Rachel to see if she knows how the firefighter fatality investigation program is funded. I can't figure that out from the Passback info I have and I'm not sure what line it's supported out of. Rachel, do you know?

Mining Program -

- 141 FTEs
- 30 FTE's RIF'd

- 108 FTE's received RIF intent notice - Effective Riff date provided in the notice is June 30th. They would receive Riff notice on May 1st. Unless there is action to reverse this notice, these people will be RIF'd.

This work will not continue unless these individuals are reinstated. The Mining Program aims to eliminate mining fatalities, injuries, and illnesses through research and impactful solutions. Personnel located in Spokane, WA and Pittsburgh, PA have extensive knowledge and experience with above ground and underground mines, including coal, metal and critical mineral mines. Personnel possess training and advanced degrees in mining engineering, material engineering, civil engineering, and geophysics and have expertise in ventilation, roof stability, and explosive environments.

Firefighter Fatality Investigation and Prevention Program and the National Firefighter Registry (NFR) for Cancer (Cincinnati and Morgantown).

- For Firefighter Fatality Investigation Program- 22 FTE's, with 7 FTEs Rif'd and 7 receiving Rif intent notice
- For NFR for Cancer-33 FTE's, with 10 FTE's Rif'd and 19 receiving Rif intent notice

NIOSH conducts investigations of firefighter line-of-duty deaths to formulate recommendations for preven ting future deaths and injuries. Established by Congress, the NFR for Cancer administers and manages the NFR for Cancer with over 20,000 firefighters voluntarily enrolled. The program employs staff with expertise in occupational medicine, industrial hygiene, epidemiology, exposure assessment, and respiratory health. Both programs employ former firefighters who have unique and extensive knowledge of fire service rules and procedures for fighting fires and understand medical standards for firefighter fitness for duty.

From: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Sent: Saturday, April 26, 2025 4:06 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: Re: Firefighter Program Issues At NIOSH--Two Programs Affected

Ok, thanks.

Matt Buzzelli
Chief of Staff
CDC
U.S. Department of Health and Human Services
[redacted]

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Saturday, April 26, 2025 4:01:47 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>
Cc: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: FW: Firefighter Program Issues At NIOSH--Two Programs Affected

Found this note- not sure what the overall FTE is for the firefighter programs but they were impacted significantly by the initial layoffs as well as DRP and retirements plus the hiring freeze

Debra Houry

Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD)
Sent: Thursday, February 27, 2025 10:25 AM
To: Howard, John (CDC/NIOSH/OD) <[redacted]>
Cc: Lubar, Debra (CDC/OD/OPPE) <[redacted]>
Subject: RE: Firefighter Program Issues At NIOSH--Two Programs Affected

+ Deb L

Deb Houry, MD, MPH
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention
[redacted]
Executive Assistant: Latrisha Smith [redacted]
Special Assistant: Melissa O'Connor [redacted]

From: Howard, John (CDC/NIOSH/OD) <[redacted]>
Sent: Wednesday, February 26, 2025 11:19 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: Firefighter Program Issues At NIOSH--Two Programs Affected

Firefighter Fatality Investigation and Prevention Program (Division of Safety Research in Morgantown)

- Anticipating the loss of 7 out of 8 budgeted firefighter investigators
  - 3 Anticipated lost during probationary period
  - 2 Employment final offers rescinded
  - 1 Final offer not extended due to freeze
  - 1 Anticipated retirement in 2025 (this person is not available for new investigations because he has a backlog of cases)

Effects: Major slowdown in conducting fatality investigations given only one investigator.

National Firefighter Registry for Cancer (Division of Field Studies and Engineering in Cincinnati)

- Anticipating the loss of 5 out of 5 firefighters doing targeted Registry enrollment
  - 1 Firefighter terminated in probationary period
  - 4 Firefighters tentatively participating DRP (1 is "on the fence")

Effects: Slowdown in enrolling new firefighter registrants.

Let me know if you need more details.

Houry, Debra E. (CDC/IOD)

From: RFK [redacted]
Sent: Thursday, July 10, 2025 9:42 AM
To: Thompson, William (Bill) (CDC/NCHHSTP/DVH); Gilboa, Suzanne (CDC/NCBDDD/DBDID)
Cc: Maenner, Matthew J. (CDC/NCBDDD/DHDD); Rattay, Karyl (CDC/NCBDDD/DHDD); Griswold, Stephanie (CDC/NCBDDD/DBDID); Tinker, Sarah (CDC/NCBDDD/DHDD); Burns, Stuart (CDC/IOD); Foster, Robert (HHS/IOS); Houry, Debra E. (CDC/IOD); Mahmood, Aisha (CDC/NCIPC/OD); Patterson, Sara S. (CDC/PHIC/OD); Weintraub, Eric (CDC/NCEZID/DHQP/ISO); Burton, Deron (CDC/NCHHSTP/DTE)
Subject: Re: CDC Data Sources for Examining Trends in Profound Autism

Bill. I'm assuming this is the verstratten original data

Get Outlook for iOS

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Wednesday, June 18, 2025 7:06:46 PM
To: Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>
Cc: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Rattay, Karyl (CDC/NCBDDD/DHDD) <[redacted]>; Griswold, Stephanie (CDC/NCBDDD/DBDID) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>; Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Weintraub, Eric (CDC/NCEZID/DHQP/ISO) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Suzanne – That is very helpful information to know. I will follow-up with you and Matt Maenner in the near future. Thanks, Bill

William W. Thompson
Senior Scientist
Division of Viral Hepatitis, NCHHSTP, CDC
[redacted]

From: Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>
Sent: Wednesday, June 18, 2025 11:56 AM
To: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Cc: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Rattay, Karyl (CDC/NCBDDD/DHDD) <[redacted]>; Griswold, Stephanie (CDC/NCBDDD/DBDID) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>; Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Weintraub, Eric (CDC/NCEZID/DHQP/ISO) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Hi Bill,

Thank you for that additional clarification, which allows us to provide more specific details. The bottom line is that we have some intermediary files that precede the analytic dataset, but we do not have copies of original source data.

To the best of our understanding:

- The original source data for vaccination information was located at schools and those records never left the schools. For this study, MADDSP staff abstracted information from those records on site using Epi Info and the data were then transferred to the CDC mainframe. As you probably know, the CDC mainframe was retired over 10 years ago. We have not found any of the original Epi Info files in our searches.
- At some point before the mainframe was retired, these data were moved from the mainframe to the consolidated statistical platform (CSP) and converted into SAS files. There are some SAS files that still exist on the CSP that are related to this project, but we do not know their completeness or relation to the original or analytic datasets.
- There are no electronic project manuals or data dictionaries accompanying the files on the CSP; it is our understanding that these materials were only available as hard copies. Some of this documentation may still exist in hard copy files here, but records retention policy for research such as this would have been 11-20 years, so it is possible that this is no longer available.

We hope this information is helpful. Please let us know next steps and how we can be supportive as you take on this task.

Thanks,

Suzanne

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Tuesday, June 17, 2025 9:49 AM
To: Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>
Cc: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Rattay, Karyl (CDC/NCBDDD/DHDD) <[redacted]>; Griswold, Stephanie (CDC/NCBDDD/DBDID) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>; Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Weintraub, Eric (CDC/NCEZID/DHQP/ISO) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Suzanne,

This is also relevant and important because Diana Schendel used the same data source to publish a 2007 study that examined a subgroup of autism cases referred to as "isolated autism". (See Table 3.)

Secretary Kennedy is particularly interested in having us examine isolated autism cases more closely using the DeStefano study data.

Thanks,

Bill

William W. Thompson
Senior Scientist
Division of Viral Hepatitis, NCHHSTP, CDC
[redacted]

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Tuesday, June 17, 2025 9:38 AM
To: Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>
Cc: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Rattay, Karyl (CDC/NCBDDD/DHDD) <[redacted]>; Griswold, Stephanie (CDC/NCBDDD/DBDID) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>; Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Weintraub, Eric (CDC/NCEZID/DHQP/ISO) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Suzanne,

Thank you for for the additional information.

We already know that the public use dataset for the DeStefano et al (2004) exists. Eric Weintraub from ISO has already made that that dataset available to HHS.

We are more interested in whether the original data sources exist. The vaccine records for the cases and control subjects were obtained from school vaccine records. The data from GA birth certificates were also merged into that dataset prior to proving me the cleaned dataset.

From the published manuscript:
***"Methods.* A case-control study was conducted in metropolitan Atlanta. Case children (*N* _ 624) were identified from multiple sources and matched to control children (*N* _ 1824) on age, gender, and school. Vaccination data were abstracted from immunization forms required for school entry. Records of children who were born in Georgia were linked to Georgia birth certificates for information on maternal and birth factors."**

FYI - I did all the analyses for the study and was provided a cleaned dataset with cases and controls already matched and the birth certificate data already merged. HHS would like access to the original data sources and would like to merge the data using those datasets to test additional hypotheses. If those datasets do not exist then we might need to create new datasets. As you know, the time and effort to create new datasets would be very time consuming and we would prefer not to have to start from scratch.

Thanks,

Bill

William W. Thompson
Senior Scientist
Division of Viral Hepatitis, NCHHSTP, CDC
[redacted]

From: Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>
Sent: Monday, June 16, 2025 5:13 PM

To: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Cc: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Rattay, Karyl (CDC/NCBDDD/DHDD) <[redacted]>; Griswold, Stephanie (CDC/NCBDDD/DBDID) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>; Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Hi Bill,

Thank you for that clarification. It is helpful for us to have a better understanding of the request so that we can be maximally responsive. The data for the 2004 DeStefano paper were pulled together in 2014 in response to a previous request and have been saved as a package by our colleagues in NCEZID/DHQP/ISO. These data were recently shared with HHS/NIH as part of a larger data transmission including VSD data, to respond to a request from HHS leadership.

As you are likely aware as a co-author, the 1996 MADDSP data were linked to vaccine records for this special study. The MADDSP data files themselves do not contain information on vaccination. For this reason, we think this existing data package is the fastest way to meet your needs. An additional advantage is that it was compiled by people who had greater familiarity with this special study at a more proximal time to the original analysis.

Please let us know if we can be of additional assistance or support.

Many thanks,

Suzanne

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Friday, June 13, 2025 1:21 PM
To: Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>
Cc: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Rattay, Karyl (CDC/NCBDDD/DHDD) <[redacted]>; Griswold, Stephanie (CDC/NCBDDD/DBDID) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>; Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Suzanne,

Yes we are trying to find out if the source data for both the cases and control data are still available. It's a starting point for beginning to design new studies and test alternative hypotheses from the original DeStefano et al (2004) study.

At this point, I don't think a conference call will help us locate data sources. We just want to know whether the data sources are still accessible. So at this point you still have access to the MADDSP 1996 autism case data but you are uncertain if the source data for control subjects still exists. If you still have access to that data we would like to know it still exists. If you don't have access to that data, then we will need consider finding alternative data sources for the control subjects.

Again, this is a high priority for Secretary Kennedy, so if you could dedicate the time and staff necessary to find this data ASAP, we would greatly appreciate it.

Thanks,

Bill

William W. Thompson
Senior Scientist
Division of Viral Hepatitis, NCHHSTP, CDC
[redacted]

From: Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>
Sent: Friday, June 13, 2025 9:51 AM
To: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Cc: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Rattay, Karyl (CDC/NCBDDD/DHDD) <[redacted]>; Griswold, Stephanie (CDC/NCBDDD/DBDID) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>; Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; REK [redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Dear Bill,

Deron has accepted a new position as Division Director in DTBE and I am stepping into the role of Acting Center Director so would like to be part of the conversation.

The DeStefano paper states that the autism case data were derived from 1996 MADDSP data, but the controls were identified separately. We can work with you on the process for sharing the 1996 MADDSP data, however it may be helpful to discuss with you what specific data you need. Are you available for a call on Monday 6/16 at 9:30? If not, we can find another time that works.

Thanks,

Suzanne

Suzanne M. Gilboa
Director
Division of Birth Defects and Infant Disorders
Centers for Disease Control and Prevention
Department of Health and Human Services
[redacted]

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Monday, June 9, 2025 3:08 PM
To: Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; REK [redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>;

Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Deron,

Could you or Matt please confirm whether the attached study used the 1996 MADDSP data? And whether the original source data still exists.

Thanks,

Bill

William W. Thompson
Senior Scientist
Division of Viral Hepatitis, NCHHSTP, CDC
[redacted]

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Monday, June 9, 2025 2:28 PM
To: Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted] <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Deron,

Thanks for the follow-up.

Yes we are interested in those data as well as any other MADDSP datasets or studies that have used MAADSP data previously.

Thanks,

Bill

William W. Thompson
Senior Scientist
Division of Viral Hepatitis, NCHHSTP, CDC
[redacted]

From: Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>
Sent: Monday, June 2, 2025 4:57 PM
To: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>; Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>
Cc: Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted] <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Hi Bill,

The team has looked into your second question. Prior to 2000, the only other MADDSP surveillance data that included autism of which we are aware is the 1996 MADDSP Surveillance Dataset; we have access to those data.

In case it is of interest, data from 1996 MADDSP were published in the following article:
https://jamanetwork.com/journals/jama/fullarticle/195703

Best regards,

Deron

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Monday, June 2, 2025 4:13 PM
To: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>; Tinker, Sarah (CDC/NCBDDD/DHDD) <[redacted]>
Cc: Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

+ Sarah Tinker given Matt has taken leave this week.

Thanks,

Bill

William W. Thompson
Senior Scientist
Division of Viral Hepatitis, NCHHSTP, CDC
[redacted]

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH)
Sent: Monday, June 2, 2025 3:59 PM
To: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>
Cc: Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Matt,

Thanks for your initial feedback.

Secretary Kennedy is asking us to prioritize determining what years you have available for the MADDSP data. So anything you can provide us ASAP would be greatly appreciated.

Thanks,

Bill

William W. Thompson

Senior Scientist
Division of Viral Hepatitis, NCHHSTP, CDC
[redacted]

From: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>
Sent: Thursday, May 29, 2025 4:08 PM
To: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Cc: Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Mahmood, Aisha (CDC/NCIPC/OD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: RE: CDC Data Sources for Examining Trends in Profound Autism

Bill,

Appreciate the interest in profound autism. To respond to your questions:

1. The profound ASD paper made use of the ADDM Network pooled dataset for surveillance year 2000 (the first year of the ADDM Network), which includes year 2000 data from MADDSP.

2. As mentioned above, we have the 2000 MADDSP data included in the ADDM pooled data for surveillance year 2000. Given the age of the data and staff changes in the years since these data were used, I cannot give you an immediate answer about 1996-1999 MADDSP data within the branch or center. It will take us time to look into this; we will let you know what we find. As a reminder, this work is proposed to move to AHA.

Sincerely,
Matt

Matthew J Maenner, PhD
Chief, Child Development and Disability Branch
Centers for Disease Control and Prevention
Department of Health and Human Services
[redacted]

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Thursday, May 29, 2025 6:55 AM
To: Maenner, Matthew J. (CDC/NCBDDD/DHDD) <[redacted]>
Cc: Burton, Deron (CDC/NCBDDD/DBDPHG) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; RFK [redacted]>
Subject: CDC Data Sources for Examining Trends in Profound Autism

Matt,

We are trying to compile a list of data sources for doing future autism studies as well as see if we can replicate previous CDC autism study results. And as you know Secretary Kennedy is also extremely interested in profound autism which you examined in the attached study.

In your study, you present trends in profound autism all the way back to the year 2000.

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Thursday, June 26, 2025 3:55 PM
To: Burns, Stuart (CDC/IOD)
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD)
Subject: follow up re Bill's email re detail

Importance: High

Stuart
As I mentioned to you in the hallway this afternoon, I'm disappointed in the unprofessional and uncalled for behavior of Bill Thompson related to his 50% detail. You asked me to help move a detail for Bill along and I have been working with OCOO and 2 Centers to make it happen as quickly as possible. I have not been part of the discussions with HHS/S1 about the scope of the detail, which is why I asked the Center to propose language for a scope of the detail that was explicitly very open to feedback.

My reputation is that of a collaborative leader who implements and gets things done. I do not appreciate Bill including the Secretary, HHS OGC, and HHS Chief of Staff on his response about the scope of the detail. This felt like a direct attack on me without first providing any input about the draft scope. I would have appreciated you or Bill revising the scope so we could easily move forward with the detail rather than bringing such high levels of HHS leadership into the discussion.

I will look to you for next steps on how you would like to handle providing this feedback to Bill and assuring HHS that we were working closely to ensure this detail was appropriately navigated. CC'ing Matt as well as I shared Bill's email with him and my concerns re professionalism.
Deb

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Ellington, Renata (CDC/NCHHSTP/OD) <[redacted]>
Sent: Thursday, June 26, 2025 1:15 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: FW: Stuart- please review scope of work for detail --- HR related tasks and my detail to NCBDDD

FYI...

Renáta

From: Wester, Carolyn (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Thursday, June 26, 2025 1:11 PM
To: Ellington, Renata (CDC/NCHHSTP/OD) <[redacted]>
Subject: FW: Stuart- please review scope of work for detail --- HR related tasks and my detail to NCBDDD

FYI

Director, Division of Viral Hepatitis
National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Thursday, June 26, 2025 12:45 PM
To: Melanson, Heather F.(HHS/IOS) <[redacted]>; Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>; Hoots, Brooke (CDC/NCHHSTP/DVH) <[redacted]>
Cc: Wester, Carolyn (CDC/NCHHSTP/DVH) <[redacted]>; RFK[redacted]; Foster, Robert (HHS/IOS) <[redacted]>; Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>; Rowe, Jarrett (OS/IEA) <[redacted]>
Subject: Re: Stuart- please review scope of work for detail --- HR related tasks and my detail to NCBDDD

I will attend to this and have reached out to Dr Thompson on this

Stuart

Get Outlook for iOS

From: Melanson, Heather F.(HHS/IOS) <[redacted]>
Sent: Thursday, June 26, 2025 12:32:41 PM
To: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>; Hoots, Brooke (CDC/NCHHSTP/DVH) <[redacted]>
Cc: Wester, Carolyn (CDC/NCHHSTP/DVH) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; RFK[redacted] <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>; Rowe, Jarrett (OS/IEA) <[redacted]>
Subject: RE: Stuart- please review scope of work for detail --- HR related tasks and my detail to NCBDDD

Hi All,

To confirm; per Bill Thompson's request, we are going to delay his detail – BUT, please note, Bill should continue to perform work for the IOS (Sec Kennedy, COS, DCOS Policy, CDC Counselor Burns) as requested. We appreciate all he does to help with important, timely projects. He's been great.

Please contact me with any questions. Thank you for your attention.

Heather

Heather Flick Melanson
Chief of Staff, HHS

From: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Sent: Thursday, June 26, 2025 7:03 AM
To: Hoots, Brooke (CDC/NCHHSTP/DVH) <[redacted]>

Cc: Wester, Carolyn (CDC/NCHHSTP/DVH) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; RFK [redacted] <[redacted]>; Melanson, Heather F.(HHS/IOS) <[redacted]>; Foster, Robert (HHS/IOS) <[redacted]>; Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Subject: FW: Stuart- please review scope of work for detail --- HR related tasks and my detail to NCBDDD

Brooke,

NCBDDD put together this statement of work without input from me, Stuart Burns (CDC OD) or Secretary Kennedy. This SOW has nothing to do with the tasks that Secretary Kennedy has assigned me to carry out. It is actually one of the most absurd SOWs I have ever seen.

So, I am going to request that my detail be delayed until we have a new CDC Director and I will continue to carry out tasks as assigned to me by Stewart Burns and Secretary Kennedy. I will also continue to keep Division of Viral Hepatitis scientific work moving forward as part of my current DVH position.

Thanks,

Bill

William W. Thompson
Senior Scientist
Division of Viral Hepatitis, NCHHSTP, CDC
[redacted]

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Wednesday, June 25, 2025 9:35 PM
To: Thompson, William (Bill) (CDC/NCHHSTP/DVH) <[redacted]>
Subject: Fw: Stuart- please review scope of work for detail

Bill, please review. I have not read it yet.....I will after ACIP ends.

Get Outlook for iOS

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, June 25, 2025 5:43 PM
To: Burns, Stuart (CDC/IOD) <[redacted]>
Cc: Gilboa, Suzanne (CDC/NCBDDD/DBDID) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: Stuart- please review scope of work for detail

Hi Stuart
Please review the scope of work for the detail Suzanne has pulled together- I have not been in your conversations with Bill or HHS so we want to make sure this is accurate/ meets your expectations.

Is there any additional senior leader engagement in oversight and if so, what that will look like? Also, given RIFs to NCBDDD we wanted to confirm if any staff resources or needed- we assume he will be working alone and will not require support from current staff as he has been an expert in this area.

Please review and make any edits- once you are done, this should be able to be processed

Thx
Deb

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Wednesday, May 21, 2025 5:22 PM
To: Burns, Stuart (CDC/IOD); Faircloth, Jordan (CDC/OD/OCS)
Cc: Patterson, Sara S. (CDC/PHIC/OD); Buzzelli, Matthew J (Matt) (CDC/IOD); Witkofsky, Nina (CDC/IOD)
Subject: FW: Starting steps for hiring process: Mark Blaxill Consultant/Expert SGE for the CDC Office of the Director
Attachments: CDC 209 (F) Distinguished Consultant Policy eff July 2020.pdf

Hi Stuart
Attached is the Title 42 requirements. A Center director over a scientific Center needs to be a T42 in order to supervise the division directors who are also T42. If it's a practice based center like PHIC, then a waiver for SES could be requested. The attached PDF mentions PhD or MD, publications, technical expertise, and other requirements. HRO has said Mark doesn't meet these requirements.

Given that NCBDDD is proposed for moving to AHA and would not be a Center in as soon as 2 weeks, I would suggest talking with Tom Engels and Dorothy Fink re a role in the maternal/child health section in AHA that could work on these issues. Happy to make the e-intro if helpful.

And, will send you the other email that has ?s re position description

From: Patrick, Clarissa (CDC/OD/OCS) <[redacted]>
Sent: Wednesday, May 21, 2025 11:18 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Cater, Evelyn V. (CDC/OD/OCS) <[redacted]>
Subject: Starting steps for hiring process: Mark Blaxill Consultant/Expert SGE for the CDC Office of the Director

Hi Deb,

Sharing the below reply from HRO. Unfortunately, the Title 42 hiring mechanism is not an option. Let me know if you'd like us to walk over to discuss further.

W/R
Clarissa

From: Conley, Tanesia (CDC/OCOO/OHR) <[redacted]>
Sent: Wednesday, May 21, 2025 11:08 AM
To: Patrick, Clarissa (CDC/OD/OCS) <[redacted]>
Cc: Anderson, Isaac (CDC/OCOO/OHR) <[redacted]>; Moore, Felicia (CDC/OCOO/OHR) <[redacted]>
Subject: RE: Starting steps for hiring process: Mark Blaxill Consultant/Expert SGE for the CDC Office of the Director

Good morning, Clarissa.

Mr. Blaxill is not qualified to be a Distinguished Consultant, so that appointment type is not an option, see the screen shot above showing what types of education are required for a Distinguished Consultant. Mr. Blaxill has a MBA.

Here is the definition/purpose of a distinguished consultant under title 42:

---

3. POLICY

A. Coverage

Appointments under 42 U.S.C. § 209(f) may only be used to fill scientific positions, and selections must be made by an official who has been delegated the appropriate authority (See Section 3.F.), of this policy for more information on the authorized recruitment activities under 42 U.S.C. § 209(f).

Here are the qualfications required for distinguished consultants:

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Thursday, May 22, 2025 1:06 PM
To: Pelfrey, Heather (CDC/OCOO/OHR); Patterson, Sara S. (CDC/PHIC/OD); Wells, Nathan (CDC/OCOO/OHR)
Cc: Arnold, Aaron (CDC/OCOO/OHR); Blackshear, Louis (CDC/OCOO/OHR)
Subject: RE: immunization safety office director lead

Thank you- I will share with Stuart Burns

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Pelfrey, Heather (CDC/OCOO/OHR) <[redacted]>
Sent: Thursday, May 22, 2025 11:30 AM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Arnold, Aaron (CDC/OCOO/OHR) <[redacted]>; Blackshear, Louis (CDC/OCOO/OHR) <[redacted]>
Subject: RE: immunization safety office director lead

GM All,

Please see the civilian PD associated with Sarah Meyer's position. If for any reason this isn't the PD you're looking for, please let me know and will re-attack.

Thanks!

Heather

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Thursday, May 22, 2025 9:26 AM
To: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Pelfrey, Heather (CDC/OCOO/OHR) <[redacted]>; Arnold, Aaron (CDC/OCOO/OHR) <[redacted]>; Blackshear, Louis (CDC/OCOO/OHR) <[redacted]>
Subject: RE: immunization safety office director lead

I will ask NCEZID.

From: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>
Sent: Thursday, May 22, 2025 10:20 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Cc: Pelfrey, Heather (CDC/OCOO/OHR) <[redacted]>; Arnold, Aaron (CDC/OCOO/OHR) <[redacted]>; Blackshear, Louis (CDC/OCOO/OHR) <[redacted]>
Subject: RE: immunization safety office director lead

Hi Debra, sure can.

Would you happen to have the PD number by any chance?

Nathan Wells
Director (Acting), Office of Human Resources (OHR)
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Thursday, May 22, 2025 10:14 AM
To: Wells, Nathan (CDC/OCOO/OHR) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: immunization safety office director lead

Can you send the PD to me?

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Patterson, Sara S. (CDC/PHIC/OD)
Sent: Tuesday, February 11, 2025 9:23 PM
To: Monarez, Susan (CDC/IOD)
Cc: Houry, Debra E. (CDC/IOD); Burns, William S. (Stuart) (CDC/IOD)
Subject: flu vaccines and pregnancy
Attachments: Safety of Thimerosal-containing influenza vaccines in pregnancy.docx

Hi Susan,

Attached is the document Deb and I worked with NCIRD and NCEZID on re: the issue of thimerosal in the flu vaccine and its relationship with pregnant women. Please let us know if you have any questions prior to sharing with HHS and if this format looks OK to you.

Thanks,
Sara

1) Which flu vaccines include thimerosal?

Multi-dose vials of flu vaccine contain thimerosal. This season, Sanofi and GSK have multidose vials that include thimerosal. The vaccines are:

- Sanofi: Fluzone® TIV (NDC 49281-0641-15)
- Seqirus: Afluria® TIV (NDC 33332-0124-10)
- Seqirus: Flucelvax® TIV (NDC 70461-0554-10)

These vaccines are licensed for ages 6+ months. More can be found at FDA's website, which includes specifics on concentrations Thimerosal and Vaccines | FDA.

2) What percentage of the flu vaccine administered or on the market has thimerosal?

CDC doesn't have doses administered information about flu vaccines, but we do query manufacturers to provide projections about how many doses they anticipate manufacturing each season. For the current, 2024-2025 season, U.S.-licensed manufacturers projected manufacturing approximately 148 million doses of flu vaccine. They estimated that approximately 6% of the doses manufactured would be the above listed thimerosal-containing vaccines.

3) Where are flu vaccines with thimerosal going nationwide?

Thimerosal is only in some multi-dose vials so it will be places that purchase multidose vials for administration of groups (such as mass clinics). CDC is checking in IQVIA data to see if we can pull any more information. CDC does not collect this information directly.

4) What is the history of the research on the safety of thimerosal?

Thimerosal-reduced and thimerosal-free flu vaccines became available in 2002 and 2003. At the time, the ACIP did not support for a preferential recommendation for use of this product in any population, including pregnant women. The committee felt that risks of thimerosal-containing influenza vaccine in pregnancy were unproven and the benefits of influenza vaccine exceeded that risk, if present. In 2004, the recommendation was revisited and remained unchanged.

Safety of Thimerosal-containing Influenza Vaccines During Pregnancy

- No safety concerns related to thimerosal-containing vaccines have been identified, other than rare hypersensitivity reactions.
    - Prevention and Control of Seasonal Influenza with Vaccines
- Available evidence suggests that prenatal exposure to thimerosal-containing vaccines is not associated with neurodevelopmental disorders, including autism spectrum disorder:
    - Prenatal and Infant Exposure to Thimerosal From Vaccines and Immunoglobulins and Risk of Autism | Pediatrics | American Academy of Pediatrics (2010): Case-control study from the VSD network of 256 children with autism spectrum

disorder (ASD) and 752 matched controls. Concluded that prenatal and early-life exposure to ethylmercury from thimerosal-containing vaccines and immunoglobulins was not related to increased risk of ASD.

- Early Thimerosal Exposure and Neuropsychological Outcomes at 7 to 10 Years | New England Journal of Medicine (2007): Cohort study from VSD network of 1,047 children aged 7-10 years that assessed the association between neuropsychological performance and exposure to mercury during the prenatal and neonatal periods and the first 7 months of life. Results did not support a causal association between early exposure to mercury from thimerosal-containing vaccines and immune globulins and deficits in neuropsychological functioning at age 7 to 10 years.

- Specifically for thimerosal-containing influenza vaccines, data from the Netherlands suggest that vaccination during pregnancy with a thimerosal-containing H1N1 vaccine was not associated with adverse pregnancy or infant outcomes.
  - Safety of vaccination against influenza A (H1N1) during pregnancy in the Netherlands: results on pregnancy outcomes and infant's health: cross-sectional linkage study - Maas - 2016 - BJOG: An International Journal of Obstetrics & Gynaecology - Wiley Online Library (2015): Among 1,920 pregnant women who completed questionnaires linked with the Netherlands Perinatal Registry, growth, developmental scores, and infection-related healthcare visits did not differ between pregnant women vaccinated in the 2nd or 3rd trimester with thimerosal-containing H1N1 vaccines and unvaccinated women.
- A recent systematic review did not identify an association between influenza vaccination during pregnancy and adverse childhood health outcomes, including neurological, behavioral, or developmental outcomes, among children aged <5 years.
  - Early Childhood Health Outcomes Following In Utero Exposure to Influenza Vaccines: A Systematic Review | Pediatrics | American Academy of Pediatrics
- Furthermore, the Institute of Medicine reviewed over 200 scientific studies that examined thimerosal-containing vaccines and autism, concluding that studies "consistently provided evidence of no association between thimerosal-containing vaccines and autism."
  - Immunization Safety Review: Vaccines and Autism | The National Academies Press
- Many other studies have assessed maternal influenza vaccination and demonstrate overall safety, including several CDC studies:
  - Trivalent inactivated influenza vaccine and spontaneous abortion - PubMed
  - Association of spontaneous abortion with receipt of inactivated influenza vaccine containing H1N1pdm09 in 2010–11 and 2011–12 - ScienceDirect
  - Inactivated influenza vaccine and spontaneous abortion in the Vaccine Safety Datalink in 2012–13, 2013–14, and 2014–15 - ScienceDirect
  - Inactivated Influenza Vaccine During Pregnancy and Risks for Adverse Obstetric Events
  - Monovalent H1N1 influenza vaccine safety in pregnant women, risks for acute adverse events - ScienceDirect

- Adverse events in pregnant women following administration of trivalent inactivated influenza vaccine and live attenuated influenza vaccine in the Vaccine Adverse Event Reporting System, 1990-2009 - ScienceDirect
- Reports of cell-based influenza vaccine administered during pregnancy in the Vaccine Adverse Event Reporting System (VAERS), 2013–2020 - ScienceDirect; Surveillance of adverse events after seasonal influenza vaccination in pregnant women and their infants in the Vaccine Adverse Event Reporting System, July, 2010 – May, 2016 - PMC

Opportunities for Further Exploration

- While a small percentage of flu vaccines contain thimerosal, the ACIP or CDC could consider explicitly noting that pregnant women can opt to get non-thimerosal containing vaccine during seasonal flu vaccination as part of shared decision making with their provider.
- Further study on this issue would be difficult because of the low percent of vaccines that contain thimerosal.

Houry, Debra E. (CDC/IOD)

From: Ford, Kenya S. (CDC/OGC)
Sent: Saturday, March 22, 2025 1:56 PM
To: Patterson, Sara S. (CDC/PHIC/OD); Houry, Debra E. (CDC/IOD)
Cc: Tress, Deborah W. (CDC/OGC); Malone, Kevin M. (CDC/OGC); Ghosh, Sudevi (CDC/OGC); McDonald, Jason (CDC/OD/OC)
Subject: Re: advice needed

Thanks!

Kenya
Kenya Ford
Deputy CDC/ATSDR Legal Advisor
DHHS Office of the General Counsel
Public Health Division
CDC/ATSDR Branch
Telephone: [redacted]
Cell phone: [redacted]
Email: [redacted]
Fax: [redacted]

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Saturday, March 22, 2025 1:51:06 PM
To: Ford, Kenya S. (CDC/OGC) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Tress, Deborah W. (CDC/OGC) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>; Ghosh, Sudevi (CDC/OGC) <[redacted]>; McDonald, Jason (CDC/OD/OC) <[redacted]>
Subject: RE: advice needed

Just sent a cc'd you.

From: Ford, Kenya S. (CDC/OGC) <[redacted]>
Sent: Saturday, March 22, 2025 12:20 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Cc: Tress, Deborah W. (CDC/OGC) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>; Ghosh, Sudevi (CDC/OGC) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; McDonald, Jason (CDC/OD/OC) <[redacted]>
Subject: FW: advice needed

Please let's try and obtain more information on this so we know exactly where it came from before we get to options for addressing. But I do think we should flag for IOS (Diane, Andrew N, Stephanie, and Hannah) given the purported source of the site.

Adding Jason because he raised to me separately and so we're all on the same page. I have also raised to the attention of the Acting General Counsel and the Chief Counsel for Food, Drugs, and Research within OGC.

Kenya
Kenya Ford
Acting Deputy General Counsel, Public Health Division
Deputy CDC/ATSDR Legal Advisor
Health and Human Services
Office of the General Counsel
[redacted]

From: Ghosh, Sudevi (CDC/OGC) <[redacted]>
Sent: Saturday, March 22, 2025 9:01:01 AM
To: Ford, Kenya S. (CDC/OGC) <[redacted]>; Tress, Deborah W. (CDC/OGC) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>
Subject: Fw: advice needed

Get Outlook for iOS

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Saturday, March 22, 2025 8:40 AM
To: Tress, Deborah W. (CDC/OGC) <[redacted]>; Malone, Kevin M. (CDC/OGC) <[redacted]>; Ghosh, Sudevi (CDC/OGC) <[redacted]>
Cc: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Subject: advice needed

Confidential/ privileged:

Hi OGC Colleagues
I just sent you a screenshot of a website that looks very similar to CDC website.
https://cdc.chdstaging.org/
Here is an article that was sent to me about this by one of our Center directors:
https://open.substack.com/pub/infoepi/p/cdc-clone-site-rife-with-false-vaccine?r=1ydpy&utm_medium=ios

Houry, Debra E. (CDC/IOD)

From: Monarez, Susan (CDC/IOD)
Sent: Saturday, March 22, 2025 1:58 PM
To: Ford, Kenya S. (CDC/OGC); Patterson, Sara S. (CDC/PHIC/OD); Buzzelli, Matthew J (Matt) (CDC/IOD); Witkofsky, Nina (CDC/IOD)
Cc: Houry, Debra E. (CDC/IOD); Coffin, Nicole (CDC/PHIC/OD); Jones, Jamila H. (CDC/OD/OC)
Subject: Re: Website of Concern for IOS Notification

Thank you!

From: Ford, Kenya S. (CDC/OGC) <[redacted]>
Sent: Saturday, March 22, 2025 1:57:43 PM
To: Monarez, Susan (CDC/IOD) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>; Coffin, Nicole (CDC/PHIC/OD) <[redacted]>; Jones, Jamila H. (CDC/OD/OC) <[redacted]>
Subject: Re: Website of Concern for IOS Notification

I alerted Sean and Bob in case IOS wants to reach to them.

Will keep you posted on anything I hear on that front.

Thanks!
Kenya

From: Monarez, Susan (CDC/IOD) <[redacted]>
Sent: Saturday, March 22, 2025 1:56 PM
To: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Coffin, Nicole (CDC/PHIC/OD) <[redacted]>; Jones, Jamila H. (CDC/OD/OC) <[redacted]>
Subject: Re: Website of Concern for IOS Notification

Thanks for flagging. Let's send up through ASPA.

Kenya - do you want to see if HHS/OGC wants to engage?

Best,
Susan

From: Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>
Sent: Saturday, March 22, 2025 1:50 PM

To: Monarez, Susan (CDC/IOD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>
Cc: Houry, Debra E. (CDC/IOD) <[redacted]>; Ford, Kenya S. (CDC/OGC) <[redacted]>; Coffin, Nicole (CDC/PHIC/OD) <[redacted]>; Jones, Jamila H. (CDC/OD/OC) <[redacted]>
Subject: Website of Concern for IOS Notification

Hi Susan, Matt, and Nina –

We were alerted to a website that looks very similar to the CDC website: https://cdc.chdstaging.org/. We also received an article related to this: https://open.substack.com/pub/infoepi/p/cdc-clone-site-rife-with-false-vaccine?r=1ydpy&utm_medium=ios. We notified OGC (Kenya Ford, copied here) and she recommended we try to confirm the source before we determine how to proceed. She also suggested we notify IOS (Diane, Stephanie, Hannah, and Andrew). Would one of you like to do that or do you want that sent up through ASPA channels? I'm also copying Nicole and Jamila for awareness.

Of note, this could be both impersonating a government website and misusing our trademarked logo, so we may need a cease and desist to address.

Thanks,

Sara

Please advise on what should be done about this and who to notify? Should this be flagged for FTC and HHS/OS? Thanks

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Monday, April 14, 2025 9:34 PM
To: Viall, Abigail H. (CDC/OD/OPHDST); CDC Directors Schedule (CDC); Lubar, Debra (CDC/OD/OPPE); Patterson, Sara S. (CDC/PHIC/OD); Buzzelli, Matthew J (Matt) (CDC/IOD); Witkofsky, Nina (CDC/IOD); Burns, Stuart (CDC/IOD)
Subject: RE: Daily IOD End of Day Touchbase

Categories: 4

And more clarification- it was a detailed question with data points about states

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD)
Sent: Monday, April 14, 2025 9:33 PM
To: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>; CDC Directors Schedule (CDC) <[redacted]>; Lubar, Debra (CDC/OD/OPPE) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: Daily IOD End of Day Touchbase

Hi all
I see the note re HHS autism- wasn't aware about this until tonight- NCBDDD let me know that they have already received an inquiry from Reuters on the CDC MMWR ADDM (they are vetting through comms channels) but not sure how this would have happened as our CDC SMEs did not give any embargoed copies to the media. Has HHS shared embargoed copies of the CDC report? If so, this would have been a draft version and not a cleared version

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Viall, Abigail H. (CDC/OD/OPHDST) <[redacted]>
Sent: Monday, April 14, 2025 3:52 PM
To: CDC Directors Schedule (CDC) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>; Lubar, Debra (CDC/OD/OPPE) <[redacted]>; Patterson, Sara S. (CDC/PHIC/OD) <[redacted]>; Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: RE: Daily IOD End of Day Touchbase

Sharing draft action items in case helpful for today's afternoon meeting. Refined list to come later as usual

Action Items	Status	

CDC Role-Based Training--Cybersecurity	Must complete by April 15th or system access will be revoked.	4
Night book	Pending receipt	4
Ethics Training	OS OGC sent email indicating you must complete initial ethics training (IET) within 3 months after your start date. Next available instance is April 21, from 12:30 - 2:00. Email from Kimoy Ellis (came 11:57am on 4/9/25). Linda placed hold on calendar	4
New Role/Title for Nina	Move Nina to a single role/ position description.	4
Budget Leave Behind (Graphic)	Tasked to Rachel, Will, and Abby to develop--group will meet Monday afternoon	4
FY23 Thefts, Loss, and Releases RTC	Review and approve Report to Congress and associated letters (links available in email linked to action item title)	4
Kody Performance Plan	Created by Jennifer Norton and available in PMAS (see email sent at 9:16am on Friday, 4/11)	4
Review draft SOW for IOD Comms Contract	Put on hold while HHS does their review of consolidated comms functions.	4
Secretary Autism Press Conference	Nina and Stuart leading CDC support for HHS materials, talking points for Secretary. Press release 1:00pm Tuesday; press conference Wednesday morning	4
STAC Reports	Received review/clear request. Deadline for HHS submission is 4/16.	4
Complete additional CDC mandatory trainings	Flagged as overdue by OCS--all should be accessible in EASI: 1) 2024 Emergency Preparedness Training- due date: 03/20/2025; 2) CDC Information Security for Executives- due date: 03/15/2025; 3) CDC Overview of Federal Records Management- due date: 03/20/2025; 4) HHS Initial Ethics Orientation- due date: 03/20/2025	4
HHS Contract Efficiency Review	Received updates for 4/14/2025; will update again before 4/16/2025	4
Confirm interest in APHA attendance so can submit conference memo	Teams have reached out to indicate that, if you want to go, we need to confirm and get into approval systems	4
Matt's annual performance plan	Need to complete and submit	4
WH Weekly Report	First draft shared by OCS. Due to HHS by 4:00pm	4
Weekly report to HHS	Prepared and ready	4
Kody AL	Request made in EASI	4
ACIP Transparency Plan--Memo Materials for HHS	Tasked to Stuart and Abby to pull together	4
Policy alignment and big opportunities briefers for Secretary	Meetings set or leaders from 4 CIOs (ORR, OPHDST, NCEZID, OS/OGC) to get them started on developing product that indicate 6-month plans for advancing Admini priorities, big ideas, and associated asks for HHS in 4 key areas: readiness/response (domestic and international stage); data; emerging ID or safe food/water (transition big ideas); new mechanisms for public private partnerships, esp. with venture capital funds/interested investors. 6 month plans to indicate how we will advance Admin priorities; big ideas/asks = additional ways we COULD advance	~ d

	priorities, and what we'd need to make that happen. Additional background: a. How we plan to advance Admin priorities b. Where we could go big/different, and what that would take (how Sec could help us move from "step by step" to "step change" c. Readiness/response (positioning ourselves as a global response leader—branded projection of soft power)à Kate, Ian, Henry, Deb H (pull from ASPR-CDC integration vision and plans) d. New mechanisms and approaches for public private partnership, e.g., with venture capitalà Deb Truss, Deb H, Sam Posner, Noah Aleshire e. Infectious disease (resurrect transition big ideas)à Dan J, Deb H, and his team f. Data and CDC as the source of truth for what's happening in nations health, as well as data for resilience, signal detection, rapid action at home (and abroad?)
Stacie Jenkins Admin Leave Reversal	Looking for this information

Abigail Viall
Senior Advisor
Centers for Disease Control and Prevention
Department of Health and Human Services
[redacted]

-----Original Appointment-----
From: CDC Directors Schedule (CDC) <[redacted]>
Sent: Monday, February 17, 2025 12:40 PM
To: CDC Directors Schedule (CDC); CDC Directors Schedule (CDC); Houry, Debra E. (CDC/IOD); Lubar, Debra (CDC/OD/OPPE); Patterson, Sara S. (CDC/PHIC/OD); Buzzelli, Matthew J (Matt) (CDC/IOD); Witkofsky, Nina (CDC/IOD); Burns, Stuart (CDC/IOD)
Cc: IOD Meetings (CDC); Corley, Ronald D. (CDC/OCOO/OCIO/CEO) (CTR); Taylor, Eric (CDC/OCOO/OCIO/CEO) (CTR)
Subject: Daily IOD End of Day Touchbase
When: Monday, April 14, 2025 4:00 PM-4:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting or DCR

***THIS MEETING INVITATION IS RESTRICTED TO THE LISTED INVITEES ONLY**

If additional people need to be added, please contact Teresa Williams ([redacted]) and Marsha R. Johnson ([redacted]). Thanks!

Microsoft Teams Need help?

Join the meeting now

[redacted]

Dial in by phone

[redacted]

For organizers: Meeting options | Reset dial-in PIN

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Thursday, April 17, 2025 9:40 AM
To: Witkofsky, Nina (CDC/IOD); Buzzelli, Matthew J (Matt) (CDC/IOD); Burns, Stuart (CDC/IOD); Patterson, Sara S. (CDC/PHIC/OD)
Subject: f/u re autism press release

Categories: 4

Hi all

Just wanted to share the below FB post from Trump's prior surgeon general. Our autism program has received quite a bit of concerns after the Secretary spoke yesterday. And, although autism is moving to AHA as the Secretary mentioned- the CDC budget was decreased for that work and HRSA's line was cut. There were a few irregularities too on the slides that our staff would have suggested presenting differently. I know our program and scientists want the Secretary and his messages to land successfully without distraction. In prior administrations, TPs, slides, etc were sent to programs and science for review to help with this. I hope we can move to this collaborative approach moving forward.

6:05

Jerome M Ada

Posts Photos Vide

Jerome M Adams

12h ·

I agree that the recent CDC
further investigation into th
increase in autism rates (th
experts believe this may be

Houry, Debra E. (CDC/IOD)

From: Viall, Abigail H. (CDC/OD/OPHDST) on behalf of Buzzelli, Matthew J (Matt) (CDC/IOD)
Sent: Tuesday, April 22, 2025 12:41 PM
To: Houry, Debra E. (CDC/IOD); Greco Kone, Rebecca (CDC/NCIRD/OD); Head, Vanessa (CDC/OCOO/OD); Patterson, Sara S. (CDC/PHIC/OD); Daskalakis, Demetre (CDC/NCIRD/OD)
Subject: FW: Two questions: ELC Funding and VFC

FYI

Abigail Viall
Senior Advisor
Centers for Disease Control and Prevention
Department of Health and Human Services
[redacted]

From: Ford, Kenya S. (CDC/OGC) <[redacted]>
Sent: Tuesday, April 22, 2025 12:40 PM
To: Callahan, Kenneth (HHS/IOS) <[redacted]>
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Johnston, Darcie (OS/IEA) <[redacted]>; Long, John (OS/IEA) <[redacted]>; Savas, Steve (HHS/IOS) <[redacted]>
Subject: RE: Two questions: ELC Funding and VFC

Sure. Happy to. Thanks!

From: Callahan, Kenneth (HHS/IOS) <[redacted]>
Sent: Tuesday, April 22, 2025 12:39 PM
To: Ford, Kenya S. (CDC/OGC) <[redacted]>
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Johnston, Darcie (OS/IEA) <[redacted]>; Long, John (OS/IEA) <[redacted]>; Savas, Steve (HHS/IOS) <[redacted]>
Subject: FW: Two questions: ELC Funding and VFC

Hi Kenya – you provided me this very helpful answer the other week – today we are hopping on the phone with the State of Texas – who as I understand it – still is interested in potentially receiving money. Can you join us today for the pre-brief with CDC? I added you to the invite.

Ken

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2. What legally needs to happen or should be considered before CDC would communicate to a state (such as Texas) that they can ask for ELC money that could be used for Measles testing?

Presuming this is not related to the recently pulled back COVID funds, there are two main options.

The first option is that the ELC recipient could submit a recipient-initiated request for supplemental funding, where the recipient asks for additional funding to undertake an activity considered to be within the scope of the existing NOFO. In general, a recipient always has to ability to submit a request for supplemental funding if

needed, whether for an emergency need or to continue work that they are currently funded to execute. If CDC concurs with the ask, CDC will need to provide new (i.e., supplemental) funds. This largely depends on the ask and whether there is available funding.

Second, the ELC recipient could undertake a post-award action. In that situation, the ELC recipient could go into their existing ELC budget/award and identify unobligated funding and seek to redirect those funds to focus on measles testing. The ELC recipient should work with their CDC ELC program official and their CDC grants management official or specialist to ensure those funds are available, and, if so, available for this specific use, and/or whether there needs to be any agency prior approvals to redirect those funds. Arguably, the ELC award's scope would allow for measles testing. However, in a budget year, if money needed to be moved from certain already-specified budget categories, that could be worked out between the ELC recipient and the respective CDC staff.

In addition, apart from the ELC award, the state may also have other awards from CDC that they could tap into, depending on what is meant by testing and surveillance and the scope of the NOFO. The state should again talk to their respective grants folks to see if the awards are in their scope.

If the request does pertain to the recently pulled back COVID funding, as of now, recipients have been notified that those funds are no longer available for any use. Even if they had been available, as COVID dollars, as a matter of appropriations law, there would need to be a showing that the proposed use of the funds had a nexus to the underlying purpose of the appropriation (i.e., if COVID dollars, there would need to be showing of a nexus between COVID and the proposed use for measles testing).

Kenya
Kenya S. Ford, J.D.
Acting Deputy General Counsel
Health and Human Services
Office of the General Counsel
[redacted]

From: Ford, Kenya S. (CDC/OGC) <[redacted]>
Sent: Sunday, March 30, 2025 1:32 PM
To: Callahan, Kenneth (HHS/IOS) <[redacted]>
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Cutler, Diane (HHS/IOS) <[redacted]>
Subject: Re: Two questions: ELC Funding and VFC

Received.

I believe the vaccines used for VFC is based on ACIP's schedule, but will look into how that might affect removal.

As for ELC, I believe all states receive that grant funding, so it may be a matter of looking at the scope of their existing grant and asking for the ability to use the funds for that purpose (if they can't already).

But let us look into both questions and confirm and add any info that is needed.

Kenya

From: Callahan, Kenneth (HHS/IOS) <[redacted]>
Sent: Sunday, March 30, 2025 12:47:09 PM
To: Ford, Kenya S. (CDC/OGC) <[redacted]>
Cc: Buzzelli, Matthew J (Matt) (CDC/IOD) <[redacted]>; Cutler, Diane (HHS/IOS) <[redacted]>
Subject: Two questions: ELC Funding and VFC

Hi Kenya,

Two questions for you:

1. What legally needs to happen or should be considered if a vaccine is going to be removed from the VFC program at CDC?
2. What legally needs to happen or should be considered before CDC would communicate to a state (such as Texas) that they can ask for ELC money that could be used for Measles testing?

Ken Callahan
Senior Advisor – Policy & Implementation
Immediate Office of the Secretary (IOS)
U.S. Department of Health and Human Services (HHS)

Pre-Decisional, Deliberative, Draft

expansive responsibilities and focus, vaccine safety monitoring may be negatively impacted.

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

Houry, Debra E. (CDC/IOD)

From: Houry, Debra E. (CDC/IOD)
Sent: Monday, March 31, 2025 5:12 PM
To: Buzzelli, Matthew J (Matt) (CDC/IOD)
Cc: Patterson, Sara S. (CDC/PHIC/OD); Witkofsky, Nina (CDC/IOD); Monarez, Susan (CDC/IOD)
Subject: some talking points about statement on moving vaccine injury program to CDC if asked (from Secretary's interview on Fox)- and issues for consideration

Key points:
Secretary Kennedy on Fox News mentioned transferring vaccine injury compensation to CDC. We are not aware of any proposed reorganization for this and flagging that this would have the potential to create several unintended consequences. This is especially true if multiple vaccine activities lose their autonomy and are combined with a single organizational unit. Some concerns include:

- **Misperception** by vaccine recipients, healthcare providers, and the public that vaccines are not safe;
- **Confusion** for vaccine recipients and the public on how to request compensation for possible vaccine injuries versus how to submit an adverse event report;
- **Real or perceived conflicts** of interest related to vaccine safety, effectiveness, and injury if the functions are combined into a single organizational unit;
- Delayed processing of compensation claims resulting from **limited resources and staff**.

More Specifics:

- It is important that Vaccine Safety remain a neutral, independent function – one that is separated organizationally from vaccine recommendations and information and from compensation for vaccine injuries.
- Co-locating VICP with CDC's Immunization Safety Office would lead to confusion about the distinction between these two separate programs, leading to false/incorrect reporting and the potential for patient safety issues. For example, if individuals don't understand the difference between reporting an adverse event after vaccination through VAERS and submitting a petition under the VICP, or if they believe that by submitting a VAERS report, they could potentially receive compensation, this provides incentives to falsely or incorrectly report adverse events, which would skew vaccine safety data and hinder CDC's ability to identify and respond to a true safety signal. Additionally, if individuals are not clear that submitting a VAERS report and a petition under the VICP require separate actions, an individual could miss an opportunity to submit a claim for and/or receive compensation they may be owed.
- By co-locating vaccine safety and effectiveness programs and vaccine injury compensation programming in the same organizational unit, there may be a perception that one vaccine program's outcomes and findings will influence the other programs. For example, there could be a perception that the agency may not be fully transparent about its vaccine safety findings for fear of increased claims and resources required to administer vaccine injury compensation programming. These perceived conflicts of interest could impact CDC's rigorous efforts around transparency and program integrity.
- The U.S. vaccine safety program has been consistently underfunded. By combining it with an extensive vaccine compensation program with its own history of limited resources and more