From: 122531-15298170@requests.muckrock.com
To: FOIA Requests (CDC)
Subject: Freedom of Information Act Request: COVID-19 Vaccine Pregnancy Studies and Data (CDC)
Date: Thursday, February 24, 2022 11:23:47 AM

Centers for Disease Control and Prevention
FOIA Office
1600 Clifton Road
Atlanta, GA 30329

February 24, 2022

This is a follow up to a previous request:

To Whom It May Concern:

Pursuant to the Freedom of Information Act, I hereby request the following records:

1. Copies of all data, reports, presentations, records, agendas, and meeting minutes related to COVID-19 vaccines and pregnancy and/or pregnant people as part of the CDC's v-safe COVID-19 Vaccine Pregnancy Registry that were presented to, or included in, meetings of the Advisory Committee on Immunization Practices (ACIP), including but not limited to all relevant data collected and/or reported by Abt Associates (https://www.abtassociates.com/projects/expanding-v-safe-covid-19-vaccine-pregnancy-registry-0) between Dec. 1, 2020 and the date this request is ultimately processed.

2. Copies of all data, studies, reports, documents, and records related to COVID-19 vaccines and pregnancy and/or pregnant people provided to the CDC's v-safe COVID-19 Vaccine Pregnancy Registry, including but not limited to data collected and/or reported by Abt Associates, between Dec. 1, 2020 and the date this request is ultimately processed.

3. Copies of all data, studies, reports, documents, and records provided to the CDC related to COVID-19 vaccines and pregnancy and/or pregnant people that were part of the CDC's three pregnancy monitoring programs including the v-safe COVID-19 Vaccine Pregnancy Registry program; the Vaccine Safety Datalink (VSD) program; and the Vaccine Adverse Event Reporting System (VAERS) between Dec. 1, 2020 and the date this request is ultimately processed. (For more clarity about the aforementioned monitoring programs, please view following the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/monitoring-pregnant-people.html)

It is important to note that the VSD website (https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html) states that its pregnancy monitoring data related to vaccines is not public but is sometimes made available to scientists outside of the CDC depending on the study. I believe this data should be available under the FOIA, given its obvious interest to the public. If there are any doubts about this on your agency's part, please feel free to let me know so that I can contact an attorney that specializes in the FOIA to work it out.

The requested information is in the immediate interest of the general public because of the following reasons:

As per the CDC website page entitled "Vaccine Pregnancy Registry" (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafepregnancyregistry.html), as of today's date: "There is currently no evidence that any vaccines, including COVID-19 vaccines, cause fertility problems. However, data are limited about the safety of COVID-19 vaccines for people who are pregnant. CDC established the v-safe COVID-19 Vaccine Pregnancy Registry to learn more about this issue."

According to that webpage, "As of December 20, 2021, more than 180,000 v-safe participants have indicated they were pregnant at the time they received COVID-19 vaccination." In spite of this, the webpage states that the v-safe program has enrolled only 8,749 pregnant people as of Dec. 20, 2021.

The webpage also states, "As CDC learns more about the effects of vaccination during pregnancy, data will be presented at the Advisory Committee on Immunization Practices (ACIP) meetings, which are open to the public, and in published reports." Upon reviewing the meeting agendas of ACIP from the last year, I was unable to locate presentations or reports specifically related to the v-safe program. However, I may have missed those reports in my research, which is part of why I am filing this FOIA request.

I was able to locate an initial study related to the CDC's monitoring, entitled "Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons," which is cited on the v-safe webpage and which was published in NEJM on April 21, 2021 (https://www.nejm.org/doi/full/10.1056/NEJMoa2104983). That initial study analyzed 3,958 pregnant people over 11 weeks in late 2020/early 2021 and indicated in its conclusions that "more longitudinal follow-up, including follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary to inform maternal, pregnancy, and infant outcomes."

As per the CDC website page entitled "COVID-19 Vaccine Monitoring Systems for Pregnant People" (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/monitoring-pregnant-people.html): "Pregnant and recently pregnant people are at increased risk for severe illness from COVID-19." In the absence of reliable government data from large populations of pregnant people over long periods of time, however, many pregnant people in the U.S. have understandably expressed concerns and hesitation until better data becomes publicly available in order to potentially protect their babies from the perceived risk of potential complications.

Because of this, it is vital to interest of the public, as well as to the journalism, scientific, medical, public policy, and statistical analysis communities, that access to higher quality data related to pregnancy and COVID-19 vaccines is released and made available by the CDC and its various monitoring programs, in order for the public and non-government scientists to more accurately assess and fully understand the impact on pregnant people.

The requested information will be made available to the general public, and this request is not being made for commercial purposes. Disclosure of the requested information to me is in the public interest because it is likely to contribute significantly to public understanding of public health and policy, as well as the operations and/or activities of the government, in addition to the other reasons mentioned above, and is not primarily in my commercial interest.

In order to help determine my status to assess fees, you should know that I am a freelance journalist whose work is published frequently by print and digital news outlets and magazines. You can view my portfolio at www.erinmariemiller.com/clips. I have previously been determined a media requester by the CDC in earlier FOIA requests. As a member of the media, I request a waiver of all fees.

In the event that there are fees, I am willing to pay up to $25 for the requested information. If the fee for this request exceeds this amount, please notify me in writing for permission prior to beginning work on the request.

I would prefer the request filled electronically, by e-mail attachment if available or CD-ROM if not.

Thank you in advance for your anticipated cooperation in this matter. I look forward to receiving your response to this request within 20 business days, as the statute requires.

Sincerely,

Erin Miller

View request history, upload responsive documents, and report problems here:
https://accounts.muckrock.com/accounts/login/?next=https%3A%2F%2Fwww.muckrock.com%2Faccounts%2Flogin%2F%3Fnext%3D%252Faccounts%252Fagency_login%252Fcenter-for-disease-control-152%252Fcovid-19-vaccine-pregnancy-studies-and-data-cdc-122531%252F%253Femail%253Dfoiarequests%252540cdc.gov&url_auth_token=AABag1fhhzE4qmWY_bkAVgazCzU%3A1nNIm9%3AsRRSVnI763bnC3cgOTH1amdyQKYmM0_jbEidWa1oFms

If prompted for a passcode, please enter:
MBLNGXBP

Filed via MuckRock.com
E-mail (Preferred): 122531-15298170@requests.muckrock.com

For mailed responses, please address (see note):
MuckRock News
DEPT MR 122531
411A Highland Ave
Somerville, MA 02144-2516

PLEASE NOTE: This request is not filed by a MuckRock staff member, but is being sent through MuckRock by the above in order to better track, share, and manage public records requests. Also note that improperly addressed (i.e., with the requester's name rather than "MuckRock News" and the department number) requests might be returned as undeliverable.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Centers for Disease Control and Prevention (CDC)
Atlanta GA 30333

February 28, 2022

Erin Miller
MuckRock News DEPT MR 122531
411A Highland Ave
Somerville, Massachusetts 02144-2516
Via email: 122531-15298170@requests.muckrock.com

Dear Ms. Miller:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your Freedom of Information Act (FOIA) request dated February 24, 2022. Your request assigned number is 22-01035-FOIA, and it has been placed in our complex processing queue.

Extension of Time

In unusual circumstances, an agency can extend the twenty-working-day limit to respond to a FOIA request.

We will require more than thirty working days to respond to your request because:
☒ We reasonably expect that two or more CDC centers, institutes, and offices (C/I/Os) may have responsive records.
☒ We reasonably expect to receive and review voluminous records in response to your request.
☒ We reasonably expect to consult with two or more C/I/O/s, or another HHS operating division or another federal agency about your request.
☒ We reasonably expect that records located would contain confidential commercial information. We are required to notify submitters of confidential information if their information is requested through a FOIA request. Submitters have 10 working days to object to the release of their information.

To process your request promptly, please consider narrowing the scope of your request to limit the number of responsive records. If you have any questions or wish to discuss reformulation or an alternative time frame for the processing of your request, you may contact the analyst handling your request Emerique Magyar at 770-488-6359 or our FOIA Public Liaison, Roger Andoh at 770-488-6277. Additionally, you may contact the Office of Government Services (OGIS) to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services; National Archives and Records Administration; 8601 Adelphi Road-OGIS; College Park, Maryland 20740-6001; e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Fee Category

Because you are considered an “Other requester” you are entitled to two hours of free search time, and up to 100 pages of duplication (or the cost equivalent of other media) without charge, and you will not

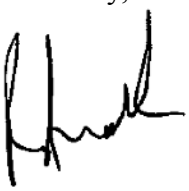
be charged for review time. We may charge for search time beyond the first two hours and for duplication beyond the first 100 pages (10 cents/page).

Cut-off-date

If you don't provide us with a date range for your request, the cut-off date for your request will be the date the search for responsive records starts.

You may check on the status of your case on our FOIA webpage https://foia.cdc.gov/app/Home.aspx and entering your assigned request number. If you have any questions regarding your request, please contact Emerique Magyar at 770-488-6359 or via email at emagyar@cdc.gov.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

22-01035-FOIA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

April 21, 2022

Erin Miller
411A Highland Ave
Somverville, Massachusetts 02144
Via email: 122531-15298170@requests.muckrock.com

Dear Ms. Miller:

This letter is in final response to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of February 24, 2022, assigned #22-01035-FOIA, for:

> 1. Copies of all data, reports, presentations, records, agendas, and meeting minutes related to COVID-19 vaccines and pregnancy and/or pregnant people as part of the CDC's v-safe COVID-19 Vaccine Pregnancy Registry that were presented to, or included in, meetings of the Advisory Committee on Immunization Practices (ACIP), including but not limited to all relevant data collected and/or reported by Abt Associates (https://www.abtassociates.com/projects/expanding-v-safe-covid-19-vaccine-pregnancy-registry-0) between Dec. 1, 2020 and the date this request is ultimately processed.
>
> 2. Copies of all data, studies, reports, documents, and records related to COVID-19 vaccines and pregnancy and/or pregnant people provided to the CDC's v-safe COVID-19 Vaccine Pregnancy Registry, including but not limited to data collected and/or reported by Abt Associates, between Dec. 1, 2020 and the date this request is ultimately processed.
>
> 3. Copies of all data, studies, reports, documents, and records provided to the CDC related to COVID-19 vaccines and pregnancy and/or pregnant people that were part of the CDC's three pregnancy monitoring programs including the v-safe COVID-19 Vaccine Pregnancy Registry program; the Vaccine Safety Datalink (VSD) program; and the Vaccine Adverse Event Reporting System (VAERS) between Dec. 1, 2020 and the date this request is ultimately processed. (For more clarity about the aforementioned monitoring programs, please view following the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/monitoring-pregnant-people.html)

For administrative convenience and in order to respond to portions of your request fully we are providing the following links and information. No information is being withheld from those documents. With regard to your request for Vaccine Safety Datalink data the Immunization Safety Office indicated the data requested does not exist in the requested format. Under the Freedom of Information Act (FOIA) agencies are not required to conduct research or create records in response to a FOIA request. Additionally, VSD data is collected under an Assurance of Confidentiality, and we are precluded from releasing that information and consequently all VSD data was withheld from release pursuant to 5 U.S.C. §552 Exemption (b)(3). The foreseeable harm standard was considered when applying these redactions.

EXEMPTION (b)(3)
Exemption (b)(3) protects information that has been specifically exempted from disclosure by statute. In this case, the information is being withheld under the authority of an Assurance of Confidentiality issued under 42 U.S.C. §308(d) (specifically, §242(k) and §242(m)(d)) and withheld in full under the authority of 5 U.S.C. §552 Exemption (b)(3).

In response to item 1 of your request, the ISO provided the following information and links:

The requested data on pregnancy reports is publicly available and can be found in the CDC Wonder Database at https://wonder.cdc.gov/vaers.html

For V-safe Pregnancy Surveillance (amendment) Protocol please visit:
https://www.cdc.gov/vaccinesafety/pdf/vsafe-pregnancy-surveillance-protocol-508.pdf

Zauche LH, Wallace B, Smoots AN, Olson CK, Oduyebo T, Kim SY, Petersen EE, Ju J, Beauregard J, Wilcox AJ, Rose CE, Meaney-Delman DM, Ellington SR, CDC v-safe COVID-19 Pregnancy Registry Team. Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion - PubMed (nih.gov). *N Engl J Med.* 2021 Sept 8. Dpo: 10.1056/NEJMc2113891.

Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, Marquez PL, Olson CK, Liu R, Chang KT, Ellington SR, Burkel VK, Smoots AN, Green CJ, Licata C, Zhang BC, Alimchandani M, Mba-Jonas A, Martin SW, Gee JM, Meaney-Delman DM, CDC v-safe COVID-19 Pregnancy Registry Team. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons - PubMed (nih.gov). *N Engl J Med*. 2021 Jun 17;384(24):2273-2282. Epub 2021 Apr 21.

For COVID-19 ACIP Vaccine Recommendations please visit:
https://www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/covid-19.html

Pregnancy was addressed in the COVID-19 ACIP Meeting on September 22 - 23, 2021:
For Meeting Agenda please visit:
https://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2021-09-22-23-508.pdf

For Meeting Minutes please visit:
https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/summary-2021-09-22-23-508.pdf

For Presentations please visit:
https://www.cdc.gov/vaccines/acip/meetings/slides-2021-09-22-23.html

Coronavirus Disease 2019 (COVID-19) Vaccines

- Introduction pdf icon[9 pages]
  Dr. M Daley
- Safety and immunogenicity for a 3rd dose of BNT162b2 pdf icon[20 pages]
  Dr. B Gruber
- Immunity and SARS-CoV-2 pdf icon[35 pages]
  Dr. N Thornburg
- Vaccine effectiveness studies in the United States pdf icon[42 pages]
  Dr. R Link-Gelles
- Modeling the potential impact of booster doses in nursing home residents pdf icon[16 pages]
  Dr. R Slayton

- Early safety monitoring for third doses of mRNA vaccines pdf icon[21 pages]
  Dr. A Hause
- VaST summary pdf icon[14 pages]
  Dr. K Talbot
- Work Group summary pdf icon[13 pages]
  Dr. S Oliver
- Pregnancy: Safety monitoring in v-safe pdf icon[24 pages]
  Dr. C Olson
- Pregnancy: Safety monitoring in VSD pdf icon[23 pages]
  Dr. E Kharbanda
- Updates on COVID-19 and pregnancy pdf icon[20 pages]
  Dr. D Meaney Delman

Coronavirus Disease 2019 (COVID-19) Vaccines

- Introduction pdf icon[6 pages]
  Dr. M Daley
- COVID-19 vaccine booster doses: Benefit/risk discussion pdf icon[25 pages]
  Dr. M Wallace
- Evidence to Recommendation Framework: Booster doses of Pfizer-BioNTech COVID-19 vaccine pdf icon[88 pages]
  Dr. S Oliver
- Clinical considerations pdf icon[19 pages]
  Dr. K Dooling
- COVID-19 vaccine booster doses
  Dr. S Oliver

In response to item 2 of your request, the ISO provided the following information and links:

For V-safe Pregnancy Surveillance (amendment) Protocol please visit:
https://www.cdc.gov/vaccinesafety/pdf/vsafe-pregnancy-surveillance-protocol-508.pdf

Zauche LH, Wallace B, Smoots AN, Olson CK, Oduyebo T, Kim SY, Petersen EE, Ju J, Beauregard J, Wilcox AJ, Rose CE, Meaney-Delman DM, Ellington SR, CDC v-safe COVID-19 Pregnancy Registry Team. Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion - PubMed (nih.gov). *N Engl J Med.* 2021 Sept 8. Dpo: 10.1056/NEJMc2113891.

Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, Marquez PL, Olson CK, Liu R, Chang KT, Ellington SR, Burkel VK, Smoots AN, Green CJ, Licata C, Zhang BC, Alimchandani M, Mba-Jonas A, Martin SW, Gee JM, Meaney-Delman DM, CDC v-safe COVID-19 Pregnancy Registry Team. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons - PubMed (nih.gov). *N Engl J Med*. 2021 Jun 17;384(24):2273-2282. Epub 2021 Apr 21.

In response to item 3 of your request, the ISO provided the following information and links:

Please visit:
https://www.cdc.gov/vaccinesafety/pdf/vsafe-pregnancy-surveillance-protocol-508.pdf

https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf

https://www.cdc.gov/vaccinesafety/pdf/VSD-1342-COVID19-RCA-Protocol_FinalV1.1_508.pdf

https://www.cdc.gov/vaccinesafety/pdf/COVID19-acute-maternal-outcomes-508.pdf

Moro PL, Panagiotakopoulos L, Oduyebo T, Olson CK, Myers T. Monitoring the safety of COVID-19 vaccines in pregnancy in the US. *Human Vaccines & Immunotherapies.* 2021 Nov 10. doi.org/10.1080/21645515.2021.1984132.

Zauche LH, Wallace B, Smoots AN, Olson CK, Oduyebo T, Kim SY, Petersen EE, Ju J, Beauregard J, Wilcox AJ, Rose CE, Meaney-Delman DM, Ellington SR, CDC v-safe COVID-19 Pregnancy Registry Team. Receipt of mRNA Covid-19 Vaccines and Risk of Spontaneous Abortion - PubMed (nih.gov). *N Engl J Med.* 2021 Sept 8. Dpo: 10.1056/NEJMc2113891.
Kharbanda EO, Haapala J, DeSilva M, Vazquez-Benitez G, Vesco KK, Naleway AL, Lipkind HS. Spontaneous Abortion Following COVID-19 Vaccination During Pregnancy. *JAMA* 2021 Sep 8. Doi:10.1001/jama.2021.15494

Razzaghi H, Meghani M, Pingali C, Crane B, Naleway A, Weintraub E, Kenigsberg TA, Lamias MJ, Irving SA, Kauffman TL, Vesco KK, Daley MF, DeSilva M, Donahue J, Getahun D, Glee S, Hambidge SJ, Jackson LJ, Lipkind HS, Nelson J, Zerbo O, Oduyebo T, Singleton JA, Patel SA. COVID-19 Vaccination Coverage Among Pregnant Women During Pregnancy — Eight Integrated Health Care Organizations, United States, December 14, 2020–May 8, 2021 | MMWR (cdc.gov). *MMWR Morb Mortal Wkly Rep*. 2021 Jun 18;70(24):895-899.

Shimabukuro TT, Kim SY, Myers TR, Moro PL, Oduyebo T, Panagiotakopoulos L, Marquez PL, Olson CK, Liu R, Chang KT, Ellington SR, Burkel VK, Smoots AN, Green CJ, Licata C, Zhang BC, Alimchandani M, Mba-Jonas A, Martin SW, Gee JM, Meaney-Delman DM, CDC v-safe COVID-19 Pregnancy Registry Team. Preliminary Findings of mRNA Covid-19 Vaccine Safety in Pregnant Persons - PubMed (nih.gov). *N Engl J Med*. 2021 Jun 17;384(24):2273-2282. Epub 2021 Apr 21.

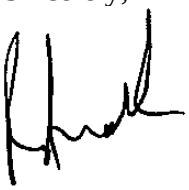
The VSD data does not exist in the requested format. VSD cannot conduct an independent analysis of the data requested on behalf of the requester. Datasets from published VSD studies from 2002 to the present may be accessed for secondary analyses at the CDC Research Data Center. VSD follows the CDC/ATSDR Policy on Releasing and Sharing Data, in order ensure the safety and proper use of the data. For more information please visit:
https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/accessing-data.html

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx.

Your appeal must be electronically transmitted by July 20, 2022.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

Enclosures

22-01035-FOIA

Deputy Agency Chief FOIA Officer,
Office of the Assistant Secretary for Public Affairs,
U.S. Department of Health and Human Services

To: FOIARequest@psc.hhs.gov

Re: Freedom of Information Act Appeal

July 20, 2022

To Whom It May Concern:

This is an appeal under the Freedom of Information Act regarding CDC FOIA request #22-01035-FOIA.

On Feb. 24, 2022, I requested the following records and information from the Centers for Disease Control and Prevention (CDC):

1. Copies of all data, reports, presentations, records, agendas, and meeting minutes related to COVID-19 vaccines and pregnancy and/or pregnant people as part of the CDC's v-safe COVID-19 Vaccine Pregnancy Registry that were presented to, or included in, meetings of the Advisory Committee on Immunization Practices (ACIP), including but not limited to all relevant data collected and/or reported by Abt Associates (https:// www.abtassociates.com/projects/expanding-v-safe-covid-19-vaccine-pregnancy- registry-0) between Dec. 1, 2020 and the date this request is ultimately processed.

2. Copies of all data, studies, reports, documents, and records related to COVID-19 vaccines and pregnancy and/or pregnant people provided to the CDC's v-safe COVID-19 Vaccine Pregnancy Registry, including but not limited to data collected and/or reported by Abt Associates, between Dec. 1, 2020 and the date this request is ultimately processed.

3. Copies of all data, studies, reports, documents, and records provided to the CDC related to COVID-19 vaccines and pregnancy and/or pregnant people that were part of the CDC's three pregnancy monitoring programs including the v-safe COVID-19 Vaccine Pregnancy Registry program; the Vaccine Safety Datalink (VSD) program; and the Vaccine Adverse Event Reporting System (VAERS) between Dec. 1, 2020 and the date this request is ultimately processed. (For more clarity about the aforementioned monitoring programs, please view following the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/monitoring-pregnant- people.html)

On April 21, 2022, Roger Andoh, CDC/ATSDR FOIA Officer at the Office of the Chief Operating Officer, partially granted my request and provided me with a final response letter containing links to various publicly-available studies and meeting minutes related to my request.

However, in the aforementioned final response letter dated April 21, 2022 from Roger Andoh, my request for Vaccine Safety Datalink (VSD) data related to pregnancy and COVID-19 vaccines was denied. The agency cited the following reasons for its denial of the requested data:

"With regard to your request for Vaccine Safety Datalink data the Immunization Safety Office indicated the data requested does not exist in the requested format. Under the Freedom of Information Act (FOIA) agencies are not required to conduct research or create records in response to a FOIA request.
"Additionally, VSD data is collected under an Assurance of Confidentiality, and we are precluded from releasing that information and consequently all VSD data was withheld from release pursuant to 5 U.S.C. §552 Exemption (b)(3). The foreseeable harm standard was considered when applying these redactions.

"EXEMPTION (b)(3) Exemption (b)(3) protects information that has been specifically exempted from disclosure by statute. In this case, the information is being withheld under the authority of an Assurance of Confidentiality issued under 42 U.S.C. §308(d) (specifically, §242(k) and §242(m)(d)) and withheld in full under the authority of 5 U.S.C. §552 Exemption (b)(3)."

I appeal the denial of my request for Vaccine Safety Datalink (VSD) data related to pregnancy and COVID-19 vaccinations based on the following arguments:

1. The agency's cited Assurance of Confidentiality exemptions under 42 U.S.C. §308(d) (specifically, §242(k) and §242(m)(d)) and 5 U.S.C. §552 Exemption (b)(3) do not apply to the requested records. The agency's claims about Assurance of Confidentiality are directly contradicted by the V-safe Pregnancy Surveillance (amendment) Protocol that the agency itself provided a link to in its final response letter (final response letter: pg. 2, paragraph 5: https://www.cdc.gov/vaccinesafety/pdf/vsafe-pregnancy-surveillance-protocol-508.pdf). The paragraph on page 6 of the V-safe Pregnancy Surveillance (amendment) Protocol relating to Human subjects considerations and confidentiality clearly states:

"This protocol will require human subjects determination at CDC because CDC is the lead site and surveillance data will include collection of personal identifiable information (PII). This data will be collected for public health surveillance, not for research purposes. No PII will be included in any v-safe analyses, manuscripts, or datasets shared externally. Participation is voluntary and individuals self-enroll. Participants can opt-out of the v-safe pregnancy registry at any time and their data will only be used for the time they were considered an active participant. In addition, this activity presents minimal risk to subjects, and use of patient data for this purpose will not adversely affect subjects' rights or welfare."

Based on the protocol linked in the response, the purpose of the requested data's collection is for public health surveillance and "no PII will be included in any v-Safe analyses, manuscripts, or datasets shared externally." Because of that, the agency's cited confidentiality exemptions do not apply to the requested records. Based on the requested data's collection protocol, it also seems that the requested data does in fact exist in the requested form under the V-safe Pregnancy Surveillance (amendment) Protocol, in that is should not contain PII of the participants.

2. The agency's application of the foreseeable harm standard does not apply to the requested records. On page 6 of the aforementioned V-safe Pregnancy Surveillance (amendment) Protocol, the paragraph relating to Human Subjects Considerations and Confidentiality states:

"No PII will be included in any v-safe analyses, manuscripts, or datasets shared externally. Participation is voluntary and individuals self-enroll. Participants can opt-out of the v-safe pregnancy registry at any time and their data will only be used for the time they were considered an active participant. In addition, this activity presents minimal risk to subjects, and use of patient data for this purpose will not adversely affect subjects' rights or welfare."

Based on the agency-provided protocol under this request, v-Safe Pregnancy Surveillance data does not meet the requirements of the foreseeable harm standard because it does not include any personal identifiable information (PII) and, according to the program's own protocol, "presents minimal risk to subjects" and will ultimately be released to the public in a final analysis, as outlined on page 7 (see next point).

3. The requested data does not meet the Assurance of Confidentiality or standard of harm criteria. On page 7 of the aforementioned V-safe Pregnancy Surveillance (amendment) Protocol, the paragraph related to Dissemination of Information states:

"Safety profile information from the registry may be presented to Advisory Committee on Immunization Practices (ACIP) subgroups (such as the Vaccine Safety Technical Subgroup [VaST]), ACIP meetings and other meetings that are requested. Further, at the conclusion of the registry, a final report will be written detailing the findings of this surveillance activity."

Because release of the requested data is left to the discretion of the agency (as outlined in the protocol above), and the data is available for presentation at public meetings, the Assurance of Confidentiality and foreseeable harm standard does not apply to the requested records.

4. The foreseeable harm standard also does not apply to this request because the agency failed to provide a specific and concrete explanation as to how or why disclosure of the requested data would create legitimate foreseeable harm, particularly in light of the fact that the v-Safe Pregnancy Surveillance data does not include PII under its own collection protocol and is undeniably more in the public interest to release than not.

In past FOIA litigation related to the foreseeable harm standard, numerous courts at the federal and district levels have ruled that an agency must provide a requester with a specific and concrete explanation about how disclosing the requested data would cause legitimate foreseeable harm in a denial under the foreseeable harm standard. (See Center for Investigative Reporting v. Department of Labor; Center for Investigative Reporting v. U.S. Customs & Border Protection; and Ecological Rights Foundation v. FEMA). (Source: Foreseeable Harm Standard. (2021, July 2). FOIA.Wiki, Retrieved 17:26, July 19, 2022 from https://foia.wiki/w/index.php?title=Foreseeable_Harm_Standard&oldid=6300.)

In a memo issued by the Dept. of Justice providing guidance on the application of the foreseeable harm standard, Attorney General Janet Reno established specific standards of open

government that strongly encouraged “agency decisionmaking under the FOIA toward the Act’s goal of maximum responsible disclosure.” That memo, issued Oct. 4, 1993, stated:

“In short, it be shall the policy of the Department of Justice to defend the assertion of a FOIA exemption only in those cases where the agency reasonably foresees that disclosure would be harmful to an interest protected by that exemption.”
(Source: https://www.justice.gov/oip/blog/foia-update-oip-guidance-applying-forseeable-harm-standard-under-exemption-five)

Having already established that the Assurance of Confidentiality and foreseeable harm standard should not apply to the requested records due to the lack of PII in the requested data and a lack of clarity on the actual harm that would be caused by its disclosure, it is important to cite the aforementioned DOJ guidance, which states:

“Where ‘only a government interest would be affected’ by a FOIA disclosure, there is a far greater potential for discretionary disclosure than exists where such interests as personal privacy or business confidentiality.”

I strongly encourage whoever handles this appeal to consider the possibility that the "foreseeable harm" in the case of this request could potentially be to protect the government's interests. I also encourage you to consider the DOJ’s strong urging toward transparency in support of the spirit of the Freedom of Information Act, which was designed to promote government transparency and accountability, which are both significant components of a well-functioning democracy.

Finally, in March 2022, someone at the CDC went back through all of the requests I have filed with the agency both independently and via MuckRock (a nonprofit organization that provides automated public records requests services), and moved many of those requests from their separate original portals into a different portal under login credentials that were different from the original credentials used to access several of the requests, including this one. Those changes rendered me unable to access the requests in their original portals and created confusion about how to access updates about each request.
The contact information for this request (#22-01035-FOIA) was changed from the original MuckRock email address I had filed it under, to my personal email address; the mailing address related to this request was also temporarily changed to one of my former residential addresses without my knowledge. It was eventually changed back after a back-and-forth with Emerique C. Magyar.

Proof of the aforementioned unauthorized portal credential changes can be found in my email communications with Emerique C. Magyar dated March 11 through March 14, 2022, as well as my email communication to the CDC IT Service Desk (ITServiceDesk@cdc.gov) on March 14, 2022, in which I complained about the changes and reported a possible security breach related to my CDC FOIA portal account.

In addition to my login credentials being changed without my knowledge or permission on this request (#22-01035-FOIA), the password to the portal for this request now seems to have also

changed, which has prevented me from accessing the portal to file this appeal in time to meet the appeal deadline July 20, 2022, as noted in the agency's final response letter.

Due to my inability to access the portal to electronically file an appeal today, which appears to again be due to actions by someone other than myself changing my portal login password, I am submitting this appeal to email addresses associated with the CDC's FOIA office and liaisons including FOIARequest@psc.hhs.gov, ogis@nara.gov and foiarequests@cdc.gov.

I have also alerted MuckRock staff about my inability to log into the portal also, as the request was originally filed via MuckRock. However, if my appeal does not reach the CDC by its deadline, I intend to request a formal investigation into the matter due to the unusual nature of the agency's prior unauthorized changes to my CDC portal login credentials for this request.

If you have any questions while handling this appeal, please provide me with a phone number where I can reach you directly.
Thank you for your consideration of this appeal.

Sincerely,

Erin Miller
MuckRock News Dept.
411A Highland Ave
Somverville, Massachusetts 02144
Via email: 122531-15298170@requests.muckrock.com

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

Case No. 2022-00213-A-PHS

July 22, 2022

Erin Miller
Sent via email: 122531-15298170@requests.muckrock.com

Dear Ms. Miller:

This letter acknowledges receipt of your Freedom of Information Act (FOIA) appeal, which was submitted to the Department of Health and Human Services (HHS), FOI/Privacy Acts Division. We received your appeal on July 22, 2022. It challenges the Centers for Disease Control and Prevention (CDC) response to your initial request, 22-01035-FOIA. We assigned your appeal the tracking number above based on when it was received in this office. Please refer to this number on any future correspondence.

Pursuant to 5 U.S.C. § 552(a)(6)(B)(i) and 5 U.S.C. § 552(a)(6)(B)(iii) of the FOIA and 45 C.F.R. § 5.24(f) of the HHS FOIA regulations, your appeal falls under "unusual circumstances" in that our office will need to consult with another office or agency that has substantial interest in the determination of the appeal. The actual processing time will depend on the complexity of the issues presented in the appeal and consultation with other U.S. Department of Health and Human Services (HHS) components involved.

Each appeal is handled on a first-in, first-out basis in relation to the other open appeals in the processing queue. Currently, there are approximately 450 open appeals in the processing queue. For more information about how your appeal will be processed please refer to the HHS FOIA regulations (https://www.federalregister.gov/documents/2016/10/28/2016-25684/freedom-of-information-regulations).

As a final note, if you are not already submitting your appeals through our Public Access Link (PAL), we recommend all future appeals be submitted through PAL - https://requests.publiclink.hhs.gov/. Submitting appeals through PAL automatically logs your appeal into our tracking system and provides you with a tracking number. Your PAL account will allow you to track the progress of your appeal, receive your response directly through the portal, and securely submit privacy-sensitive or business-sensitive documents.

If you have any questions, please email us at foiarequest@psc.hhs.gov.

Sincerely yours,

Alesia Y. Williams

Alesia Y. Williams
Director, FOIA Appeals and Litigations
FOI/Privacy Acts Division

NATIONAL ARCHIVES and RECORDS ADMINISTRATION
8601 ADELPHI ROAD - OGIS | COLLEGE PARK, MD 20740-6001
www.archives.gov/ogis | ogis@nara.gov | o: 202.741.5770 | f: 202.741.5769 | t: 877.684.6448

August 3, 2022—Sent via email

Erin Miller
122531-15298170@requests.muckrock.com

Dear Erin Miller:

This responds to your July 19, 2022 submission to the Office of Government Information Services (OGIS). OGIS is the federal Freedom of Information Act (FOIA) Ombudsman. We assist the public and federal agencies by helping them resolve their FOIA disputes, and by addressing their questions and concerns about the FOIA process. OGIS has no investigatory or enforcement power, nor can we compel an agency to release documents. Instead, OGIS provides information to FOIA requesters and federal agencies to increase understanding and resolve disputes.

We carefully reviewed your submission of information, however it is unclear what assistance you seek from this office. We note that you have appealed the Centers for Disease Control and Prevention (CDC) response to FOIA request no. **22-01035-FOIA**. Please note, OGIS does not process administrative appeals on behalf of other agencies. We contacted the Department of Health and Human Services (HHS)—the appellate authority for the CDC—regarding the status of your appeal. HHS FOIA officials informed us that your appeal was received on July 21, 2022 and assigned tracking no. **2022-00213-A-PHS**. HHS FOIA officials also informed us that there are approximately 451 appeals ahead of yours and they anticipate responding to your appeal in several months.

The appeal is an important part of the FOIA administrative process, and OGIS's assistance does not replace the appeal process. By filing an appeal, you preserve your administrative rights and give the agency a chance to look at the request anew and carefully review and reconsider every part of the initial response. Based on the available information, the appeals office will independently determine whether the agency properly processed your request at the initial stage. The agency will notify you of its appeal determination in writing.

Since you have already filed an administrative appeal, the best course of action is to wait until HHS processes your appeal and has sent you a final determination. It is important to know that all federal agencies have resources in place for you to check the status of your request and appeal. We have found that requesters often find it more efficient to contact the agency directly to obtain status information, rather than asking OGIS to act as an intermediary. Should you wish to receive an updated estimated date of completion in the coming months, you may wish to contact Jonathan Nelson at Jonathan.nelson@hhs.gov.

If you dispute the appeal determination or have questions or concerns that we have not addressed, please contact us again and provide us with the following:

- a brief description of the FOIA issue or dispute (*e.g.*, inadequate search, disputing exemptions, challenging fees) and the assistance you seek from OGIS;
- the CDC's response to your request; and
- the agency's response to your appeal.

Please note, due to the COVID-19 outbreak, at present we can only receive and respond to inquiries via email and encourage you to send materials as PDF attachments to ogis@nara.gov should you need further assistance from OGIS.

We hope you find this information useful. Thank you for bringing this matter to OGIS; at this time we will take no further action.

Best regards,
The OGIS Staff

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 9, 2022

Erin Miller
411A Highland Avenue
Somerville, Massachusetts 02144
Via email: 122531-15298170@requests.muckrock.com

Dear Ms. Miller:

This letter is our final response regarding your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of March 7, 2022, assigned #22-01108-FOIA, for

> *As per the CDC website page entitled "COVID-19 Vaccine Breakthrough Case Investigation and Reporting" (https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm): 'Beginning May 1, 2021, CDC transitioned from monitoring all reported COVID-19 vaccine breakthrough infections to investigating only those among patients who are hospitalized or die, thereby focusing on the cases of highest clinical and public health significance.'*
>
> *Despite this decision, the CDC has continued to monitor all reported cases of COVID-19 in unvaccinated people, regardless of severity. From a quantitative analysis perspective, such differences in methodology (i.e., using two different sets of variables to track data differently between two different populations) has the potential to create statistical biases. It can make it difficult, if not impossible, to normalize numbers from each population for the purpose of comparing them.*
>
> *Because of this, it is vital to interests of the public, as well as the journalism, scientific, medical, public policy, and statistical analysis communities, to fully understand the logic and reasoning behind the CDC's decision to track COVID-19 cases in vaccinated and unvaccinated populations so differently.*
>
> *In light of recent news reports about alleged waning and potential decreases in vaccine effectiveness over time, especially as it relates to the new Omicron variant and concerns about future mutations of the virus, it is also vital to the public interest to fully understand the CDC's data tracking choices.*
>
> *Understanding the factors behind the CDC's data tracking decisions could be helpful for policy analysts to determine whether more consistent methodologies should be implemented between each population now, in order to better identify new variants as they occur and to track vaccine effectiveness over time. That said, I hereby request the following records pursuant to the Freedom of Information Act:*
>
> 1. ***All records in possession of your agency created between the dates of December 31, 2020 and May 1, 2021 relating to the CDC decision to cease monitoring all reported vaccine breakthrough cases. Emails (including their attachments), internal discussions, supporting documents and scientific models, and other records that might be relevant to understanding the decision should be included in the responsive documents.***

For items #1 and #2, we located 574 pages, eight Excel spreadsheets, and one .CSV file of responsive records (154 pages released in full; 127 pages released in part; 293 pages and eight Excel spreadsheets and one .CSV file withheld in full). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemptions 5 and 6. The foreseeable harm standard was considered when applying these redactions.

Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the deliberative process privilege. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include deliberative communications and draft protocols.

Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as patient identification numbers. We have determined that the individuals to whom this information pertains has a substantial privacy interest in withholding it.

You may contact our FOIA Public Liaison at 770-488-6246 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

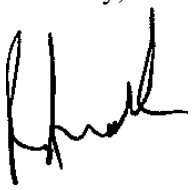
If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by Tuesday, February 7, 2023.

We also located 124 pages belonging to the U.S. Department of Health and Human Services (HHS) and 18 pages belonging to the Indian Health Service (IHS), an agency within the HHS. In accordance with HHS's implementing regulations, CDC does not make decisions on the release or denial of other agencies' documents. We have referred these records along with your request to HHS and to IHS respectively for their release determination and direct reply to you. Contact information for each agency is as follows:

Department of Health and Human Services (HHS)
Freedom of Information Officer
Hubert H. Humphrey Building, Room 729H
200 Independence Avenue, SW
Washington, D.C. 20201
Submit requests to: https://requests.publiclink.hhs.gov/App/Index.aspx
Phone: 202-690-7453
Fax: 202-690-8320
FOIA Officer: Brandon Gaylord
FOIA Public Liaison: Beth Kramer; email: HHS_FOIA_Public_Liaison@hhs.gov

Indian Health Service FOIA Office
Division of Regulatory and Policy Coordination/FOIA
5600 Fishers Lane, Mailstop 09E70
Rockville, Maryland 20857
Email your status inquiry to: IHSFOIAMailbox@ihs.gov .

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
Phone: (770) 488-6399
Fax: (404) 235-1852

Enclosures

22-01108-FOIA

Deputy Agency Chief FOIA Officer,
Office of the Assistant Secretary for Public Affairs,
U.S. Department of Health and Human Services

To: FOIARequest@hhs.gov

Subject: RE: Freedom of Information Act Request #22-01035-FOIA

February 7, 2023

To Whom It May Concern:

This is an appeal under the Freedom of Information Act regarding CDC FOIA request #22-01035-FOIA.

On Feb. 24, 2022, I requested the following records and information from the Centers for Disease Control and Prevention (CDC):

1. Copies of all data, reports, presentations, records, agendas, and meeting minutes related to COVID-19 vaccines and pregnancy and/or pregnant people as part of the CDC's v-safe COVID-19 Vaccine Pregnancy Registry that were presented to, or included in, meetings of the Advisory Committee on Immunization Practices (ACIP), including but not limited to all relevant data collected and/or reported by Abt Associates (https:// www.abtassociates.com/projects/expanding-v-safe-covid-19-vaccine-pregnancy- registry-0) between Dec. 1, 2020 and the date this request is ultimately processed.

2. Copies of all data, studies, reports, documents, and records related to COVID-19 vaccines and pregnancy and/or pregnant people provided to the CDC's v-safe COVID-19 Vaccine Pregnancy Registry, including but not limited to data collected and/or reported by Abt Associates, between Dec. 1, 2020 and the date this request is ultimately processed.

3. Copies of all data, studies, reports, documents, and records provided to the CDC related to COVID-19 vaccines and pregnancy and/or pregnant people that were part of the CDC's three pregnancy monitoring programs including the v-safe COVID-19 Vaccine Pregnancy Registry program; the Vaccine Safety Datalink (VSD) program; and the Vaccine Adverse Event Reporting System (VAERS) between Dec. 1, 2020 and the date this request is ultimately processed. (For more clarity about the aforementioned monitoring programs, please view following the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/monitoring-pregnant- people.html)

My initial request was partially denied by the agency. On July 20, 2022, I appealed the agency's partial denial.

On November 9, 2022, Roger Andoh partially approved my appeal and ordered the delivery of additional requested records under my request. According to Mr. Andoh's letter, some

information was withheld under Exemption 5 (the letter specifically cited the deliberative process privilege) and Exemption 6.

I hereby appeal the withholding of information under Exemption 5 (the deliberative process privilege) based on the following arguments, per FOIA.Wiki:

1. In Chilivis v. S.E.C., 673 F.2d 1205, 1212 (11th Cir. 1982), "Waiver can occur when communications are disclosed to private individuals or nonfederal agencies." In this case, the agency waived the privilege when it voluntarily shared the requested records, data and information with other private individuals and nonfederal agencies, as indicated in the V-safe Pregnancy Surveillance (amendment) Protocol, which can be viewed here: https://www.cdc.gov/vaccinesafety/pdf/vsafe-pregnancy-surveillance-protocol-508.pdf. On page 7, the paragraph related to Dissemination of Information states: "Safety profile information from the registry may be presented to Advisory Committee on Immunization Practices (ACIP) subgroups (such as the Vaccine Safety Technical Subgroup [VaST]), ACIP meetings and other meetings that are requested. Further, at the conclusion of the registry, a final report will be written detailing the findings of this surveillance activity." The requested information has also been voluntarily shared with Abt Associates (https://www.abtassociates.com/projects/expanding-v-safe-covid-19-vaccine-pregnancy-registry-0). Therefore, any reference to the requested data should not be excluded due to this fact.

2. Due to the fact that the agency has already publicly claimed that COVID-19 mRNA vaccines are "safe and effective" for use in pregnant women, the requested information is not pre-decisional. Therefore, the deliberative process privilege does not apply to the requested records. For evidence of the agency's claims, refer to the following links:
a) "CDC Recommends COVID-19 Vaccine During Pregnancy" - WebMD, April 26, 2021: https://www.webmd.com/vaccines/covid-19-vaccine/news/20210426/cdc-recommends-covid-19-vaccine-during-pregnancy
b) "The CDC recommends that pregnant people receive the COVID-19 vaccine," said CDC director Rochelle Walensky, MD during a White House briefing on April 23, 2021: https://www.c-span.org/video/?511197-1/white-house-covid-19-response-team-briefing

3. The agency has not provided evidence that disclosure of drafts would cause public confusion about final public policy. Documents that have at least some markings that indicate they are drafts (including deliberative emails, which are obviously not final policy) are unlikely to be mistaken for final agency policy. (See Judicial Watch, Inc. v. United States Dep't of Justice, No. 19-CV-800 (TSC), 2020 WL 5798442, at *3 (D.D.C. Sept. 29, 2020).

4. The public interest vastly outweighs the need for deliberative secrecy here. As early as April 23, 2021, representatives of the agency publicly claimed multiple times that COVID-19 vaccines using mRNA technology were "safe and effective" for pregnant women (see "The CDC recommends that pregnant people receive the COVID-19 vaccine," said CDC director Rochelle Walensky, MD during a White House briefing on April 23, 2021: https://www.c-span.org/video/?511197-1/white-house-covid-19-response-team-briefing). At the time that final policy was shared publicly, mRNA technology was being used on humans for the first time in history following a rushed development and approval process. There was extremely limited

evidence to support the agency's safety claims. There was also an indisputable and total absence of long-term studies regarding the safety of mRNA vaccine use in pregnant women or their children, given the very short amount of time mRNA vaccines had been in use. The decision of the agency to make clearly premature safety claims for pregnant women in the absence of long-term data set a dangerous precedent for public health in America; the public interest in understanding why such decisions were made by the agency clearly outweighs the need for deliberative secrecy in this case. When it comes to ensuring the safety of pregnant human beings -- and the safety of future generations of Americans that have yet to be born -- deliberative privilege should never apply.

5. There is no foreseeable harm in the release of the requested information. Further, the agency has failed to identify any foreseeable harm related to the release of the requested information. In Reporters Committee for Freedom of the Press v. FBI, the D.C. Circuit Court stated: In the context of withholdings made under the deliberative process privilege, the foreseeability requirement means that agencies must concretely explain how disclosure “would”—not “could”—adversely impair internal deliberations. [...] A perfunctory statement that disclosure of all the withheld information—regardless of category or substance—would jeopardize the free exchange of information between senior leaders within and outside of the agenc will not suffice. [...] Instead, what is needed is a focused and concrete demonstration of why disclosure of the particular type of material at issue will, in the specific context of the agency action at issue, actually impede those same agency deliberations going forward. Naturally, this inquiry is context specific. (See Reporters Committee for Freedom of the Press v. Federal Bureau of Investigation, 3 F.4th 350 (D.C. Cir 2021). Because of the agency's failure to identify any foreseeable harm, the deliberative privilege does not apply.

6. Executive privilege only applies to materials “'solicited and received’ by the President or his immediate White House advisors.” (See Judicial Watch, Inc., 365 F.3d at 1114 (quoting In re Sealed Case, 121 F.3d. 729, 752 (D.C. Cir. 1997)). It does not extend to other any documents that were not actually "submitted for Presidential consideration." (See Judicial Watch, Inc., 365 F.3d at 1114 (quoting In re Sealed Case, 121 F.3d. 729, 752 (D.C. Cir. 1997)).

Finally, in a similar fashion to my initial appeal, my login password to the FOIA portal has again been changed without my knowledge or permission by one of your agency's staff. Should you attempt to dispute this claim, I will not hesitate to request that a formal investigation be opened into the matter of whether or not my account was breached from within your agency and whether or not my password was changed during that breach. I have no doubts that such an investigation would end favorably for me.

However, I expect that sending my appeal to this email address (which is listed on your agency's website as the correct email address to send appeals) will be sufficient.

If you have any questions about this appeal, please feel free to contact me at this email address. If a phone conversation is necessary, please provide a phone number where I can reach you directly.

Thank you for your consideration of this appeal.

Sincerely,

Erin Marie Miller
MuckRock News Dept.
411A Highland Ave
Somverville, Massachusetts 02144
via email: 122531-15298170@requests.muckrock.com