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FDA FREEDOM OF INFORMATION ACT APPEAL

SUBMITTED VIA EMAIL October 14, 2022

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
FDAFOIA@fda.hhs.gov

Re: *Appeal of FOIA Request #2022-4856 (IR#0802N)*

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, on June 30, 2022, we submitted a request for records from the files of Food and Drug Administration ("**FDA**") pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). The FDA designated the request as FOIA Control # 2022-4856 (the "**FOIA Request**"). On August 17, 2022, the FDA issued a final response to the FOIA Request (the "**Final Response**"). ICAN writes now to appeal the Final Response.

A. FOIA Control # 2022-4856 (IR#0802N)

On June 30, 2022, ICAN submitted a request to the FDA for the following documents:

> **All records related to Proportional Reporting Ratio (PRR) analyses performed "to identify AEs that are disproportionately reported relative to other AEs" pursuant to Sections 2.0, 2.3., and 2.3.1 of the VAERS Standard Operating Procedures for COVID-19. This should include, but not be limited to, all communications concerning PRR analyses including communications concerning any decision to not conduct PRR analyses.**
>
> **Information helpful to fulfilling the request: The FDA's Center for Biologics Evaluation and Research is the likely custodian of responsive records.**

(**Exhibit 1**.)[1] (Footnotes omitted)

B. FDA's Final Response

On August 17, 2022, FDA issued a final response letter. The letter stated in part,

> **Your request was received in the Center for Biologics Evaluation and Research on July 5, 2022.**
>
> **After a thorough and diligent investigation, a search of our records did not locate any documents responsive to your request.**

(**Exhibit 2**.)

C. Argument

FDA has failed to conduct an adequate search of the requested records. An agency's search is adequate only if it is "reasonably calculated to uncover all relevant documents." *Zemansky v. E.P.A.*, 767 F.2d 569, 571 (9th Cir. 1985) (quoting *Weisberg v. U.S. Dep't. of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984)) (internal quotation marks omitted). "An agency fulfills its obligations under FOIA if it can demonstrate *beyond material doubt* that its search was reasonably calculated to uncover all relevant documents." *Defs. of Wildlife v. United States Border Patrol,* 623 F. Supp. 2d 83, 91 (D.D.C. 2009) (quoting *Valencia-Lucena v. U.S. Coast Guard,* 180 F.3d 321, 325 (D.C. Cir. 1999)) (emphasis added). To satisfy its FOIA obligations, an agency needs to adequately describe the scope and methods of its searches, which can reasonably be expected to uncover the records sought and demonstrate that the places most likely to contain responsive materials were searched. *Davidson v. E.P.A*., 121 F. Supp. 2d 38, 39 (D.D.C. 2000). At minimum, the agency must specify "what records were searched, by whom, and through what process." *Steinberg v. U.S. Dep't. of Justice*, 23 F.3d 548, 552 (D.C. Cir. 1994).

To determine whether a search for responsive records was adequate, a court must first determine the scope of the documents the plaintiff requested. *Wallick v. Agric. Mktg. Serv*., 281 F. Supp. 3d 56, 66 (D.D.C. 2017). It has been long established that an agency has a duty to construe FOIA requests liberally. *Hemenway v. Hughes*, 601 F. Supp. 1002, 1005 (D.D.C. 1985); *Conservation Force v. Ashe*, 979 F. Supp. 2d 90, 100-104 (D.D.C. 2013); *Rodriguez v. DOD*, 236 F. Supp. 3d 26, 36-38 (D.D.C. 2017). This means an agency is compelled to interpret requests broadly, even if a narrower reading is also reasonable. *Id*. An agency has a duty under the FOIA to select the interpretation that would likely yield the greatest number of responsive documents. *Conservation Force*, 979 F. Supp. 2d at 102; *Nat'l Sec. Counselors v. CIA*, 849 F. Supp. 2d 6, 12 (D.D.C. 2012). Technical precision is not required in FOIA requests, and a request certainly should not fail where the agency knew or should have known what the requester was seeking all along. *Institute for Justice v. Internal Revenue Service,* 941 F.3d 567, 572 (D.C. Cir. 2019). An

[1] All "Exhibits" referenced herein are appended to this letter.

"agency may [not] ignore what it cannot help but know." *Kowalcyk v. DOJ*, 73 F.3d 386, 389 (D.C. Cir. 1996). A court can conclude a search is inadequate when the facts reveal a "positive indication of overlooked materials." *Valencia-Lucena v. United States Coast Guard*, 180 F.3d 321, 326 (D.C. Cir. 1999).

FDA's search was inadequate for three reasons. First, FDA's Final Response failed to specify what records were searched, by whom, and through what process. *Steinberg*, 23 F.3d 552. Therefore, FDA did not fulfill its obligations under FOIA of demonstrating beyond material doubt that its search was reasonably calculated to uncover all relevant documents. *Valencia-Lucena,* 180 F.3d at 325.

Second, it unclear whether FDA liberally construed the FOIA Request. The FOIA Request contains, at least, three major elements:

(1) All records related to Proportional Reporting Ratio (PRR) analysis performed to identify AEs that are disproportionately reported relative to other AEs' pursuant to Sections 2.0, 2.3., and 2.3.1 of the VAERS Standard Operating Procedures for COVID-19;
(2) All communications concerning PRR analyses; and
(3) Communications concerning any decision to not conduct PRR analyses.

(**Exhibit 1**.) FDA's Final Response does not adequately describe its search, therefore, it is impossible to know whether it properly interpreted the scope of the request; or searched for each element of the request. Furthermore, despite the request indicating that the "FDA's Center for Biologics Evaluation and Research is the likely custodian of responsive records," it should have not precluded FDA from searching other divisions it should have reasonably known were likely to possess responsive records. *Conservation Force*, 979 F. Supp. 2d at 102; *Institute for Justice,* 941 F.3d at 572. *Kowalcyk*, 73 F.3d at 389.

Lastly, and notably, there is a positive indication of overlooked materials. In response to an identical request sent to the Centers of Disease Control and Prevention ("**CDC**"), CDC indicated that,

> **it was determined that the Proportional Reporting Ratio (PRR) analyses would not be performed. Instead, the U.S. Food and Drug Administration (FDA) performs Empirical Bayesian (EB) data mining with VAERS data.**

(**Exhibit 3**.) However, despite CDC claiming otherwise, according to a recent letter issued by CDC's Director Rochelle Walensky, PRR analyses and communications took place before and during the processing of theses FOIA requests concerning PRR analyses and communications. In the letter, Dr. Walensky stated, "CDC performed PRR analysis between March 2022, through July 31, 2022 to corroborate the results of EB data mining. Notably, **results from PRR analysis** were generally consistent with EB data mining…" (**Exhibit 4**) (emphasis added). This statement acknowledges that PRR analyses were carried out and that results of those analyses exist – those analyses and results fall squarely within this Request.

Based on Dr. Walensky's statements, and interagency memoranda, its likely FDA was involved with the relevant PPR analyses, or at the very least, possesses records or communications relating to the PPR analyses conducted by the CDC. For example, according to an interagency memorandum between the CDC and FDA concerning VAERS, FDA responsibilities include:

- **Lead product specific safety surveillance for all US licensed vaccines, including data mining and other pharmacovigilance methods, with adjusted schedules as needed for seasonal influenza products, newly licensed vaccines, and product specific outcomes of interest. Generally this will include clinical review for all serious reports including deaths.**
- **Perform[ing] regulatory science research on VEAERS cases to enhance vaccine safety, including methods for statistical and epidemiologic analysis and biomarker discovery.**

(**Exhibit 5** at 2.) Dr. Walensky's letter states that "CDC **and the Food and Drug Administration (FDA)** chose to rely on Empirical Bayesian (EB) data mining" and that PRR was used to "corroborate the results of EB data mining." (Exhibit 4) (emphasis added).

Moreover, within this interagency memorandum, under the title "CDC/FDA Shared Responsibilities," it states both agencies have a responsibility to,

- **Share/collaborate on vaccine safety signals of importance and vaccine safety concerns that arise**
- **Communicate and asses VAERS data in CDC/FDA monthly meetings**

Id.

Therefore, in light of the responsibilities outlined by the interagency memoranda concerning VAERS, and in light of the admissions in Dr. Walensky's letter, it is likely FDA would have received or created some records regarding the PPR analyses or communications of the same. Thus, these facts reveal a positive indication of overlooked materials. *Valencia-Lucena*, 180 F.3d at 326.

For all the reasons detailed above, FDA has failed to demonstrate beyond a material doubt that its search was reasonably calculated to uncover all relevant documents. *Valencia-Lucena,* 180 F.3d at 325; *Campbell*, 164 F.3d at 28. Therefore, its search was not adequate.

D. Appellate Request

Given the foregoing, ICAN hereby appeals and requests that the documents responsive to the FOIA Requests be produced within 20 days of this appeal. Thank you for your time and

attention to this matter. If you require any additional information, please contact us at **(212) 532-1091** or through email at **foia@sirillp.com**.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin Farnsworth, Esq.

Enclosures

Exhibit 1

Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI
PHOENIX | DETROIT | DENVER | AUSTIN

200 Park Avenue, 17th Floor, New York, NY 10166
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FDA FREEDOM OF INFORMATION ACT REQUEST

VIA ONLINE PORTAL June 30, 2022

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857

Re: "Proportional Reporting Ratio" – VAERS Standard Operating Procedures for COVID-19 (IR#0802N)

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, please provide the following records to foia@sirillp.com in electronic form:

> **All records related to Proportional Reporting Ratio (PRR) analyses performed "to identify AEs that are disproportionately reported relative to other AEs" pursuant to Section 2.0, 2.3., and 2.3.1 of the VAERS Standard Operating Procedures for COVID-19.[1] This should include, but not be limited to, all communications concerning PRR analyses including communications concerning any decision to not conduct PRR analyses.**
>
> **Information helpful to fulfilling the request: The FDA's Center for Biologics Evaluation and Research is the likely custodian of responsive records.**

We ask that you waive any and all fees or charges pursuant to 5 U.S.C. § 552(a)(4)(A)(iii). ICAN is a not-for-profit news media organization whose mission is to raise public awareness about vaccine safety and to provide the public with information to give informed consent. (**Exhibit A**.) As part of its mission, ICAN actively investigates and disseminates information regarding vaccine

[1] *See* https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.

safety issues for free, including through its website,[2] a weekly health news and talk show,[3] and through press events and releases. ICAN is seeking the information in this FOIA request to allow it to contribute to the public understanding of the government's vaccine safety programs, including the government's efforts to promote vaccine safety. The information ICAN is requesting will not contribute to any commercial activities. Therefore, ICAN should be properly categorized as a media requester, and it is entitled to the search and processing privileges associated with such a category designation. Accordingly, ICAN will be forced to challenge any agency decision that categorizes it as any other category of requester.

Please note that the FOIA provides that if only portions of a requested file are exempted from release, the remainder must still be released. We therefore request that we be provided with all non-exempt portions which are reasonably segregable. We further request that you describe any deleted or withheld material in detail and specify the statutory basis for the denial as well as your reasons for believing that the alleged statutory justification applies. Please also separately state your reasons for not invoking your discretionary powers to release the requested documents in the public interest. Such statements may help to avoid unnecessary appeal and litigation. ICAN reserves all rights to appeal the withholding or deletion of any information.

Access to the requested records should be granted within twenty (20) business days from the date of your receipt of this letter. Failure to respond in a timely manner shall be viewed as a denial of this request and ICAN may immediately take further administrative or legal action.

Furthermore, we specifically request that the agency provide us with an estimated date of completion for this request.

If you would like to discuss our request or any issues raised in this letter, please feel free to contact us at (212) 532-1091 or foia@sirillp.com during normal business hours. Thank you for your time and attention to this matter.

Very truly yours,

/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Colin M. Farnsworth Esq.

[2] https://www.icandecide.org/.

[3] https://thehighwire.com/.

Exhibit A

DECLARATION OF CATHARINE LAYTON

STATE OF TEXAS

COUNTY OF Hays

I, Catharine Layton, being duly sworn on oath do say:

1. I am the Chief Operating Officer of the Informed Consent Action Network (ICAN), a not-for-profit 501(c)(3) organization whose mission is to disseminate scientific health information to the public.

2. I have been an officer of ICAN since its founding in 2016. I oversee all day-to-day operations of the organization and all ICAN's programs. Together with our CEO and Board, I ensure that all efforts are focused on our mission statement and ensure that ICAN stays in compliance with all required rules and regulations.

3. In pursuit of its mission, ICAN relies primarily on its own investigative reporting. ICAN is both instrumental in orchestrating cutting edge investigations into the safety of various medical products, as well as widely disseminating its findings through various media channels. Most notably, ICAN's popular website hosts the organization's largest education program, The HighWire with Del Bigtree. Utilizing its media teams' 40+ years of experience in TV production and investigative journalism, The HighWire provides hours of new video content to the public each week for free.

4. The HighWire website has approximately 3.4 million weekly visitors. On Twitter, The HighWire has approximately 140,000 followers and 1 to 2.5 million impressions in a 28-day period. Between Rumble and Bitchute, The HighWire has approximately 60,000 followers and growing. Additionally, ICAN has 29,000 text subscribers and 194,245 email subscribers.

5. The size of ICAN's audience and subscribers continues to grow and is illustrative of the wide public interest in the subject of health and medical safety. Moreover, critical to ICAN's mission is its proven ability to find and review critical scientific and governmental records and meaningfully report about their social impacts.

6. One of the tools ICAN uses to gather the raw material it uses in its popular investigative reporting is the Freedom of Information Act (FOIA).

7. ICAN uses records it obtains from its FOIA requests to carry out its public mission and support its role as a non-profit news-media organization in the field of health and medical safety, but as a non-profit, ICAN does not have a commercial interest in the records it seeks through FOIA.

8. Based on what I know as the Chief Operating Officer, as well what has been demonstrated by ICAN's past and current investigative reporting, for purposes of FOIA's Fee Waiver provisions, ICAN certainly qualifies as a "representative of the news media."

Signed 3 day of May 2022

Signature of Catharine Layton

I, Amy Blackwell Notary public for the state of Texas witnessed said Catharine Layton sign the above statement this 3 day of May (month), 2022

Notary Public for

AMY MARIE BLACKWELL
Notary ID #132597493
My Commission Expires
July 30, 2024

Exhibit 2

August 17, 2022

Aaron Siri, Esq.
Siri & Glimstad LLP
200 Park Avenue Ste 3300
New York, NY 10166

In reply refer to file: 2022-4856 (IR# 0802N)

Dear Mr. Siri,

This letter is in reply to your Freedom of Information Act request dated June 30, 2022, in which you requested "All records related to Proportional Reporting Ratio (PRR) analyses performed "to identify AEs that are disproportionately reported relative to other AEs" pursuant to Section 2.0, 2.3., and 2.3.1 of the VAERS Standard Operating Procedures for COVID-19." Your request was received in the Center for Biologics Evaluation and Research on July 5, 2022.

After a thorough and diligent investigation, a search of our records did not locate any documents responsive to your request.

You have the right to appeal this determination. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of this response, to:

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

Please clearly mark both the envelope and your letter "FDA Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact Sarah Kotler at 301-796-8976.

If you are not satisfied with any aspect of the processing and handling of this request, please contact:

Ms. Suzann Burk
Director, Division of Disclosure and Oversight Management
Office of Communication Outreach and Development
Center for Biologics Evaluation and Research (CBER)
U.S. Food and Drug Administration (FDA)
20903 New Hampshire Avenue
E-mail: suzann.burk@fda.hhs.gov
Direct Phone: 240-402-8028
Main Phone: 240-402-7800

You may also contact the FDA FOIA Public Liaison for assistance at:

Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road–OGIS
College Park, MD 20740-6001
Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Fax: 202-741-5769
E-mail: ogis@nara.gov

If you have any questions or if I can be of further assistance, please let me know by referencing the above file number. You can contact me by phone at 240-402-8001 or by e-mail at Elizabeth.Sly@fda.hhs.gov.

Sincerely,

Elizabeth A. Sly -S Digitally signed by Elizabeth A. Sly -S
Date: 2022.08.17 14:20:56 -04'00'

for

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch
Center for Biologics Evaluation and Research
Food and Drug Administration

Exhibit 3

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

SENT VIA EMAIL

July 29, 2022

Aaron Siri
Attorney
Siri & Glimstad
200 Park Avenue, 17th Floor
New York, New York 10166
foia@sirillp.com

2nd Letter Subject: Final Response Letter

Dear Mr. Siri:

The Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) received your June 30, 2022, Freedom of Information Act (FOIA) request on June 30, 2022, seeking:

> "All records related to Proportional Reporting Ratio (PRR) analyses performed "to identify AEs that are disproportionately reported relative to other AEs" pursuant to Sections 2.0, 2.3., and 2.3.1 of the VAERS Standard Operating Procedures for COVID-19. This should include, but not be limited to, all communications concerning PRR analyses including communications concerning any decision to not conduct PRR analyses.
>
> Information helpful to fulfilling the request: The CDC's Immunization Safety Office is the likely custodian of responsive records."

A search of our records failed to reveal any documents pertaining to your request. The CDC National Center for Emerging and Zoonotic Infectious Diseases (NCEZID) Division of Healthcare Quality Promotion (DHQP) Immunization Safety Office (ISO) relayed the following:

> *There are no written communications regarding the use of EB over PRR for purposes of signal detection.*
>
> *The VAERS Standard Operating Procedures (SOP) is a planning document for internal use by CDC with collaborating partners. It is a dynamic document this is used, revised, and implemented based on the current science of the COVID-19 pandemic. Please see the "Disclaimer" excerpt from the SOP below.*
>
> > *"Disclaimer: This document is a draft planning document for internal use by the Centers for Disease Control and Prevention, with collaborating contractors. Numerous aspects (including but not limited to specific adverse events to be monitored, timeframes for report processing, data elements to be reported, and data analysis) are dynamic and subject to change without notice."*
>
> *Therefore, it was determined that the Proportional Reporting Ratio (PRR) analyses would not be performed. Instead, the U.S. Food and Drug Administration (FDA) performs Empirical Bayesian (EB) data mining with VAERS data. EB data mining is a statistical method of detecting disproportionate reporting and is considered the "gold standard" for disproportionality analysis.*

There are no written communications regarding the use of EB over PRR for purposes of signal detection. EB has been used for years for this purpose. It is widely accepted as the choice method for detecting potential safety signals (with passive pharmacovigilance data, at least), and thus was assumed to be the preferred method of detecting safety signals among COVID-19 vaccines. PRR is included in the SOP as a potential alternative or adjunct method, but EB was always understood to be the superior method.

For more information, please see the below links:

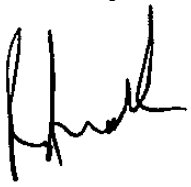
https://link.springer.com/article/10.2165/00002018-200225060-00001
Use of Screening Algorithms and Computer Systems to Efficiently Signal Higher-Than-Expected Combinations of Drugs and Events in the US FDA's Spontaneous Reports Database | SpringerLink

https://onlinelibrary.wiley.com/doi/10.1002/pds.1107
Comparing data mining methods on the VAERS database - Banks - 2005 - Pharmacoepidemiology and Drug Safety - Wiley Online Library

You may contact our FOIA Public Liaison at 770-488-6277 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 by writing 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?aspxerrorpath=/App/Index/aspx. or via e-mail at FOIARequest@psc.hhs.gov or via mail at Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by October 27, 2022.

Sincerely,



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

#22-01788-FOIA

Exhibit 4

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

September 2, 2022

The Honorable Ron Johnson
United States Senate
Washington, DC 20510

Dear Senator Johnson:

Thank you for your letters dated June 23 and July 25, 2022, regarding the Centers for Disease Control and Prevention's (CDC) tracking of reports of coronavirus disease 2019 (COVID-19) vaccine adverse events.

The Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures (SOP) for COVID-19 is a CDC planning document developed with internal and external partners, including federal entities.[1] Within the VAERS SOP disclaimer it states, the VAERS SOP was designed to be a dynamic resource that is used, revised, and implemented based on the current science of the COVID-19 pandemic and has since been updated from the version referenced in Freedom of Information Act (FOIA) Request #22-01479 and mentioned in your letters.[2]

The weekly data tables that were produced during the time period of February 26, 2021, to September 30, 2021, were provided to the FOIA requester and are included as an addendum to this response. The reported incident counts reflect preliminary information, details of which might not have been confirmed by a medical provider interview or medical record review.[3] Revised descriptions of the weekly tables and the information they provide are also found in the updated VAERS SOP.

Regarding your question about the use of proportional reporting ratio (PRR) analysis, CDC and the Food and Drug Administration (FDA) chose to rely on Empirical Bayesian (EB) data mining—a more robust technique used to analyze disproportionate reporting—rather than PRR calculations to mitigate potential false signals. CDC performed PRR analysis between March 25, 2022, through July 31, 2022, to corroborate the results of EB data mining. Notably, results from PRR analysis were generally consistent with EB data mining, revealing no additional unexpected safety signals. CDC also recently addressed a previous statement made to the *Epoch Times* to clarify PRRs were not run between February 26, 2021, to September 30, 2021. Given the strength of the EB data mining method, CDC and FDA plan to continue relying upon EB data mining moving forward.

[1] www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf
[2] www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-02-02-2022-508.pdf
[3] https://vaers.hhs.gov/data.html

CDC consistently performs extensive data collection and analysis to detect potential adverse events and safety signals and then communicates this information to the public. For example, VAERS staff conducted assessments showing that causal associations exist between thrombosis with thrombocytopenia syndrome and Janssen's COVID-19 vaccine and between myocarditis and mRNA COVID-19 vaccination. The outcomes of this work were presented at multiple Advisory Committee on Immunization Practices[4] meetings, and were published in the biomedical literature—which, in turn, informed national vaccine policy.

I appreciate your letter and support, and that of Congress overall, as we work together to fight COVID-19. CDC remains committed to leading with science, promoting equity, and protecting the American public during this pandemic. If you have further questions, please have your staff contact Jeff Reczek in our CDC Washington Office at (202) 245-0600 or JReczek@cdc.gov.

Sincerely,

Rochelle P. Walensky, MD, MPH
Director, CDC

[4] www.cdc.gov/vaccines/acip/index.html

Exhibit 5

Terms of Reference Document
Between the
Centers for Disease Control and Prevention, (CDC)
Coordinating Centers for Infectious Diseases (CCID)
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Division of Healthcare Quality Promotion (DHQP)
Immunization Safety Office (ISO)
And
Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Division of Epidemiology (DE)
Office of Biostatistics and Evaluation (OBE)

I. PURPOSE: This terms of reference agreement establishes a cooperative relationship with the Centers for Disease Control and Prevention (CDC), Immunization Safety Office (ISO), Division of Healthcare Quality Promotion(DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), and the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research(CBER), Division of Epidemiology(DE), Office of Biostatistics and Evaluation(OBE) through which the agencies will collaborate on conducting safety surveillance for vaccines through the Vaccine Adverse Event Reporting System (VAERS) and related activities. CDC and FDA have a common goal of monitoring the safety of vaccines to promptly detect vaccine safety concerns, which they do utilizing a variety of tools.

In 1986, the National Childhood Vaccine Injury Act (NCVIA)[1] was passed, requiring health care providers to report adverse events following immunization. In response to this mandate, VAERS was developed, to be co-administered by the FDA and the CDC. VAERS is a national passive reporting system that accepts reports from healthcare providers, vaccine manufacturers, vaccinees and others on adverse events associated with vaccines primarily licensed in the United States. During 2006-2010, approximately 33,000 VAERS reports (foreign + domestic) were filed annually, with 14.3% classified as serious (resulting in disability, hospitalization, prolongation of hospitalization, life-threatening illness or death). VAERS received an average of 28,000 US primary reports during 2006-2010 and of those, 8% were serious.

CDC and FDA share common goals in protecting public health. However, there are both similarities and differences in responsibilities based on the mission and role of each agency to enhance vaccine safety.

FDA licenses vaccines and monitors the safety of US-licensed vaccine products and regulates their production. Their focus is regulatory in nature. FDA has agency-wide expertise in product/brand specific safety, lot safety and data mining. Additionally, FDA has subject matter experts for pre-licensure vaccine trials.

CDC also monitors vaccine safety as part of a comprehensive national vaccine program. CDC collaborates closely with states, immunization programs, and the Advisory Committee on Immunization Practices (ACIP)[2]. CDC has agency-wide expertise in outbreak and field investigations and subject matter experts and lab capacity for vaccine-preventable diseases.

The objectives of VAERS are divided into two categories and we have outlined roles and responsibilities of each agency for each of these categories.

1) Scientific and Public Health Response
    1. Detect new, unusual, or rare vaccine adverse events (VAEs)
    2. Assess the safety of newly licensed vaccines and/or newly recommended vaccines
    3. Identify vaccine lots with increased numbers or types of reported adverse events
    4. Identify potential risk factors in vaccinees for particular types of adverse events
    5. Monitor trends in known adverse events, particularly increases

FDA Responsibilities[3]

- Lead product specific safety surveillance for all US licensed vaccines, including data mining and other pharmacovigilance methods, with adjusted schedules as needed for seasonal influenza products, newly licensed vaccines, and product specific outcomes of interest. Generally this will include clinical review for all serious reports including deaths.
- Perform regulatory science research on VAERS cases to enhance vaccine safety, including methods for statistical and epidemiologic analysis and biomarker discovery.
- Support monitoring of vaccine quality including lot specific analysis of adverse events as needed.
- Serve as primary point of contact regarding VAERS communications with vaccine manufacturers, except as noted under Advisory Committee on Immunization Practices, below.
- Executes Food and Drug Administration Amendments Act of 2007 (FDAAA) mandated adverse event reporting

CDC Responsibilities

- Lead safety surveillance for CDC priority vaccines including monitoring reporting trends over time
- Do outcome focused safety surveillance (e.g. intussusception after rotavirus vaccines)
- Perform seasonal influenza vaccine safety monitoring (not including product specific monitoring)
- Update the Advisory Committee on Immunization Practices (ACIP) on VAERS data related to newly licensed or newly recommended vaccines when requested
- Monitor ACIP recommendations that are not licensed ("off-label" recommendations)
- Serve as primary point of contact for VAERS communications with CDC vaccine programs, laboratory activities, and ACIP

CDC/FDA Shared Responsibilities

- Share/collaborate on vaccine safety signals of importance and vaccine safety concerns that arise
- Perform clinical review of VAERS reports
- Consult routinely and have ongoing discussions on all new vaccines and CDC priority vaccines.
- Write peer-reviewed scientific surveillance summary publications
- Communicate and assess VAERS data in CDC/FDA monthly meetings
- Provide support to the other agency on high priority projects when feasible (e.g. advisory committee meetings)
- Jointly plan and implement communication and scientific publications/abstracts around VAERS activities particularly new vaccine safety concerns and high profile issues
- Perform VAERS safety surveillance of special population (e.g. pregnant women)

2) Programmatic/Informational Technology Infrastructure

1. Provide a reporting mechanism for VAEs that maintain submitted report
2. Ensure data in the VAERS reports are reported and accessible to the public as required by law and International Requirements (P.L. 99-660, section 2125, FDAAA[4], ICH E2B(R3)[5], 21 CFR Parts 310, 314, and 600[6]), and in accordance with policies to protect individual's privacy

3. Support CDC and FDA scientific staff in using VAERS data to rapidly respond to vaccine safety concerns or public health emergencies and in conducting epidemiologic and other scientific studies
4. Provide information and education about the VAERS program, reporting methods and requirements and the VAERS data to vaccine providers, state health departments and the public through the VAERS website and other venues
5. Provide support to state health departments, including quarterly transmission of reports submitted from state health department officials

FDA Responsibilities

- Lead Freedom of Information Act (FOIA) responses
- Lead agency specific inquiries (e.g. foreign matter in vaccine vial)
- Participate in VAERS contract management
- Provide technical consultation to CDC on VAERS requirements for regulatory science, regulatory reporting[2] and harmonization[3], including specifications for data transfers from manufacturers to VAERS.
- Participate in VAERS follow-up activities
- Provide technical specification development regarding data transfer requirements from manufacturers to the VAERS system

CDC Responsibilities

- Lead and manage VAERS contract
- Ensure that security and privacy standards are maintained in VAERS under the direction of the CDC IT Security group
- Lead follow-up activity of VAERS reports
- Respond to public, clinician and state inquiries (excluding FOIA, regulatory and controlled correspondence)
- Develop and maintain VAERS Wide-ranging Online Data for Epidemiologic Research (WONDER) and VAERS downloadable data for the public
- Serve as the primary point of contact to states for VAERS issues
- Provide education and outreach regarding VAERS
- Provide the mechanism for data transfers from manufacturers to the VAERS system with technical guidance from FDA

CDC/FDA Shared Responsibilities

- Each agency provides support to the other for programmatic and IT tasks that the other agency leads
- Participate in VAERS coding issues

References:

1. The National Childhood Vaccine Injury Act of 1986, at Section 2125 of the Public Health Service Act as codified at 42 U.S.C. §300aa- (Suppl.1987)
2. Advisory Committee on Immunization Practices (ACIP) Charter available at http://www.cdc.gov/vaccines/recs/acip/charter.htm
3. U.S. National Vaccine Plan, 2010, Appendix 3. National Vaccine Program Office, U.S. Department of Health and Human Services. Available at http://www.hhs.gov/nvpo/vacc_plan/index.html. Accessed 5/4/2011.
4. Food and Drug Administration Amendment Act of 2007. http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/ucm184271.htm

5. International Conference on Harmonization E2B (R3) Guideline including ICSR M2 Version 2.3 Specification Document. Documents available at www.ICH.org. Accessed 5/4/2011.
6. 21 CFR Parts 310, 314, 600. FDA Mandatory Electronic Reporting Rule. Federal Register August 21, 2009.