Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
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FREEDOM OF INFORMATION ACT APPEAL
VIA ONLINE PORTAL August 19, 2021

Director, Office of the Executive Secretariat
US Food & Drug Administration
5630 Fishers Lane, Room 1050
Rockville, MD 20857

Re: **Appeal of FOIA Request Nos.: 2021-2759 (IR#0479); 2021-2761 (IR#0481); 2021-2954 (IR#0484); 2021-3130 (IR#0487)**

Dear Sir or Madam:

This firm represents Informed Consent Action Network ("**ICAN**"). On behalf of ICAN, we submitted four requests on April 22, 2021; April 26, 2021; May 4, 2021; and May 11, 2021 for records from the files of the Food and Drug Administration ("**FDA**")[1] pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("**FOIA**"). The FDA assigned the requests the following numbers: 2021-2759, 2021-2761, 2021-2954, and 2021-3130 respectively (the "**FOIA Requests**"). Thereafter, the FDA produced some documents responsive to the FOIA Requests while redacting and/or witholding portions of the responsive documents pursuant to 5 U.S.C. § 552(b)(3) and (b)(6) (the "Redacted Documents"). ICAN writes now to appeal (i) these redactions and/or witholdings and (ii) the adequacy of the search.

A. The FOIA Requests and Correspondance with the FDA

1. The First Request

On April 22, 2021, ICAN submitted a FOIA Request (the "**First Request**") to the Centers for Disease Control and Prevention ("**CDC**"). In the First Request, ICAN requested the following:

> All documents concerning VAERS Report No. 1074247.

(**Exhibit A.1**.)[2]

On April 23, 2021, the CDC issued an acknowledgement and assigned the number 21-01155-FOIA to the First Request. (**Exhibit A.2**.) On April 27, the CDC referred the First Request

[1] As explained further below, two of the four FOIA Requests were initially submitted to the Centers for Disease Control and Prevention, but were ultimately referred to the FDA.

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

to the FDA stating that the request falls under the FDA's jurisdiction. (**Exhibit A.3**.) On the same day, the FDA provided ICAN an acknowledgement and assigned the First Request the number 2021-2759. (**Exhibit A.4**.)

On May 21, 2021, the FDA produced 2 pages and a document titled "Important Information from the FDA About the Vaccine Adverse Event Reporting System (VAERS)" and responded to the First Request as follows:

> This is in reply to your Freedom of Information Act request dated April 22, 2021, in which you requested "all documents concerning VAERS report no. 1074247." Your request was received in the Center for Biologics Evaluation and Research on April 27, 2021.
>
> Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request.
>
> We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.
>
> In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

(**Exhibit A.5**.)

2. The Second Request

On April 26, 2021, ICAN submitted a second FOIA Request (the "**Second Request**") to the CDC. In the Second Request, ICAN requested the following:

> All documents concerning VAERS Report Nos. 1099241-1 and 1166062-1.

(**Exhibit B.1**.)

On April 26, 2021, the CDC issued an acknowledgement and assigned the number 21-01163-FOIA to the Second Request. (**Exhibit B.2**.) On April 27, the CDC referred the Second Request to the FDA stating that it fell under the FDA's jurisdiction. (**Exhibit B.3**.) On the same day, the FDA provided ICAN an acknowledgement assigning number 2021-2761 to the Second Request. (**Exhibit B.4**.)

On May 21, 2021, the FDA produced 4 pages and a document titled "Important Information from the FDA About the Vaccine Adverse Event Reporting System (VAERS)" and responded to the Second Request as follows:

> This is in reply to your Freedom of Information Act request dated April 26, 2021, in which you requested "all documents concerning VAERS report nos. 1099241-1 and 1166062-1." Your request was received in the Center for Biologics Evaluation and Research on April 27, 2021.
>
> Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request.
>
> We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.
>
> In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

(**Exhibit B.5**.)

With regard to VAERS Report Nos. 1099241, the FDA indicated that it withheld 28 pages in full pursuant to exemptions (b)(3)(A) and (b)(6). (**Exhibit B.6**.)

3. The Third Request

On May 4, 2021, ICAN submitted a third FOIA Request (the "**Third Request**") to the FDA. In the Third Request, ICAN requested the following:

> All documents concerning the following VAERS Report Nos.: 1187918, 1199455, 1218081, 1225942, 1242573, 1243487, 1243516.

(**Exhibit C.1**.)

On May 4, 2021, the FDA issued an acknowledgement and assigned the number 2021-2954 to the Third Request. (**Exhibit C.2**.)

On June 1, 2021, the FDA produced 18 pages and a document titled "Important Information from the FDA About the Vaccine Adverse Event Reporting System (VAERS)" and responded to the Third Request as follows:

> This is in reply to your Freedom of Information Act request dated May 4, 2021, in which you requested "all documents concerning the following VAERS report numbers:1187918, 1199455, 1218081, 1225942, 1242573, 1243487, 1243516." Your request was received in the Center for Biologics Evaluation and Research on May 4, 2021.
>
> Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request. Please note VAERS ID 1218081 and 1199455 are linked as well as VAERS ID 1225942 and 1243516.
>
> We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.
>
> In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

(**Exhibit C.3**.)

4. The Fourth Request

On May 11, 2021, ICAN issued a fourth FOIA Request (the "**Fourth Request**") to the FDA. In the Fourth Request, ICAN requested the following:

> All documents concerning the following VAERS Report Nos.: 1255745 and 1261766.

(**Exhibit D.1**)

On May 12, 2021, the FDA issued an acknowledgement and assigned the number 2021-3130 to the FOIA Request. (**Exhibit D.2**.)

On June 11, 2021, the FDA produced 6 pages and a document titled "Important Information from the FDA About the Vaccine Adverse Event Reporting System (VAERS)" and responded to the FOIA Request dated May 11, 2021 (Request Number 2021-3130) as follows:

> This is in reply to your Freedom of Information Act request dated May 12, 2021, in which you requested "all documents concerning the following VAERS report numbers: 1255745 and 1261766." Your request was received in the Center for Biologics Evaluation and Research on May 12, 2021.
>
> Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request.
>
> We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.
>
> In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

(**Exhibit D.3**.)

B. Argument

1. The FDA Failed to Conduct an Adequate Search to Uncover All Responsive Records

An agency's search is adequate only if it is "reasonably calculated to uncover all relevant documents." *Zemansky v. EPA*, 767 F.2d 569, 571 (9th Cir. 1985) (quoting *Weisberg v. U.S. Dept. of Justice*, 745 F.2d 1476, 1485 (D.C. Cir. 1984)) (internal quotation marks omitted). In the FOIA Requests, ICAN requested "**[a]ll documents** concerning the following VAERS Reports Nos:" 1074247 (the First Request), 1099241-1 and 1166062-1 (the Second Request), 1187918, 1199455, 1218081, 1225942, 1242573, 1243487, and 1243516 (the Third Request), and 1255745 and 1261766 (the Fourth Request). (Exhibits A.1, B.1, C.1, D.1.) (emphasis added). The FOIA Requests are broad enough to capture, *inter alia*, any and all reports, notes, email communications, memorandums, records, or any other document evidencing, discussing, or in any way relating to the VAERS reports identified in the FOIA Requests.

In response to each of the FOIA Requests, the FDA produced: (1) heavily redacted versions of the VAERS reports referenced in the FOIA Requests; and (2) a document titled "Important Information from the FDA About the Vaccine Adverse Event Reporting System (VAERS)." As to (1), the information in the FDA's production is, for the most part, the same information as is

available publicly through VAERS.[3] In some instances, the FDA even redacted information in its production that is publicly available and known to ICAN – for example, the date of death and state/territory of the patient.[4] In no circumstance did the FDA produce communications with the individual who made the reports, communications with any vaccine manufacturer regarding the reports, internal communications, notes or memoranda regarding the reports, or any other documents evidencing, discussing, or otherwise relating to the FOIA Requests.

CDC's VAERS Standard Operating Procedures for COVID-19 as of January 29, 2021 (the "SOP") defines death as an "adverse events of special interest" or a "serious report."[5] According to the SOP, CDC performs "clinical reviews" for adverse events of special interest, the "FDA routinely reviews all serious[] . . . reports daily and performs data mining," and "contractor staff . . . request additional information including" hospital records, autopsy reports, and medical records.[6] As to data mining, the SOP states that "FDA and CDC will share and discuss results of data mining analyses and signals."[7] In addition, CDC/FDA receive "daily e-mail alerts . . . with a list of VAERS ID numbers for all serious . . . reports of adverse events of special interest . . . after COVID-19 vaccines." The SOP further provides:

> Summaries (or other deliverables, as needed) will be based on data processing, coding and follow-up, automatied data, and clinical review, as well as field investifations as appropriate. COVID-19 vaccine safety coordination meetings among ISO team members and FDA will be scheduled weekly (or more frequently, as needed) to discuss results of the automated data and (if indicated) clinical review).[8]

Each of the VAERS reports at issue in the FOIA requests resulted in death. According to the SOP, therefore, FDA should have produced the 'clinical reviews,' daily reports, hospital records, autopsy reports, medical records, daily e-mail alerts, summaries, and any other document or communication concerning the VAERS reports referenced in each FOIA request. FDA's failure to produce these documents, which the SOP indicates exist, is a violation of the FDA's obligations under FOIA.

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[3] The only exception ICAN is aware of is that for VAERS ID No. 1187918, the FDA produced two separate reports, only one of which appeared in ICAN's search of the VAERS database.

[4] Copies of the publicly available data as compared to the data in the FDA's production for three of the VAERS reports at issue in the FOIA Requests are attached hereto as **Exhibit E**. For VAERS ID No. 107427-1, the FDA redacted the date the patient died (p. 4) even though that information is publicly available (p. 6). For VAERS ID No. 1099241, the FDA redacted the date the patient developed jaundice (p. 9) even though that information is publicly available (p. 11). Finally, for VAERS ID No. 1166062, the FDA redacted the date the patient died (p. 15) even though that information is publicly available (p. 17).

[5] https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at pp. 4, 7, 11 (last visited August 19, 2021).

[6] *Id.*

[7] *Id.* at 17.

[8] *Id.* at 11.

Further, the document titled "Important Information from the FDA About the Vaccine Adverse Event Reporting System (VAERS)," which the FDA produced in its response to each of the four FOIA Requests, states that "[i]n analyzing individual reports, [the FDA] examine[s] the medical information about the event, **and obtain[s] more specific information from the reporting doctors whenever necessary**." (**Exhibit F**.) Therefore, in addition to the documents referenced in the SOP, any documents reflecting or responding to a request by the FDA for "more specific information" should have been producedto ICAN.

Based on the above, the FDA has not demonstrated that it conducted an adequate search for all responsive records.

2. <u>The FDA's Final Response Letters Fail to Sufficiently Justify the Redactions and/or Witholdings Pursuant to Exemption 3</u>

The FDA failed to meet its burden of proving the applicability of Exemption 3 to the redacted and/or withheld records. Exemption 3 applies to prevent disclosure of matters that are exempted from disclosure by statute. . 5 U.S.C. § 552(b)(3). In *Ancient Coin Collectors Guild v. United States Department of State*, the D.C. Circuit Court stated "an agency withholding responsive documents from a FOIA request bears the burden of proving the applicability of the claimed exemptions." 641 F.3d 504, 509 (D.C. Cir. 2011) (citing *American Civil Liberties Union v. U.S. Dept. of Defense*, 628 F.3d 612, 619 (D.C. Cir.2011)). This can be accomplished through "[u]ncontradicted, plausible affidavits showing reasonable specificity and a logical relation to the exemption." *Id*. (citing *Larson v. Dep't of State*, 565 F.3d 857, 862 (D.C. Cir. 2009)). The FDA's Final Response letters merely state the statutory language without specifying which statute prevents the disclosure of the redacted and/or withheld records. This is insufficient to discharge the FDA's burden of proving the applicability of Exemption 3 under FOIA.

On May 25, 2021, Ms. Sonal Jain, then law clerk at Siri & Glimstad LLP, sent an email to Ms. Catherine Wilusz, the FOIA Officer at the FDA, inquiring about which federal statute the FDA was invoking to claim Exemption 3.[9] On June 22, 2021, Ms. Wilusz responded stating "the federal statute for the Exemption 3 redactions … is the National Childhood Vaccine Injury Act." ICAN also appeals the applicability of the National Childhood Vaccine Injury Act to justify redactions under Exemption 3. First, the National Childhood Vaccine Injury Act only applies to vaccines that appear on the Vaccine Injury Table codified at 42 U.S.C. § 300aa-14 (the "**Table**"). 42 U.S.C. § 300aa-11(b)(1)(A). COVID-19 vaccines do not appear on the Table. 42 U.S.C. § 300aa-14. According to the Health Resources and Services Administration, "COVID-19 vaccines are covered countermeasures under the Countermeasures Injury Compensation Program (CICP), not the National Vaccine Injury Compensation Program."[10] Second, Exemption 3 does not apply because the National Childhood Vaccine Injury Act neither "requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue" nor "establishes particular criteria for withholding or refers to particular types of matters to be withheld[.]" 5 U.S.C. §

[9] The email correspondence is attached hereto as **Exhibit G**.

[10] https://www.hrsa.gov/vaccine-compensation/faq#:~:text=Will%20the%20National%20Vaccine%20Injury,injured%20by%20COVID%2D19%20vaccine%3F&text=COVID%2D19%20vaccines%20are%20covered,National%20Vaccine%20Injury%20Compensation%20Program.

552(b)(3)(A). Therefore, the FDA has failed to meet its burden to show that Exemption 3 justifies the FDA's redactions.

For the same reasons, the FDA has also failed to meet its burden to show that Exemption 3 justifies any withholdings.

3. The FDA has Improperly Witheld Non-Private Information Which is not Linked to Any Identifiable Individual Under FOIA Exemption 6

The FDA also failed to meet its burden of proving the applicability of Exemption 6 to the redacted and/or withheld records. Exemption 6 applies to prevent disclosure of "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). When evaluating withholdings under Exemption 6, there is a "presumption in favor of disclosure [that] is as strong as can be found anywhere in the Act." *Multi Ag Media LLC v. U.S. Dep't of Agric.*, 515 F.3d 1224, 1227 (D.C. Cir. 2008) (quoting *Nat'l Ass'n of Homebuilders v. Norton*, 309 F.3d 26, *32 (D.C. Cir. 2002)). (internal quotation marks omitted). Therefore, an agency may withhold personal information only if "disclosure would compromise a substantial, as opposed to a *de minimis*, privacy interest." *Nat'l Ass'n of Retired Fed. Emps. v. Horner*, 879 F.2d 873, 875 (D.C. Cir. 1989). Courts have held that adverse event data, when not tied to a patient's personally identifying data "does not warrant redaction pursuant to Exemption 6." *Informed Consent Action Network v. Nat'l Inst. of Health*, No. CV-20-01277-PHX-JJT, 2021 U.S. Dist. LEXIS 118185, at *21 (D. Ariz. June 24, 2021) (citing *United States Dep't of State v. Ray*, 502 U.S. 164, 175-176 (U.S. 1991)). Furthermore, the public has a significant interest in reviewing adverse event data because it "will allow the public to better understand [the agency's] actions and bases for its decisions." *Id.* at *22.

The FDA's productions include myriad of redactions under Exemption 6 which are wholly improper. These redactions include, for example, the results or outcome of reported adverse event, portions of the description of the adverse event, and additional information collected. The FDA has not and cannot justify withholding this information in the VAERS reports because this information is not tied to any personally identifying information. ICAN is not seeking access to the names, addresses, or contact numbers of the patients. Without access to such personally identifying information, ICAN has no way to discover the identities of any of the patients reflected in the documents. Therefore, the disclosure of information related to the reported adverse event does not constitute an invation of any significant privacy interest.

For the same reasons, the FDA has also failed to meet its burden to show that Exemption 6 justifies any withholdings.

C. Appellate Request

Given the foregoing, ICAN hereby appeals and requests that the FDA conduct a diligent search to uncover all responsive documents to the FOIA Requests and produce the redacted and/or withheld materials within 20 days of this appeal. Thank you for your time and attention to this matter. If you require any additional information, please contact me at **(212) 532-1091** or through email at **foia@sirillp.com**.

Very truly yours,

/s/ Gabrielle G. Palmer
Gabrielle G. Palmer, Esq.

Enclosures

EXHIBIT A.1

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL April 22, 2021

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333
Fax: (404) 235-1852
Email: FOIARequests@cdc.gov

Re: Documents Concerning VAERS Report No. 1074247 (IR#0479)

Dear Mr. Andoh:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("FOIA"). Please provide the records in your possession via email to foia@sirillp.com:

All documents concerning VAERS Report No. 1074247.[1]

Request For Expedited Processing

ICAN requests expedited processing for this request. ICAN is "primarily engaged in disseminating information to the general public" and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

ICAN's mission is to raise public awareness about public health safety and to provide the public with information to give informed consent regarding related health interventions. The SARS-CoV-2, also known as COVID-19, pandemic has affected myriad aspects of every American's life.

Numerous experimental therapeutics and vaccines against COVID-19 are in development and those processes are highly publicized. Three of these vaccines are being widely distributed and used pursuant to Emergency Use Authorizations granted by the FDA, with one being recently paused due to safety concers.

[1] A copy of the report is attached herein as **Ex. 1**.

The attached VAERS report shows that a two-year old child died shortly after receiving the Pfizer vaccine. Pfizer is currently enrolling and conducting pediatric trials to determine the safety and efficacy of its COVID-19 vaccine and recently sought FDA authorization to start vaccinating children as young as 12 years.[2] Thus, there is an urgent need to inquire into the event reported through VAERS so that a timely and full investigation can be initiated into the same. Relatedly, institutions such as Coopertown Dream Park are requiring that all children 12 years of age and older be vaccinated against COVID-19 in order to participate in its camps,[3] despite none of the vaccines having been cleared for use in pediatric populations yet. Many other institutions are likely to follow suit. Therefore, there is an urgent need for ICAN to gather and disseminate additional information concerning these trials such that members of the public can fully understand the risks involved with these vaccines prior to vaccinating their children.

ICAN certifies that the information in the request is true and correct to the best of ICAN's knowledge and belief.

Fees and charges for this search are to be waived pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii) since ICAN is a not-for-profit 501(c)(3) organization and its mission is to raise public awareness about vaccine safety and provide the public with information to give informed consent. As part of its mission, ICAN investigates and disseminates information regarding vaccine safety, including through their website, 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 requested in this FOIA request will not contribute to any commercial activities.

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 of course 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 file an administrative appeal.

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

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[2] https://abcnews.go.com/Politics/pfizer-asks-regulators-give-vaccine-kids-young-12/story?id=76975422
[3] https://www.cooperstowndreamspark.com/2021-season-update

Very truly yours,

/s/ Elizabeth A. Brehm
Elizabeth A. Brehm, Esq.

EXHIBIT 1

VAERS Event Details

Details for VAERS ID: 1074247-1

Event Information			
Patient Age	2.00	**Sex**	Female
State / Territory	Virginia	**Date Report Completed**	2021-03-05
Date Vaccinated	2021-02-25	**Date Report Received**	2021-03-05
Date of Onset	2021-03-01	**Date Died**	2021-03-03
Days to onset	4		
Vaccine Administered By	Private	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	17
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	2	IM	RA

Symptom
DEATH

Adverse Event Description
Death

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time Of Vaccination	History/Allergies
	,

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats:

Data contains VAERS reports processed as of 4/10/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information. (/wonder/help/vaers.html#Reporting)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Apr 22, 2021 2:02:15 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/10/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Apr 22, 2021 2:02:15 PM

EXHIBIT A.2

S&G Information Request Staff

From: Centers for Disease Control and Prevention / Agency for Toxic Substances and Disease Registry <foiarequests@cdc.gov>
Sent: Friday, April 23, 2021 3:01 PM
To: S&G Information Request Staff
Subject: Request Acknowledgement by FOIA

Dear Elizabeth Brehm,

Case Number 21-01155-FOIA has been assigned to the request you submitted. In all future correspondence regarding this request please reference case number 21-01155-FOIA.

Regards,
FOIA

EXHIBIT A.3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

April 27, 2021

Elizabeth Brehm
Siri & Glimstad
200 Park Avenue
17th Floor
New York, NY 10166

Dear Ms. Brehm:

This letter is to acknowledge receipt of your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of April 22, 2021, regarding:

"IR0479 All documents concerning VAERS Report No. 1074247.1"

Your request has been referred to the Division of Freedom of Information for the Food and Drug Administration. The information you requested falls under their jurisdiction. Should you have questions about the status of your request, you may contact:

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

Sincerely,

Hana Medlin

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

cc:
Sarah Kotler, Director FDA FOIA

21-01155-FOIA

EXHIBIT A.4

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

April 27, 2021

Elizabeth Brehm
Siri & Glimstad
200 Park Avenue
17th Floor
New York, NY 10166
Via email: foia@sirillp.com

Dear Ms. Brehm:

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 April 22, 2021. Your request assigned number is 21-01155-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.

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 Hana Medlin at 404-498-4049 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.

Expedited Processing

You requested that we expedite processing your request. Your request is denied because:
- You have failed to show that there is an imminent threat to the life or physical safety of an individual.
- You have not demonstrated that you are a person primarily engaged in disseminating information.

Fees and Fee Waivers

You requested that we waive fees associated with processing your request, your request is denied because it doesn't meet the following criteria:
- You have failed to demonstrate that you disseminate information to the public.
- You have failed to provide enough information to warrant a waiver of fees.

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

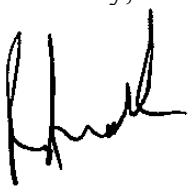
If you don't provide us with a date range for your request, the cut-off date for your request will be the date the search for responsive records starts.

Appeal Rights

You have the right to appeal the agency's expedited processing and fee waiver response to your request. You may mail your appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201.
You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Your appeal must be postmarked or electronically transmitted by July 26, 2021.

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 Hana Medlin at 404-498-4049 or via email at qoo2@cdc.gov.

Sincerely,



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

21-01155-FOIA

EXHIBIT A.5

U.S. FOOD & DRUG ADMINISTRATION

May 21, 2021

Elizabeth Brehm
Siri & Glimstad LLP
200 Park Ave. 17th Floor
New York, NY 10166

In reply refer to file: F21-2759

Dear Ms.Brehm,

This is in reply to your Freedom of Information Act request dated April 22, 2021, in which you requested "all documents concerning VAERS report no. 1074247." Your request was received in the Center for Biologics Evaluation and Research on April 27, 2021.

Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request.

We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

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 Katherine Uhl at 301-796-8975.

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 have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact Catherine Wilusz by phone at 240-402-8008 or by e-mail at Catherine.wilusz@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052489, cn=Beth A. Brockner Ryan -S
Date: 2021.05.21 14:21:14 -04'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch

EXHIBIT B.1

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL April 26, 2021

Roger Andoh
Freedom of Information Officer
Centers for Disease Control and Prevention
1600 Clifton Road, N.E., Building 57, Room MS D-54
Atlanta, Georgia 30333
Fax: (404) 235-1852
Email: FOIARequests@cdc.gov

Re: Documents Concerning VAERS Report No. 1099241-1 and 1166062-1. (IR#0481)

Dear Mr. Andoh:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("FOIA"). Please provide the records in your possession via email to foia@sirillp.com:

> **All documents concerning VAERS Report Nos. 1099241-1 and 1166062-1.**[1]

Request For Expedited Processing

ICAN requests expedited processing for this request. ICAN is "primarily engaged in disseminating information to the general public" and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

ICAN's mission is to raise public awareness about public health safety and to provide the public with information to give informed consent regarding related health interventions. The SARS-CoV-2, also known as COVID-19, pandemic has affected myriad aspects of every American's life.

Numerous experimental therapeutics and vaccines against COVID-19 are in development and those processes are highly publicized. Three of these vaccines are being widely distributed and used pursuant to Emergency Use Authorizations granted by the FDA, with one being recently paused due to safety concers.

[1] Copies of the VAERS reports are attached as **Ex. 1**.

The attached VAERS reports show that one infant died and another has been hospitalized shortly after their mothers received one of the COVID-19 vaccine with a possible transmission of vaccine components via breastmilk. While CDC maintains that there is "no data on the safety of COVID-19 vaccines in lactating people or the effects of COVID-19 vaccines on the breastfed infant or milk production or excretion," yet it continues to recommend the vaccine to lactating people.[2] Thus, there is an urgent need to inquire into the events reported through VAERS so that a timely and full investigation can be initiated into the same. There is also an urgent need for ICAN to gather and disseminate additional information concerning these events such that members of the public can fully understand the risks involved with these vaccines prior to vaccinating.

ICAN certifies that the information in the request is true and correct to the best of ICAN's knowledge and belief.

Fees and charges for this search are to be waived pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii) since ICAN is a not-for-profit 501(c)(3) organization and its mission is to raise public awareness about vaccine safety and provide the public with information to give informed consent. As part of its mission, ICAN investigates and disseminates information regarding vaccine safety, including through their website, 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 requested in this FOIA request will not contribute to any commercial activities.

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 of course 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 file an administrative appeal.

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

Very truly yours,

/s/ Elizabeth A. Brehm
Elizabeth A. Brehm, Esq.

[2] https://www.cdc.gov/vaccines/covid-19/info-by-product/clinical-considerations.html#pregnant

VAERS Event Details

Details for VAERS ID: 1099241-1

Event Information			
Patient Age	1.33	**Sex**	Female
State / Territory	California	**Date Report Completed**	2021-03-14
Date Vaccinated	2021-03-10	**Date Report Received**	2021-03-14
Date of Onset	2021-03-11	**Date Died**	
Days to onset	1		
Vaccine Administered By	Private	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	Unknown
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (JANSSEN))	JANSSEN	NONE	UNK		

Symptom
EXPOSURE VIA BREAST MILK
HAEMOLYTIC ANAEMIA
JAUNDICE

Adverse Event Description
Patient is breastfed by mother, who was vaccinated on 3/10. Patient developed jaundice 3/11, and was admitted for evaluation of hemolytic anemia. Evaluation ongoing. Likely not related to vaccine, but occurred within 2 days of possible to vaccine components via breastmilk

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	None	

Medications At Time Of Vaccination	History/Allergies
None	None,None

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats:

Data contains VAERS reports processed as of 4/16/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information. (/wonder/help/vaers.html#Reporting)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Apr 23, 2021 12:07:31 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/16/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Apr 23, 2021 12:07:31 PM

CDC WONDER FAQs Help Contact Us WONDER Search

VAERS Event Details

Details for VAERS ID: 1166062-1

Event Information			
Patient Age	0.42	**Sex**	Male
State / Territory	Unknown	**Date Report Completed**	2021-04-04
Date Vaccinated	2021-03-17	**Date Report Received**	2021-04-04
Date of Onset	2021-03-18	**Date Died**	2021-03-20
Days to onset	1		
Vaccine Administered By	Work *	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	2
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	2	SYR	LA

Symptom
DEATH
DIET REFUSAL
EMOTIONAL DISTRESS
EXPOSURE VIA BREAST MILK
FAILURE TO THRIVE
HEPATIC ENZYME INCREASED
PYREXIA
RASH
THROMBOTIC THROMBOCYTOPENIC PURPURA

Adverse Event Description
Patient received second dose of Pfizer vaccine on March 17, 2020 while at work. March 18, 2020 her 5 month old breastfed infant developed a rash and within 24 hours was inconsolable, refusing to eat, and developed a fever. Patient brought baby to local ER where assessments were performed, blood analysis revealed elevated liver enzymes. Infant was hospitalized but continued to decline and passed away. Diagnosis of TTP. No known allergies. No new exposures aside from the mother's vaccination the previous day.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time Of Vaccination	History/Allergies
	,

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats:

Data contains VAERS reports processed as of 4/16/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information. (/wonder/help/vaers.html#Reporting)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Apr 23, 2021 12:10:16 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/16/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Apr 23, 2021 12:10:16 PM

EXHIBIT B.2

S&G Information Request Staff

From: Centers for Disease Control and Prevention / Agency for Toxic Substances and Disease Registry <foiarequests@cdc.gov>
Sent: Monday, April 26, 2021 11:31 AM
To: S&G Information Request Staff
Subject: Request Acknowledgement by FOIA

Dear Elizabeth Brehm,

Case Number 21-01163-FOIA has been assigned to the request you submitted. In all future correspondence regarding this request please reference case number 21-01163-FOIA.

Regards,
FOIA

EXHIBIT B.3

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

April 27, 2021

Elizabeth Brehm
Siri & Glimstad
200 Park Avenue
17th Floor
New York, NY 10166

Dear Ms. Brehm:

This letter is to acknowledge receipt of your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of April 26, 2021, regarding:

"IR0481 All documents concerning VAERS Report Nos. 1099241-1 and 1166062-1.1."

Your request has been referred to the Division of Freedom of Information for the Food and Drug Administration. The information you requested falls under their jurisdiction. Should you have questions about the status of your request, you may contact:

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

Sincerely,

Hana Medlin

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

cc:
Sarah Kotler, Director FDA FOIA

21-01163-FOIA

EXHIBIT B.4

FDA U.S. FOOD & DRUG ADMINISTRATION

April 27, 2021

SIRI & GLIMSTAD LLP
ELIZABETH BREHM
200 PARK AVE 17TH FLOOR
NEW YORK NY 10166 USA

In Reply refer to
FOIA Control #:
2021-2761

Requester reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

VAERS REPORT RECORDS

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Claire B. Stansbury, Information Technician, at (301) 796-8979 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

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

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

EXHIBIT B.5

U.S. FOOD & DRUG ADMINISTRATION

May 21, 2021

Elizabeth Brehm
Siri & Glimstad LLP
200 Park Ave. 17th Floor
New York, NY 10166

In reply refer to file: F21-2761

Dear Ms.Brehm,

This is in reply to your Freedom of Information Act request dated April 26, 2021, in which you requested "all documents concerning VAERS report nos. 1099241-1 and 1166062-1." Your request was received in the Center for Biologics Evaluation and Research on April 27, 2021.

Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request.

We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

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 Katherine Uhl at 301-796-8975.

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 have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact Catherine Wilusz by phone at 240-402-8008 or by e-mail at Catherine.wilusz@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300052489, cn=Beth A. Brockner Ryan -S
Date: 2021.05.21 14:22:22 -04'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch

EXHIBIT C.1

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL May 4, 2021

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857
FDAFOIA@fda.hhs.gov

Re: Documents Concerning VAERS Reports Reflecting Death of Minors. (IR#0484)

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("FOIA"). Please provide the records in your possession via email to foia@sirillp.com:

> **All documents concerning the following VAERS Report Nos.: 1187918, 1199455, 1218081, 1225942, 1242573, 1243487, 1243516[1]**

Request For Expedited Processing

ICAN requests expedited processing for this request. ICAN is "primarily engaged in disseminating information to the general public" and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

ICAN's mission is to raise public awareness about public health safety and to provide the public with information to give informed consent regarding related health interventions. The SARS-CoV-2, also known as COVID-19, pandemic has affected myriad aspects of every American's life.

Numerous experimental therapeutics and vaccines against COVID-19 are in development and those processes are highly publicized. Three of these vaccines are being widely distributed and used pursuant to Emergency Use Authorizations granted by the FDA.

[1] Copies of the reports are attached herein as **Ex. 1**.

The attached VAERS reports show that at least six minors have died shortly after receiving one of the COVID-19 vaccines due to a cardiac arrest. Thus, there is an urgent need to inquire into the events reported through VAERS so that a timely and full investigation can be initiated into the same. There is also an urgent need for ICAN to gather and disseminate additional information concerning these events such that members of the public can fully understand the risks involved with these vaccines prior to vaccinating.

ICAN certifies that the information in the request is true and correct to the best of ICAN's knowledge and belief.

Fees and charges for this search are to be waived pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii) since ICAN is a not-for-profit 501(c)(3) organization and its mission is to raise public awareness about vaccine safety and provide the public with information to give informed consent. As part of its mission, ICAN investigates and disseminates information regarding vaccine safety, including through their website, 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 requested in this FOIA request will not contribute to any commercial activities.

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 of course 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 file an administrative appeal.

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

Very truly yours,

/s/ Elizabeth A. Brehm
Elizabeth A. Brehm, Esq.

EXHIBIT C.2

U.S. FOOD & DRUG ADMINISTRATION

May 04, 2021

In Reply refer to
FOIA Control #:
2021-2954

Requester reference:

INFORMED CONSENT ACTION NETWORK
ELIZABETH BREHM, ESQ
200 PARK AVE FL 17
17th Floor
NEW YORK NY 10166 US

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

All documents concerning the following VAERS Report Nos.: 1187918, 1199455, 1218081, 1225942, 1242573, 1243487, 12435161

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Claire B. Stansbury, Information Technician, at (301) 796-8979 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

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

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

EXHIBIT C.3

U.S. FOOD & DRUG ADMINISTRATION

June 1, 2021

Elizabeth Brehm
Siri & Glimstad LLP
200 Park Ave. 17th Floor
New York, NY 10166

In reply refer to file: F21-2954

Dear Ms.Brehm,

This is in reply to your Freedom of Information Act request dated May 4, 2021, in which you requested "all documents concerning the following VAERS report numbers:1187918, 1199455, 1218081, 1225942, 1242573, 1243487, 1243516." Your request was received in the Center for Biologics Evaluation and Research on May 4, 2021.

Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request. Please note VAERS ID 1218081 and 1199455 are linked as well as VAERS ID 1225942 and 1243516.

We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

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."

EXHIBIT D.1

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

FREEDOM OF INFORMATION ACT REQUEST
EXPEDITED PROCESSING REQUESTED

VIA ONLINE PORTAL May 11, 2021

Food and Drug Administration
Division of Freedom of Information
Office of the Secretariat, OC
5630 Fishers Lane, Room 1035
Rockville, MD 20857
FDAFOIA@fda.hhs.gov

Re: Documents Concerning VAERS Reports Reflecting Death of Minors. (IR#0487)

Dear Sir or Madam:

This firm represents the Informed Consent Action Network ("ICAN"). On behalf of ICAN, we are requesting records pursuant to the Freedom of Information Act (5 U.S.C. § 552, as amended) ("FOIA"). Please provide the records in your possession via email to foia@sirillp.com:

> **All documents concerning the following VAERS Report Nos.: 1255745 and 1261766.**[1]

Request For Expedited Processing

ICAN requests expedited processing for this request. ICAN is "primarily engaged in disseminating information to the general public" and there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II).

ICAN's mission is to raise public awareness about public health safety and to provide the public with information to give informed consent regarding related health interventions. The SARS-CoV-2, also known as COVID-19, pandemic has affected myriad aspects of every American's life.

Numerous experimental therapeutics and vaccines against COVID-19 are in development and those processes are highly publicized. Three of these vaccines are being widely distributed and used pursuant to Emergency Use Authorizations granted by the FDA. Recently, the FDA

[1] Copies of the reports are attached herein as **Ex. 1**.

granted an EUA for the use of the Pfizer COVID-19 vaccine in minors between the ages 12 and 15.

The attached VAERS reports show that at least two minors have died shortly after receiving one of the COVID-19 vaccines. Thus, there is an urgent need to inquire into the events reported through VAERS so that a timely and full investigation can be initiated into the same. There is also an urgent need for ICAN to gather and disseminate additional information concerning these events such that members of the public can fully understand the risks involved with these vaccines prior to vaccinating.

ICAN certifies that the information in the request is true and correct to the best of ICAN's knowledge and belief.

Fees and charges for this search are to be waived pursuant to 5 U.S.C. § 552 (a)(4)(A)(iii) since ICAN is a not-for-profit 501(c)(3) organization and its mission is to raise public awareness about vaccine safety and provide the public with information to give informed consent. As part of its mission, ICAN investigates and disseminates information regarding vaccine safety, including through their website, 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 requested in this FOIA request will not contribute to any commercial activities.

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 of course 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 file an administrative appeal.

If you would like to discuss our requests or any issues raised in this letter, please feel free to contact me at (212) 532-1091 or via email at 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.

VAERS Event Details

Details for VAERS ID: 1255745-1

Event Information			
Patient Age	2.00	**Sex**	Female
State / Territory	Virginia	**Date Report Completed**	2021-04-23
Date Vaccinated	2021-02-25	**Date Report Received**	2021-04-25
Date of Onset	2021-02-25	**Date Died**	2021-03-03
Days to onset	0		
Vaccine Administered By	Unknown	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	USPFIZER INC2021438454	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	2		

Symptom
DEATH
PRODUCT ADMINISTERED TO PATIENT OF INAPPROPRIATE AGE

Adverse Event Description
she was going to die/dies after vaccine; 2-year-old patient; This is a spontaneous report from a non-contactable consumer via a Pfizer-sponsored program. A 2-year-old female patient received bnt162b2 (PFIZER-BIONTECH COVID-19 VACCINE), second dose at the age of 2-years-old via an unspecified route of administration on 25Feb2021 (Batch/Lot number was not reported) as single dose for covid-19 immunisation. The patient's medical history and concomitant medications were not reported. It was reported that the 2-year-old dies after vaccine on 03Mar2021. Reported on VAERS. Look for the researchers to exclude her from the study, probably claiming her death had nothing to do with the shot, she was going to die that day, five days after vaccination anyway. That's how they roll. The patient died on 03Mar2021. The outcome of the event was fatal. No follow-up attempts are possible. Information on lot/batch cannot be obtained. No further information is expected.; Reported Cause(s) of Death: she was going to die

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time Of Vaccination	History/Allergies
	,

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats:

Data contains VAERS reports processed as of 4/30/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. (/wonder/help/vaers.html#Reporting)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: May 11, 2021 10:23:20 AM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/30/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on May 11, 2021 10:23:20 AM

CDC WONDER FAQs Help Contact Us WONDER Search

VAERS Event Details

Details for VAERS ID: 1261766-1

Event Information			
Patient Age	1.00	**Sex**	Male
State / Territory	Florida	**Date Report Completed**	2021-04-27
Date Vaccinated	2021-04-08	**Date Report Received**	2021-04-27
Date of Onset	2021-04-10	**Date Died**	2021-04-10
Days to onset	2		
Vaccine Administered By	Unknown	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	No
Days in Hospital	None
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (MODERNA))	MODERNA	NONE	1	IM	LA

Symptom
BODY TEMPERATURE INCREASED
DEATH
SEIZURE

Adverse Event Description
increased body temperature, seizure, death

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time Of Vaccination	History/Allergies
	,

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats:

Data contains VAERS reports processed as of 4/30/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. (/wonder/help/vaers.html#Reporting)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: May 11, 2021 10:22:18 AM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/30/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on May 11, 2021 10:22:18 AM

EXHIBIT D.2

U.S. FOOD & DRUG ADMINISTRATION

May 12, 2021

In Reply refer to
FOIA Control #:
2021-3130

Requester reference:

INFORMED CONSENT ACTION NETWORK
AARON SIRI, ESQ.
200 PARK AVE FL 17
17th Floor
New York NY 10166 US

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:

All documents concerning the following VAERS Report Nos.: 1255745 and 1261766.

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact us to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

Due to an increase in the number of incoming requests, we may be unable to comply with the twenty-working-day time limit in this case, as well as the ten additional days provided by the FOIA. The actual processing time will depend on the complexity of your request and whether sensitive records, voluminous records, extensive search, and/or consultation with other HHS components or other executive branch agencies are involved. Please note that requests for medical device approval records (e.g. 510K, PMA, DEN) may take up to 18 to 24 months to process.

If you have any questions about your request, please call Claire B. Stansbury, Information Technician, at (301) 796-8979 or write to us at:
Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the FOIA control number provided above which will help us to answer your questions more quickly.

You also have the right to seek dispute resolution services from:

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

and/or

FDA FOIA Public Liaison
Office of the Executive Secretariat
US Food Administration
5630 Fishers Lane, Room 1050
Email: FDAFOIA@fda.hhs.gov

Sincerely,

SARAH KOTLER
Director

EXHIBIT D.3

U.S. FOOD & DRUG ADMINISTRATION

June 11, 2021

Aaron Siri, Esq
Informed Consent Action Network
200 Park Ave. 17th Floor
New York, NY 10166

In reply refer to file: F21-3130

Dear Mr. Siri,

This is in reply to your Freedom of Information Act request dated May 12, 2021, in which you requested "all documents concerning the following VAERS report numbers: 1255745 and 1261766." Your request was received in the Center for Biologics Evaluation and Research on May 12, 2021.

Enclosed please find the results of a query of the Vaccine Adverse Event Reporting System (VAERS) using the search parameters listed in your FOIA request.

We have withheld portions of pages under Exemption (b)(3), 5 U.S.C. § 522(b)(3). That exemption prohibits the release of information that is otherwise prohibited from disclosure by another federal statute.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

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."

EXHIBIT E

FDA Production for VAERS
Report No: 1074247

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VAERS ID: 1074247

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 1074247 - 1
E-Number: 334672
Doc Number: 1488811
Date Received: 03/05/2021 1:14 AM
Severity: Death
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (b) (6), (b) (3) (A) (last) (b) (6), (b) (3) (A)
Address: (b) (6), (b) (3) (A)
City: (b) (6), (b) (3) (A)
State: **ZIP:** (b) (6), (b) (3) (A)
County: (b) (6), (b) (3) (A)
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 02/25/2021 **Time:** 11:17

5. Date and time adverse event started: 03/01/2021 **Time:** 11:17

6. Age at vaccination: 2 yr.

7. Today's date: 03/05/2021

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6) (b) (6)
Relation to Patient: Healthcare professional/staff
Address: (b) (6)
City: (b) (6)
State: **ZIP:**
Phone:
Email:

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: (b) (6)
Fax:
Facility Address: (b) (6)
Phone:

16. Type of facility: Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech		Intramuscular - IM	Right Arm	2

18. Describe the adverse event(s), treatment, and outcome(s), if any:

21. Result or outcome of adverse event(s): (Check all that apply).

(symptoms, signs, time course, etc.)
Death

* Hospitalization (17 days, Hospital: (b) (6)
(b) (6)
* Patient Died (b) (6)

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?: No
Description (adverse event, patient age at vaccination, vaccination dates, vaccine type, and brand name):

24. Patient's race: White

25. Patient's ethnicity: Not Hispanic or Latino

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site:

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

Publicly Available Information Regarding VAERS Report No: 1074247

CDC WONDER FAQs Help Contact Us WONDER Search

VAERS Event Details

Details for VAERS ID: 1074247-1

Event Information			
Patient Age	2.00	**Sex**	Female
State / Territory	Virginia	**Date Report Completed**	2021-03-05
Date Vaccinated	2021-02-25	**Date Report Received**	2021-03-05
Date of Onset	2021-03-01	**Date Died**	2021-03-03
Days to onset	4		
Vaccine Administered By	Private	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	17
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	2	IM	RA

Symptom
DEATH

Adverse Event Description
Death

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time Of Vaccination	History/Allergies
	,

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats:

Data contains VAERS reports processed as of 4/10/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information. (/wonder/help/vaers.html#Reporting)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Apr 22, 2021 2:02:15 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/10/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Apr 22, 2021 2:02:15 PM

FDA Production for VAERS
Report No: 1099241

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VAERS ID: 1099241

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 1099241 - 1
E-Number: 355796
Doc Number: 1515690
Date Received: 03/14/2021 7:36 PM
Severity: Serious
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (last)
Address:
City:
State: ZIP:
County:
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Female

4. Date and time of vaccination: 03/10/2021 **Time:** 13:00

5. Date and time adverse event started: 03/11/2021 **Time:** 12:00

6. Age at vaccination: 1 yr. 4 mon.

7. Today's date: 03/14/2021

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:
None

10. Allergies to medications, food, or other products:
None

11. Other illnesses at the time of vaccination and up to one month prior:
None

12. Chronic or long-standing health conditions:
None

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name) (b) (6)
Relation to Patient: Healthcare professional/staff
Address: (b) (6)
City: (b) (6)
State
Phone:
Email: (b) (6)
Comm Pref from Esub Form: Email

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: (b) (6) **Ext:**

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name: (b) (6)
Fax:
Facility Address:
City:
State: ZIP:
Phone:

16. Type of facility:
Doctor's office, urgent care, or hospital

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1203 - COVID19 (COVID19 (Janssen))	Janssen				

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)

21. Result or outcome of adverse event(s): (Check all that apply).
* Hospitalization

Patient is breastfed by mother, who was vaccinated on 3/10. Patient developed jaundice(b) (6) and was admitted for evaluation of hemolytic anemia. Evaluation ongoing. Likely not related to vaccine, but occurred within 2 days of possible to vaccine components via breastmilk

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race:

25. Patient's ethnicity: **26. Immuniz. proj. report no.:**

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination: **28. Vaccinated at Military/DoD site:**

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

Publicly Available Information Regarding VAERS Report No: 1099241

VAERS Event Details

Details for VAERS ID: 1099241-1

Event Information			
Patient Age	1.33	**Sex**	Female
State / Territory	California	**Date Report Completed**	2021-03-14
Date Vaccinated	2021-03-10	**Date Report Received**	2021-03-14
Date of Onset	2021-03-11	**Date Died**	
Days to onset	1		
Vaccine Administered By	Private	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	No
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	Unknown
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	No
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (JANSSEN))	JANSSEN	NONE	UNK		

Symptom
EXPOSURE VIA BREAST MILK
HAEMOLYTIC ANAEMIA
JAUNDICE

Adverse Event Description
Patient is breastfed by mother, who was vaccinated on 3/10. Patient developed jaundice 3/11, and was admitted for evaluation of hemolytic anemia. Evaluation ongoing. Likely not related to vaccine, but occurred within 2 days of possible to vaccine components via breastmilk

Lab Data	Current Illness	Adverse Events After Prior Vaccinations
	None	

Medications At Time Of Vaccination	History/Allergies
None	None,None

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats:

Data contains VAERS reports processed as of 4/16/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information. (/wonder/help/vaers.html#Reporting)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Apr 23, 2021 12:07:31 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/16/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Apr 23, 2021 12:07:31 PM

FDA Production for VAERS
Report No: 1166062

This page contains Patient Personally Identifiable Information and should be safeguarded against unauthorized viewing.

VAERS ID: 1166062

EReport Event Data

VACCINE ADVERSE EVENT REPORTING SYSTEM
24 Hour Toll-free information line: 1-800-822-7967
Fax number: 1-877-721-0366
P.O. Box 1100, Rockville, MD 20849-1100
PATIENT IDENTITY KEPT CONFIDENTIAL

For CDC/FDA Use Only
VAERS Number: 1166062 - 1
E-Number: 405683
Doc Number: 1591502
Date Received: 04/04/2021 8:46 AM
Severity: Death
Received By: Web Report
Version: This is the original information from the reporter.

INFORMATION ABOUT THE PATIENT WHO RECEIVED THE VACCINE

1. Patient Name: (first) (last)
Address:
City:
State: ZIP:
County:
Phone:
Email:

2. Date of birth: (b) (6)

3. Sex: Male

4. Date and time of vaccination: 03/17/2021 **Time:**

5. Date and time adverse event started: 03/18/2021 **Time:**

6. Age at vaccination: yr. 5 mon.

7. Today's date: 04/04/2021

8. Pregnant at the time of vaccination?: No

9. Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination:

10. Allergies to medications, food, or other products:

11. Other illnesses at the time of vaccination and up to one month prior:

12. Chronic or long-standing health conditions:

INFORMATION ABOUT THE PERSON COMPLETING THIS FORM

13. Form completed by: (name)
Relation to Patient: Healthcare professional/staff
Address:
City:
State: ZIP:
Phone:
Email:
Comm Pref from Esub Form: Postal Mail

14. Best doctor/healthcare professional to contact about the adverse event:
Name:
Phone: Ext:

INFORMATION ABOUT THE FACILITY WHERE VACCINE WAS GIVEN

15. Facility/clinic name:
Fax:
Facility Address:
City:
State: ZIP:
Phone:

16. Type of facility: Workplace clinic

WHICH VACCINES WERE GIVEN? WHAT HAPPENED TO THE PATIENT?

17. Enter all vaccines given on the date listed in item 4: (Route is HOW vaccine was given, Body site is WHERE vaccine was given).

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series
1200 - COVID19 (COVID19 (Pfizer-BioNTech))	Pfizer\BioNTech		Needle and Syringe (not specified further) - SYR	Left Arm	2

18. Describe the adverse event(s), treatment, and outcome(s), if any: (symptoms, signs, time course, etc.)

21. Result or outcome of adverse event(s): (Check all that apply).
* Emergency room/department or urgent care

Patient received second dose of Pfizer vaccine on March 17, 2020 while at work. March 18, 2020 her 5 month old breastfed infant developed a rash and within 24 hours was inconsolable, refusing to eat, and developed a fever. Patient brought baby to local ER where assessments were performed, blood analysis revealed elevated liver enzymes. Infant was hospitalized but continued to decline and passed away. Diagnosis of TTP. No known allergies. No new exposures aside from the mother's vaccination the previous day.

* Hospitalization (2 days)
* Patient Died (b) (6)

19. Medical tests and laboratory results related to the adverse event(s):

20. Has the patient recovered from the adverse event(s)?: No

ADDITIONAL INFORMATION

22. Any other vaccines received within one month prior to the date listed in item 4:

Vaccine	Manufacturer	Lot Number	Route	Site	Dose number in series	Date
1082 - DTaP + HepB + IPV (Pediarix)	GlaxoSmithKline Biologicals					02/01/2020 (02/2020)

23. Has the patient ever had an adverse event following any previous vaccine?:

24. Patient's race: White

25. Patient's ethnicity:

26. Immuniz. proj. report no.:

COMPLETE ONLY FOR U.S. MILITARY/DEPARTMENT OF DEFENSE (DoD) RELATED REPORTS

27. Status at time of vaccination:

28. Vaccinated at Military/DoD site: No

PAGE 2 ADDITIONAL INFORMATION

Use the space below to provide any additional information:

Publicly Available Information Regarding VAERS Report No: 1166062

VAERS Event Details

Details for VAERS ID: 1166062-1

Event Information			
Patient Age	0.42	**Sex**	Male
State / Territory	Unknown	**Date Report Completed**	2021-04-04
Date Vaccinated	2021-03-17	**Date Report Received**	2021-04-04
Date of Onset	2021-03-18	**Date Died**	2021-03-20
Days to onset	1		
Vaccine Administered By	Work *	**Vaccine Purchased By**	Not Applicable *
Mfr/Imm Project Number	NONE	**Report Form Version**	2
Recovered	No	**Serious**	Yes

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"Not Applicable" will appear when information is not available on this report form version.

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	Yes
Days in Hospital	2
Existing Hospitalization Prolonged	No
Emergency Room / Office Visit **	N/A
Emergency Room *	Yes
Office Visit *	No

* VAERS 2.0 Report Form Only
** VAERS-1 Report Form Only
"N/A" will appear when information is not available on this report form version.

Vaccine Type	Vaccine	Manufacturer	Lot	Dose	Route	Site
COVID19 VACCINE	COVID19 (COVID19 (PFIZER-BIONTECH))	PFIZER\BIONTECH	NONE	2	SYR	LA

Symptom
DEATH
DIET REFUSAL
EMOTIONAL DISTRESS
EXPOSURE VIA BREAST MILK
FAILURE TO THRIVE
HEPATIC ENZYME INCREASED
PYREXIA
RASH
THROMBOTIC THROMBOCYTOPENIC PURPURA

Adverse Event Description
Patient received second dose of Pfizer vaccine on March 17, 2020 while at work. March 18, 2020 her 5 month old breastfed infant developed a rash and within 24 hours was inconsolable, refusing to eat, and developed a fever. Patient brought baby to local ER where assessments were performed, blood analysis revealed elevated liver enzymes. Infant was hospitalized but continued to decline and passed away. Diagnosis of TTP. No known allergies. No new exposures aside from the mother's vaccination the previous day.

Lab Data	Current Illness	Adverse Events After Prior Vaccinations

Medications At Time Of Vaccination	History/Allergies
	,

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats:

Data contains VAERS reports processed as of 4/16/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. More information. (/wonder/help/vaers.html#Reporting)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Apr 23, 2021 12:10:16 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 4/16/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Apr 23, 2021 12:10:16 PM

EXHIBIT F

IMPORTANT INFORMATION FROM THE FDA ABOUT THE VACCINE ADVERSE EVENT REPORTING SYSTEM (VAERS)

VAERS was created by the Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) to receive reports about adverse events which may be associated with vaccines. No prescription drug or biological product, such as a vaccine, is completely free from side effects. Vaccines protect many people from dangerous illnesses, but vaccines, like drugs, can cause side effects, a small percentage of which may be serious. The FDA continually monitors reports to determine whether any vaccine or vaccine lot has a higher than expected rate of events.

About 85% of vaccines adverse event reports concern relatively minor events, such as ordinary fevers or redness and swelling at the injection site. The remaining 15% describe serious events, such as seizures, high fevers, life-threatening illnesses, or deaths. The reports of serious events are of greatest concern to the FDA and receive the most careful scrutiny.

The report of an adverse event to VAERS is not documentation that a vaccine caused the event. With regard to childhood vaccines, over ten million vaccinations per year are given to children less than one year old, usually between 2 months and 6 months of age. At this stage of development, infants are at greatest risk for certain medical events, including high fevers, seizures, and sudden infant death syndrome (SIDS). Some infants will by coincidence experience such an event shortly after a vaccination. In such situations, the event may be caused by an infection, congenital abnormality, injury, or some other provocation. Because of such coincidences, it is usually not possible to be sure whether a particular adverse event resulted from a concurrent condition or from a vaccination, even when it occurred soon afterward. Therefore, doctors and other vaccine providers are encouraged to report adverse events, whether or not they believe the vaccination was the cause. Since it is difficult to distinguish a coincidental event from one truly caused by a vaccine, the VAERS database will contain events of both types.

In addition, it is often the case that more than one vaccine was administered, making it difficult to know to which of the vaccines the event might be attributed. In analyzing individual reports, we examine the medical information about the event, and obtain more specific information from the reporting doctors whenever necessary. We also analyze patterns of reporting associated with vaccines and vaccine lots.

In analyzing patterns of adverse events reporting, the FDA considers more than just the number of reports for a lot. More reports will be received for a large lot than a small one, simply because vaccine from the large lot will be given to more children. Some lots contain as many as 700,000 doses, while others as few as 20,000 doses. Similarly, more reports will be received for a lot that has been in use for a long time than a lot in use for short time. Even among lots of similar size and time in use, some lots will receive more reports than others simply due to chance. The FDA continually looks for lots that have

received more serious reports than should be expected on the basis of such factors as size, time in use, and chance variation. When such a lot is detected, further investigations are initiated that could lead to recall of the lot under some circumstances.

Many complex factors must be considered in order to decide whether a lot of vaccine is unsafe. At the FDA, we apply procedures and methods of analysis to help us to understand these complex factors and closely monitor the safety of vaccines. We continually analyze these many factors to help ensure that all lots in use are safe. We hope that this brief explanation of the factors associated with vaccines and adverse events will assist you in understanding the data you have requested.

EXHIBIT G

Sonal Jain

From: Wilusz, Catherine <Catherine.Wilusz@fda.hhs.gov>
Sent: Tuesday, June 22, 2021 10:23 AM
To: Sonal Jain
Subject: RE: [EXTERNAL] Follow up on Response - Freedom of Information Act Request f21-2761

Good morning,

We are responding to your inquiry of May 25, 2021 in which you requested the federal statute the agency is invoking under exemption (b) (3).
Thank you for your inquiry. The federal statute for the Exemption 3 redactions that you asked about is the National Childhood Vaccine Injury Act.

Best Regards,
Cathy Wilusz
Consumer Safety Officer
Access Litigation and Freedom of Information Branch
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
240-402-8008

From: Sonal Jain <sjain@sirillp.com>
Sent: Monday, June 21, 2021 9:58 AM
To: Wilusz, Catherine <Catherine.Wilusz@fda.hhs.gov>
Subject: RE: [EXTERNAL] Follow up on Response - Freedom of Information Act Request f21-2761

Dear Ms. Wilusz,

I am following up on my inquiry below. Do you have a response for us yet?

Best,
Sonal

Sonal Jain, Law Clerk
Siri | Glimstad
200 Park Avenue
Seventeenth Floor
New York, NY 10166
Main: 212-532-1091
Facsimile: 646-417-5967
www.sirillp.com

From: Wilusz, Catherine <Catherine.Wilusz@fda.hhs.gov>
Sent: Thursday, May 27, 2021 3:45 PM
To: Sonal Jain <sjain@sirillp.com>
Subject: RE: [EXTERNAL] Follow up on Response - Freedom of Information Act Request f21-2761

Good afternoon,

I wanted to confirm receipt of your inquiry. We will respond as soon as possible.

Best regards,
Catherine Wilusz
Consumer Safety Officer
Access Litigation and Freedom of Information Branch
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Food and Drug Administration
240-402-8008

From: Sonal Jain <sjain@sirillp.com>
Sent: Tuesday, May 25, 2021 9:46 AM
To: Wilusz, Catherine <Catherine.Wilusz@fda.hhs.gov>
Subject: [EXTERNAL] Follow up on Response - Freedom of Information Act Request f21-2761

Dear Ms. Wilusz,

We received your response letter dated May 21, 2020. The Response Letter and the documents produced mention that some records were withheld pursuant to FOIA Exemption 3, 5 U.S.C. 552 (b)(3), as "otherwise prohibited from disclosure by another federal statute." Can you please advise which federal statute is the agency invoking under this exemption?

Best,
Sonal Jain, Law Clerk
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