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 <u>foia@sirillp.com</u>:

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.

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

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

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

[&]quot;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

SymptomDEATH

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

^{**} VAERS-1 Report Form Only

[&]quot;Not Applicable" will appear when information is not available on this report form version.

^{**} VAERS-1 Report Form Only

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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

CDC WONDER

FAQs

Help

Contact Us

WONDER Search

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

[&]quot;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

[&]quot;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		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

^{**} VAERS-1 Report Form Only

^{**} VAERS-1 Report Form Only

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

Event Categories	
Death	Yes
Life Threatening	No
Permanent Disability	No
Congenital Anomaly / Birth Defect *	No
Hospitalized	
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

[&]quot;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)

^{**} VAERS-1 Report Form Only

[&]quot;Not Applicable" will appear when information is not available on this report form version.

^{**} VAERS-1 Report Form Only

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

Siri | Glimstad

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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, 1243516¹

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.

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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.



Search Results

From the 4/23/2021 release of VAERS data:

Found 10 cases where Age is under-0.5 or 0.5-or-more-and-under-1 or 1-or-moreand-under-3 or 3-or-more-and-under-6 or 6-or-more-and-under-18 and Vaccine is **COVID19 and Patient Died**

Table

↓	↑ ↓		
Age	Count Percent		
< 3 Years	3	30%	
12-17 Years	4	40%	
17-44 Years	3	30%	
TOTAL	10	100%	

Case Details

VAERS ID: <u>958443</u> (history) Version 2.0 Form: Age: 1.08 Sex: Female

Location: Unknown

2020-12-Vaccinated:

2020-12-Onset: 26

Days after 2 vaccination:

0000-00-Submitted: 2021-01-Entered:

08

Vaccination / Manufacturer		Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	-/-

Administered by: Other Purchased by: ?

Symptoms: Completed suicide, Death, Gun shot wound

SMQs:, Suicide/self-injury (narrow), Accidents and injuries (narrow), Hostility/aggression (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2020-12-26 Days after onset: 0 Permanent Disability? No Recovered? No Office Visit? No

ER Visit? No ER or Doctor Visit? No Hospitalized? No **Previous Vaccinations:** Other Medications: **Current Illness:**

Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type:

Age:

Sex:

Write-up: death by suicide Narrative: death by suicide; 12/26/20, self inflicted gun shot wound; found deceased by family member

VAERS ID: <u>1074247 (history)</u> Version 2.0 Form:

2.0 Female Location: Virginia

2021-02-Vaccinated: 25

2021-03-Onset: 01 Days after

vaccination: 0000-00-Submitted: 00

2021-03-Entered:

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH

Administered by: Private Symptoms: Death

SMQs:

Life Threatening? No Birth Defect? No

Purchased by: ?

Died? Yes
Date died: 2021-03-03
Days after onset: 2
Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? No Hospitalized? Yes, 17 days Extended hospital stay? No

Extended hospital stay? No Previous Vaccinations: Other Medications:

Current Illness: Preexisting Conditions: Allergies:

Diagnostic Lab Data: CDC Split Type: Write-up: Death

VAERS ID: <u>1166062 (history)</u> **Form:** Version 2.0 **Age:** 0.42

Male

Location: Unknown

Sex:

Vaccinated: 2021-03-17 Onset: 2021-03-18

Days after vaccination:

Submitted: 0000-00-00 2021-04-

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	-/2	LA / SYR

Administered by: Work Purchased by: ?

Symptoms: Death, Diet refusal, Emotional distress, Exposure via breast milk, Failure to thrive, Hepatic enzyme increased, Pyrexia, Rash, Thrombotic thrombocytopenic purpura SMQs:, Liver related investigations, signs and symptoms (narrow), Anaphylactic reaction (broad), Haemorrhage terms (excl laboratory terms) (narrow), Neuroleptic malignant syndrome (broad), Anticholinergic syndrome (broad), Embolic and thrombotic events, arterial (narrow), Depression (excl suicide and self injury) (broad), Renovascular disorders (broad), Neonatal exposures via breast milk (narrow), Neonatal disorders (broad), Hypersensitivity (narrow), Drug reaction with eosinophilia and systemic symptoms syndrome (broad), Immune-mediated/autoimmune disorders (narrow)

Life Threatening? No Birth Defect? No Died? Yes Date died: 2021-03-20 Days after onset: 2 Permanent Disability? No Recovered? No

Recovered? No
Office Visit? No
ER Visit? No
ER or Doctor Visit? Yes
Hospitalized? Yes 2 day

Hospitalized? Yes, 2 days
Extended hospital stay? No
Previous Vaccinations:
Other Medications:

Current Illness: Preexisting Conditions: Allergies:

Diagnostic Lab Data:

CDC Split Type:

Write-up: 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.

 VAERS ID:
 1187918 (history.)
 Vaccinated:
 0000-00-00

 Form:
 Version 2.0
 Onset:
 2021-04-05

 Age:
 15.0
 Submitted:
 0000-00-00

 Sex:
 Female
 Entered:
 2021-04-09

Location: New Hampshire

Vaccination / Manufacturer	Lot / Dose	Site / Route
COVID19: COVID19 (COVID19 (MODERNA)) / MODERNA	- / UNK	-/-

Administered by: Private Purchased by: ? Symptoms: Cardiac arrest. Intensive care

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or

cardiac conditions (excl torsade de pointes) (narrow), Acute central respiratory depression (broad), Cardiomyopathy (broad), Respiratory failure (broad)

Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-04-06 Days after onset: 1 Permanent Disability? No Recovered? No Office Visit? No

ER Visit? No
ER or Doctor Visit? No
Hospitalized? No

Previous Vaccinations:
Other Medications: levothyroxine

Current Illness:

Preexisting Conditions: Trisomey 21, Atrioventricular canal s/p repair, hypothyroidism, asthma, obstructive sleep apnea, cervical spine instability, hypotonia, scoliosis, feeding

difficulties, renal dysplasia, autism, chronic constipation, bronchopulmonary dysplasia, mixed conductive and sensorineural hearing loss, binocular vision disorder, gastroesophgeal

Allergies: Cefdinir, Sulfa, Ex-Lax, NSAIDS

Diagnostic Lab Data: **CDC Split Type:**

Write-up: I do not know the exact date of the first or second Moderna Vaccine. I am the PICU attending who cared for the patient after her cardiac arrest which we believe was about 3-4 days after her second Moderna Vaccine

VAERS ID: <u>1199455 (history)</u> Form:

Vaccinated: Version 2.0

2021-04-02

17.0 Age: Sex: Female Location: Wisconsin

2021-04-Onset: 10

Days after vaccination:

8

0000-00-Submitted: 00 2021-04-Entered: 12

Vaccination / Manufacturer		Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	- / UNK	-/-

Administered by: Private

Purchased by: ?

Symptoms: Cardiac arrest, Chest pain, Death, Dyspnoea

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (narrow), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Acute central respiratory depression (broad), Pulmonary hypertension (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (broad), Cardiomyopathy (broad), Respiratory failure (broad)

Life Threatening? No

Birth Defect? No

Died? Yes

Date died: 2021-04-10 Days after onset: 0 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes Hospitalized? No

Previous Vaccinations:

Other Medications: fluoxetine, fesoterodine, ortho-tricyclen, oxybutynin

Vaccinated:

Preexisting Conditions: spina bifida, spinal meningocele, VP shunt, scoliosis, neurogenic bladder, constipation

2021-04-

02 2021-04-

10

Allergies: bananas, cephalexin, kiwi, mango, pineapple, latex

Diagnostic Lab Data: CDC Split Type:

Write-up: Patient reported difficulty breathing and chest pain; suffered cardiac arrest and death

VAERS ID: <u>1218081</u> (history) Form: Version 2.0

Sex:

17.0 Age:

Female Location: Wisconsin

Onset: Days after

vaccination:

0000-00-Submitted: 00 2021-04-Entered: 16

Vaccination / Manufacturer		Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	EW0150 / 1	RA / IM

Administered by: Private

Purchased by: ?

Symptoms: Apnoeic attack, Blood culture positive, CSF culture positive, Chest pain, Culture urine positive, Death, Dyspnoea, Enterococcal infection, Escherichia bacteraemia, Pulmonary artery occlusion, Pulseless electrical activity, Renal dysplasia, Respiratory arrest, Resuscitation, SARS-CoV-2 test negative, Syncope

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Congenital, familial and genetic disorders (narrow), Embolic and thrombotic events, arterial (narrow), Acute central respiratory depression (narrow), Pulmonary hypertension (broad), Guillain-Barre syndrome (broad), Gastrointestinal nonspecific symptoms and therapeutic procedures (broad), Cardiomyopathy (broad), Cardiac arrhythmia terms, nonspecific (narrow), Hypotonic-hyporesponsive episode (broad), Hypersensitivity (broad), Respiratory failure (narrow), Hypoglycaemia (broad), Sepsis (broad), Opportunistic infections (broad), COVID-19 (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-04-10

Davs after onset: 0 Permanent Disability? No

Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? Yes

Hospitalized? No **Previous Vaccinations:**

Other Medications: **Current Illness:**

Preexisting Conditions: see previous report history of spina bifida, high lumbar myelomenigocele status post repair, ventriculoperitoneal shunt and associate neurogenic bladder requiring self catheterization, neurogenic bowel and non mobile lower extremities.

Allergies: see previous report

Diagnostic Lab Data: COVID-19 nasopharyngeal swab: negative Urine cultures (prelim): Escherichia coli and Enterococcus faecalis CSF cultures (prelim) E. faecalis, Streptococcus species, E. coli Blood cultures (prelim) Staphylococcus species Right lung cultures (prelim) gram-positive cocci in chains Left lung cultures (prelim) young microbial growth Respiratory Possible pulmonary embóli; histologic examination pending- near complete to complete occlusion of right upper pulmonary artery. Partial occlusion of left upper pulmonary artery. Possible dilated vasculature and airways at peripheral pleura in left lung, pending histologic examination Genitourinary small dysplastic right kidney lobulated left

kidney, pending histologic examination Hematolymphoid: splenomegaly: 220g No other overt gross abnormalities, pending histologic examination

Sex:

Write-up: From Post mortem report from Hospital: when on 4/10/21, she was in the process of self catheterization and began experiencing difficulty breathing and chest pain. Shortly after she collapsed and was not breathing. EMS arrived and found her apneic and in pulseless electrical activity. Resuscitation began and continued upon arrival to the ED. Aside from a short period of returned pulses, she remained in PEA despite an estimated 45-50 minutes of resuscitation. She died at 11:20am on 4/10/21. - Directly from Pathology report 4.12.21

VAERS ID: 1225942 (history) Version 2.0 Form: Age: 16.0 Onset:

Female

Location: Wisconsin

2021-03-Vaccinated: 19 2021-03-

28 Days after 9

vaccination:

0000-00-Submitted: 00 2021-04-

Entered: 18

Vaccination / Manufacturer		Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	UNKNOWN / 1	-/-

Administered by: Unknown

Purchased by: ? Symptoms: Cardiac arrest, Death, Laboratory test, Lung assist device therapy, Oral contraception, Pulmonary embolism, Resuscitation

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (broad), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Embolic and thrombotic events, venous (narrow), Acute central respiratory depression (broad), Cardiomyopathy (broad),

Respiratory failure (broad) Life Threatening? No Birth Defect? No Died? Yes

Date died: 2021-03-30 Days after onset: 2 Permanent Disability? No Recovered? No Office Visit? No

ER Visit? No ER or Doctor Visit? No Hospitalized? No **Previous Vaccinations:**

Other Medications: Reported to be on Drospirenone-Ethinyl Estradiol 3-0.02 MG per tab

Current Illness:

Preexisting Conditions: Allergies:

Diagnostic Lab Data: **CDC Split Type:**

Write-up: Patient was a 16yr female who received Pfizer vaccine 3/19/21 at vaccine clinic and presented with ongoing CPR to the ED 3/28/21 after cardiac arrest at home. Patient placed on ECMO and imaging revealed bilateral large pulmonary embolism as likely etiology of arrest. Risk factors included oral contraceptive use. Labs have since confirmed absence of Factor V leiden or prothrombin gene mutation. Patient declared dead by neurologic criteria 3/30/21.

VAERS ID: <u>1242573</u> (history) Form: Version 2.0

Vaccinated:

2021-04-Onset: 19

Age: 15.0 Sex: Male

Location: Colorado

Days after vaccination:

0000-00-Submitted: 00 2021-04-Entered: 22

Vaccination / Manufacturer		Site / Route
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	-/1	RA / IM

2021-04-

18

1

Administered by: Public Purchased by: ?

Symptoms: Cardiac failure, Death

SMQs:, Cardiac failure (narrow), Cardiomyopathy (broad)

Life Threatening? No Birth Defect? No

Died? Yes

Date died: 2021-04-20 Days after onset: 1 Permanent Disability? No Recovered? No

Office Visit? Yes ER Visit? No ER or Doctor Visit? No Hospitalized? No **Previous Vaccinations:**

Other Medications: Vaccinated with Pfizer/Biontech, died 04/20/2021, 2 days after vaccination

Current Illness: No Preexisting Conditions: No Allergies: Nothing Diagnostic Lab Data: **CDC** Split Type: Write-up: Heart failure

VAERS ID: <u>1243487</u> (history) 2021-04-Vaccinated: 13 Version 2.0 Age: 17.0 Onset: 21 Sex: Male

2021-04-

Days after 8

vaccination:

0000-00-Submitted: 00

2021-04-Entered: 22

Vaccination / Manufacturer Lot / Dose Site / Route COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH EW010 / 1 LA / IM

Administered by: Unknown

Purchased by: ? Symptoms: Completed suicide

SMQs:, Suicide/self-injury (narrow)

Life Threatening? No Birth Defect? No Died? Yes

Location: Michigan

Date died: 2021-04-21 Days after onset: 0 Permanent Disability? No Recovered? No Office Visit? No ER Visit? No

ER or Doctor Visit? No Hospitalized? No **Previous Vaccinations:**

Other Medications: Unknown, History of Mental Illness

Current Illness: Mental Illness. Preexisting Conditions: Mental Illness Allergies: None Reported

Diagnostic Lab Data: None

CDC Split Type:

Sex:

Write-up: Patient Committed Suicide with a firearm.

VAERS ID: <u>1243516</u> (history) Version 2.0 Form: Age:

16.0 Female

19 2021-03-Onset: 28 Days after Location: Wisconsin 9

Vaccinated:

vaccination:

0000-00-Submitted: 00

2021-04-Entered:

Vaccination / Manufacturer		Site / Route	l
COVID19: COVID19 (COVID19 (PFIZER-BIONTECH)) / PFIZER/BIONTECH	RT2613 / 1	UN / IM	l

2021-03-

Administered by: Private

Purchased by: ?

Symptoms: Cardiac arrest, Circulatory collapse, Computerised tomogram thorax abnormal, Death, Lung assist device therapy, Pulmonary embolism

SMQs:, Torsade de pointes/QT prolongation (broad), Anaphylactic reaction (narrow), Arrhythmia related investigations, signs and symptoms (broad), Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock conditions (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock conditions (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock conditions (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock conditions (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock conditions (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock conditions (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock conditions (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock conditions (narrow), Torsade de pointes, shock-associated conditions (narrow), Hypovolaemic shock-associat conditions (narrow), Anaphylactic/anaphylactoid shock conditions (narrow), Hypoglycaemic and neurogenic shock conditions (narrow), Embolic and thrombotic events, venous (narrow), Acute central respiratory depression (broad), Cardiomyopathy (broad), Hypersensitivity (narrow), Respiratory failure (broad)

Life Threatening? No Birth Defect? No

Died? Yes Date died: 2021-03-30 Davs after onset: 2 Permanent Disability? No Recovered? No

Office Visit? No ER Visit? No ER or Doctor Visit? Yes

Hospitalized? Yes, 2 days Extended hospital stay? No **Previous Vaccinations:**

Other Medications: Oral contraceptives Sertraline Loratadine Fluticasone Doxycycline, albuterol

Current Illness: Asthma, ADHD, Anxiety

Preexisting Conditions:

Allergies: NKDA Diagnostic Lab Data: Bilateral PE on CT Scan

CDC Split Type:

Write-up: Hemodynamic collapse at home. Persistent cardiac arrest requiring ECMO. Event believed secondary to pulmonary embolism. Death by neurologic criteria.

New Search

Link To This Search Result: https://www.medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&DIED=Yes&AGES[]=1&AGES[]=2&AGES[]=3&AGES[]=4&AGES[]=5

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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, Esq.

CDC WONDER

FAQs

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WONDER Search

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

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

[&]quot;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
ı			

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:

^{**} VAERS-1 Report Form Only

[&]quot;Not Applicable" will appear when information is not available on this report form version.

^{**} VAERS-1 Report Form Only

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

VAERS Event Details 5/11/2021

CDC WONDER

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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

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

[&]quot;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
ı	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

^{**} VAERS-1 Report Form Only

[&]quot;Not Applicable" will appear when information is not available on this report form version.

^{**} VAERS-1 Report Form Only