Sent: 6/24/2021 7:19:17 AM
To: Marion Gruber [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=gruber]; Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]
CC: Nair, Narayan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=debe49605be845e5a44d59cf099b8cb8-Narayan.Nai]; Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Richard Forshee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Marion and Doran,

-----Original Message-----
From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, June 24, 2021 7:15 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Reporting purported SAE in trial. Janet W

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

do you know the story of this girl? She was in the Pfizer trial.

She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 6/24/2021 8:06:03 AM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]
CC: Nair, Narayan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=debe49605be845e5a44d59cf099b8cb8-Narayan.Nai]; Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran and Marion,

Getting an answer on this one way or the other will help to reassure Dr. Woodcock that we are being appropriately diligent. Thanks so much.

Best Regards,
Peter

-----Original Message-----
From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Thursday, June 24, 2021 8:02 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Doran or I can forward that email to Donna Boyce as a next step, Marion

-----Original Message-----
From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Thursday, June 24, 2021 7:56 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran,

Thanks so much for this information. If Marion is comfortable with it, I am comfortable having someone reach out to Pfizer about this. We don't have to be accusatory, just can note that there is a lot of adverse event "noise" at the moment, and that we just want to evaluate if there is any validity here or not. Thanks so much.

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Peter

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, June 24, 2021 7:52 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

The one detail I can confirm is that the adolescent EUA safety database did not include any serious adverse event report that matches this description - all of the reported SAEs in were summarized in our review memo. Similar to the previous inquiry about a purported death in a 2 year-old (which I recall was inaccurate in all respects), we would have to reach out to Pfizer to ask if they know anything about this purported case.

Thanks,
Doran

Doran L. Fink, MD, PhD

Deputy Director – Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

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We will discuss after the ICMRA WS this am and circle back.
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Dear Marion and Doran,

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Reporting purported SAE in trial. Janet W

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Sent: 6/24/2021 8:31:37 AM
To: Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
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Dear Doran,

Thanks so much for pursuing this.

Best Regards,
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Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Sorry, on further review of the SAEs, there was one that could potentially be a match, but not clear at all and would need additional information from Pfizer. Summary of the event from the EUA submission is below - I will reach out to Pfizer with the subject ID and ask for an update on this subject, and if any other events in the trial that could match the description provided.

"The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
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Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Thanks,
Doran

Doran L. Fink, MD, PhD

Deputy Director – Clinical

Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
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To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Nair, Narayan <Narayan.Nair@fda.hhs.gov>; Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Marion and Doran,

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To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Reporting purported SAE in trial. Janet W

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Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Sent: 6/24/2021 10:53:56 AM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Attachments: c4591001-narratives-30apr21-ir_subject 1620.pdf

FYI, I found some information posted online that makes me almost certain that this trial participant is the same as the for SAE described below. We asked Pfizer during our review for additional information about this SAE, and they didn't have any beyond what is summarized in the quotes and the unhelpful information in the attached "narrative."

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Thursday, June 24, 2021 9:22 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Doran,
Thanks for reaching out. I will look into this and get back to you as soon as possible.
Kind regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, June 24, 2021 8:23 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Importance: High

Good morning Donna,

Janet Woodcock received the email below, and we are trying to gather more information so that she can respond quickly. Can Pfizer provide any information to clarify details of this purported adverse event (participant's name is in the email subject line)? We have reviewed again the information submitted with the adolescent EUA amendment, and the only SAE that could potentially fit the description is for the participant with Unique Subject ID: C4591001 1007 10071620, described as follows:

"The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

Could Pfizer please also provide any available update on this participant?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

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-steve

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
22MAY2008	12	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
155.5 cm	57.1 kg	23.6 kg/m2	30DEC2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Attention deficit disorder	Attention deficit hyperactivity disorder	2018	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	30DEC2020 (1)	10:26
2	BNT162b2	20JAN2021 (22)	16:30

Adverse Events											
AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	GASTR	Abdominal pain	Abdominal pain	21JAN2021 (23)		09FEB2021 (42)		20	2	TC	N
2	GASTR	Abdominal pain	Functional Abdominal Pain	28FEB2021 (61)		ONGOING			3	TC	Y
3	GASTR	Constipation	Constipation	28FEB2021 (61)		ONGOING			3	TC	Y
4	SKIN	Dermatitis contact	contact dermatitis bilateral arms	12FEB2021 (45)		ONGOING			1	TC	N
5	GASTR	Gastritis	Gastritis	30JAN2021 (32)		ONGOING			2	TC	N
6	NERV	Neuralgia	generalized Functional neurologic pain	21JAN2021 (23)		ONGOING			2	TC	Y
7	INFEC	Vulval abscess	Vulvar boil	24JAN2021 (26)		26JAN2021 (28)		3	1	TC	N

Adverse Events					
AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (09FEB2021)	Study Treatment	2	2	N
2	Yes	NOT RELATED/OTHER: no organic cause; no known precipitating factors	2	40	Y
3	Yes	NOT RELATED/OTHER: no organic cause identified	2	40	Y
4	Yes	NOT RELATED/OTHER: suspected reaction to tape	2	24	N
5	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	11	N
6	Yes	NOT RELATED/OTHER: unspecified	2	2	Y
7	Resolved (26JAN2021)	NOT RELATED/OTHER: Presumed staph infection	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30DEC2020	
Completed	VACCINATION	18FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

From: Gruber, Marion [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=019CD2669C7048F7A116D72B7682DE44-GRUBER]
Sent: 6/24/2021 11:16:07 AM
To: Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

all we need though...

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Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Totally agree, just keeping you updated that this does not appear to be a spurious report (though causal relationship is another matter altogether).

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From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Thursday, June 24, 2021 11:11 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Doran,
I think at this point we need to wait for Pfizer, hopefully they can clarify.
Marion

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To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
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Donna

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Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

From: Fink, Doran [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3BFBF3E7BEA40B1B726937796EBA4E8-FINKDO]
Sent: 6/25/2021 9:06:42 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Nair, Narayan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=debe49605be845e5a44d59cf099b8cb8-Narayan.Nai]
Subject: RE: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed
Attachments: c4591001-narratives-30apr21-ir_subject 1620.pdf

Will do - Pfizer is looking into it, and Donna Boyce has promised to get back to us ASAP. Meantime, I found some posts to the internet (on anti-vaccine sites) purported to be from this girl's parents, and based on age and dates of vaccination it is looking likely that this is the same trial participant described in our adolescent EUA review memo and excerpted in my email yesterday, and again below:

"The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

During the review, we asked Pfizer for additional information about this case, and they could not provide anything aside from the narrative attached, which is not helpful. According to postings to the internet, the working diagnosis is functional neurologic disorder (i.e., not GBS or other neuroinflammatory disorder, and these would need to have been excluded to arrive at the functional disorder diagnosis), so causal attribution would be difficult. But ultimately we need Pfizer to provide more information from medical records and not rely on what's on the internet.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, June 25, 2021 8:13 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Nair, Narayan <Narayan.Nair@fda.hhs.gov>
Subject: FW: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed

Dear Doran,

Would appreciate any updates on this potential case when we have any more information.

Best Regards,
Peter

-----Original Message-----
From: Marks, Peter
Sent: Friday, June 25, 2021 8:08 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed

Dear Janet,

Our staff is looking into this. We will keep you updated.

Best Regards,
Peter

-----Original Message-----
From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, June 25, 2021 8:05 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed
Importance: High

More on this. jw

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Friday, June 25, 2021 1:10 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed
Importance: High

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

She's still paralyzed. Has to eat via feeding tube. cannot walk on her own. She was in the Pfizer clinical trial in January.

You know this right?

-steve

Demography				
Date of Birth	Age at Enrollment (Years)	Race	Ethnicity	Sex
22MAY2008	12	White	Hispanic/Latino	F

Vital Signs - Baseline			
Height	Weight	BMI	Date Collected (Study Day)
155.5 cm	57.1 kg	23.6 kg/m2	30DEC2020 (1)

Medical History			
Investigator Text	MedDRA Preferred Term	Start Date	Disease Status
Attention deficit disorder	Attention deficit hyperactivity disorder	2018	Present

Study Vaccination(s)			
Vaccination Number	Vaccine	Vaccination Date (Study Day)	Time of Vaccination
1	BNT162b2	30DEC2020 (1)	10:26
2	BNT162b2	20JAN2021 (22)	16:30

Adverse Events

AE Number	MedDRA SOC	MedDRA Preferred Term	Investigator Text	Start Date (Study Day)	Start Time	Stop Date (Study Day)	Stop Time	Duration (Days)	Toxicity Grade	Action to Subject	SAE
1	GASTR	Abdominal pain	Abdominal pain	21JAN2021 (23)		09FEB2021 (42)		20	2	TC	N
2	GASTR	Abdominal pain	Functional Abdominal Pain	28FEB2021 (61)		ONGOING			3	TC	Y
3	GASTR	Constipation	Constipation	28FEB2021 (61)		ONGOING			3	TC	Y
4	SKIN	Dermatitis contact	contact dermatitis bilateral arms	12FEB2021 (45)		ONGOING			1	TC	N
5	GASTR	Gastritis	Gastritis	30JAN2021 (32)		ONGOING			2	TC	N
6	NERV	Neuralgia	generalized Functional neurologic pain	21JAN2021 (23)		ONGOING			2	TC	Y
7	INFEC	Vulval abscess	Vulvar boil	24JAN2021 (26)		26JAN2021 (28)		3	1	TC	N

Adverse Events

AE Number	AE Still Present?	AE Related To:	Prior Vaccination Number	Relative Day From Prior Vaccination	Narrative Event
1	Resolved (09FEB2021)	Study Treatment	2	2	N
2	Yes	NOT RELATED/OTHER: no organic cause; no known precipitating factors	2	40	Y
3	Yes	NOT RELATED/OTHER: no organic cause identified	2	40	Y
4	Yes	NOT RELATED/OTHER: suspected reaction to tape	2	24	N
5	Yes	NOT RELATED/CONCOMITANT DRUG TREATMENT	2	11	N
6	Yes	NOT RELATED/OTHER: unspecified	2	2	Y
7	Resolved (26JAN2021)	NOT RELATED/OTHER: Presumed staph infection	2	5	N

Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30DEC2020	
Completed	VACCINATION	18FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

From: Nair, Narayan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DEBE49605BE845E5A44D59CF099B8CB8-NARAYAN.NAI]
Sent: 6/25/2021 9:54:52 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: Automatic reply: [EXTERNAL] Pfizer clinical trial did NOT report Maddie de Garay's result that she was paralyzed

I am (b) (6) and will have limited access to emails. Please contact Dr. Meghna Alimchandani at meghna.alimchandani@fda.hhs.gov for anything time sensitve.

From: Fink, Doran [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3BFBF3E7BEA40B1B726937796EBA4E8-FINKDO]
Sent: 6/29/2021 10:56:45 AM
To: Boyce, Donna [(b) (6)@pfizer.com]
CC: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Gurtman, Alejandra C [Alejandra.Gurtman@pfizer.com]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Attachments: c4591001-narratives-30apr21-ir_subject 1620.pdf

Dear Donna,

Thanks for the update. Just to be clear, the narrative provided with the EUA submission (attached) was pretty scant on details, and no additional details were available from Pfizer when we asked during the review. I appreciated that Pfizer may not have had access to any additional details at the time, so it will be very helpful to have the more detailed follow-up that is forthcoming.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Tuesday, June 29, 2021 9:49 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Dear Doran,
My apologies. I thought this message had been sent to you last week. You are correct and this is participant 10071620. This case from the COVID-19 C4591001 study was reported in the EUA with a narrative. It was also presented to the ACIP working group and many other recommending bodies. We are collating the SAEs follow up and will send to you shortly. In the meantime, Dr Alejandra Gurtman spoke with Dr Frenck who is the Principal Investigator at Cincinnati's Children today and confirmed that this case is not related to the vaccine and that the participant has had extensive work up with consultations with various specialties including pulmonary, neurology, pain management and psychiatry with no findings of anything organic.
We will include all pertinent data in the follow up.
Best Regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 9:32 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Hi Donna,

Please update us on where things stand with this request so that we can get back to Peter Marks and Janet Woodcock.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Thursday, June 24, 2021 9:22 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Doran,
Thanks for reaching out. I will look into this and get back to you as soon as possible.
Kind regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, June 24, 2021 8:23 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Importance: High

Good morning Donna,

Janet Woodcock received the email below, and we are trying to gather more information so that she can respond quickly. Can Pfizer provide any information to clarify details of this purported adverse event (participant's name is in the email subject line)? We have reviewed again the information submitted with the adolescent EUA amendment, and the only SAE that could potentially fit the description is for the participant with Unique Subject ID: C4591001 1007 10071620, described as follows:

"The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

Could Pfizer please also provide any available update on this participant?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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do you know the story of this girl? She was in the Pfizer trial.

She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

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Prohibited Concomitant Medications
No Prohibited Concomitant Medications

Nonstudy Vaccines
No Nonstudy Vaccines

Subject Summary			
Status	Study Phase	Withdrawal/Completion Date	Reason for Withdrawal
Completed	SCREENING	30DEC2020	
Completed	VACCINATION	18FEB2021	
	REPEAT SCREENING 1		
	OPEN LABEL TREATMENT		
	FOLLOW-UP		

Sent: 6/29/2021 11:05:04 AM
To: Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]
CC: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran,

Thanks so much for forwarding this along

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 10:59 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Peter,

Still waiting on Pfizer to provide additional details, and I bothered them again this morning. Response below, with a promise of more to come.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Tuesday, June 29, 2021 9:49 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Dear Doran,
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Hi Donna,

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Thanks,
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Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
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Sent: Thursday, June 24, 2021 9:22 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Doran,
Thanks for reaching out. I will look into this and get back to you as soon as possible.
Kind regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
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To: Boyce, Donna <(b) (6)@pfizer.com>
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Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Importance: High

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Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

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Sent: Wednesday, June 23, 2021 11:41 PM
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Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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-steve

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 6/29/2021 11:07:23 AM
To: Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]
CC: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran,

Thanks so much for forwarding this along - very much appreciated.

Best Regards,
Peter

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From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 10:59 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
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To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Hi Donna,

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Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
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From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Thursday, June 24, 2021 9:22 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
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Doran,
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Kind regards,
Donna

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To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Importance: High

Good morning Donna,

Janet Woodcock received the email below, and we are trying to gather more information so that she can respond quickly. Can Pfizer provide any information to clarify details of this purported adverse event (participant's name is in the email subject line)? We have reviewed again the information submitted with the adolescent EUA amendment, and the only SAE that could potentially fit the description is for the participant with Unique Subject ID: C4591001 1007 10071620, described as follows:

"The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

Could Pfizer please also provide any available update on this participant?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

do you know the story of this girl? She was in the Pfizer trial.

She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

From: Gurtman, Alejandra C [Alejandra.Gurtman@pfizer.com]
Sent: 6/30/2021 10:29:54 AM
To: Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]
CC: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Boyce, Donna [(b) (6)@pfizer.com]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Attachments: 2021101980 medical summary.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Doran,
Attached please find the updated narrative for this participant. Please note that it has been downloaded from our system and an official CIOMS form will follow but we wanted you to have the information.
I have been in regular contact with the Principal Investigator as well and his assessment remains that the events described are not related to the vaccine
Please let me know if you have any questions.
Best regards
Alejandra

-----Original Message-----
From: Gurtman, Alejandra C
Sent: Tuesday, June 29, 2021 11:11 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran
We are putting together a comprehensive narrative of the case for your review.
Hope to have it ready for you within the next day or so Best regards, Alejandra

Alejandra Gurtman, MD
Vice President
Pfizer Vaccine Clinical Research and Development
Tel (b) (6) Cel (b) (6)
Fax 845 474 3219
Email: alejandra.gurtman@pfizer.com

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 10:57 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Donna,

Thanks for the update. Just to be clear, the narrative provided with the EUA submission (attached) was pretty scant on details, and no additional details were available from Pfizer when we asked during the review. I appreciated that Pfizer may not have had access to any additional details at the time, so it will be very helpful to have the more detailed follow-up that is forthcoming.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Tuesday, June 29, 2021 9:49 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Dear Doran,
My apologies. I thought this message had been sent to you last week. You are correct and this is participant 10071620. This case from the COVID-19 C4591001 study was reported in the EUA with a narrative. It was also presented to the ACIP working group and many other recommending bodies. We are collating the SAEs follow up and will send to you shortly. In the meantime, Dr Alejandra Gurtman spoke with Dr Frenck who is the Principal Investigator at Cincinnati's Children today and confirmed that this case is not related to the vaccine and that the participant has had extensive work up with consultations with various specialties including pulmonary, neurology, pain management and psychiatry with no findings of anything organic.
We will include all pertinent data in the follow up.
Best Regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 9:32 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Hi Donna,

Please update us on where things stand with this request so that we can get back to Peter Marks and Janet Woodcock.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Thursday, June 24, 2021 9:22 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Doran,
Thanks for reaching out. I will look into this and get back to you as soon as possible.
Kind regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, June 24, 2021 8:23 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Importance: High

Good morning Donna,

Janet Woodcock received the email below, and we are trying to gather more information so that she can respond quickly. Can Pfizer provide any information to clarify details of this purported adverse event (participant's name is in the email subject line)? We have reviewed again the information submitted with the adolescent EUA amendment, and the only SAE that could potentially fit the description is for the participant with Unique Subject ID: C4591001 1007 10071620, described as follows:

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Could Pfizer please also provide any available update on this participant?

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Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
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-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

Medical Summary

Case Number: **2021101980**

General Case Information

Report Type	Pfizer Spons Interv Study
Initial Receipt Date	01-Feb-2021
Case Creation Time	02-Feb-2021 06:00
Country of Incidence	UNITED STATES
Health Care Professional	Yes

Study Information

Study Project ID	PF-07302048
Study ID	C4591001
Study Center ID	1007
Pat. ID	10071620

Patient Information

Age	12 Years
Date of Birth	22-MAY-2008
Weight	57.100 kg
Patient Height in.	155.500 cm
Race Information	Caucasian
Gender	Female
Pregnant	

Reporter Information

Reporter Type	Physician	**Country**	UNITED STATES	**Email Address**	IN CONFIDENCE
Reporter Name	Dr. Robert Frenck				

Narrative / Comment

Narrative

A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's behalf.

A 12-year-old female subject received blinded study vaccine (BNT162; PLACEBO), first dose on 30Dec2020 at 10:26 and second dose on 20Jan2021 at 16:30, both intramuscularly on left deltoid at single doses for coronavirus disease 2019 (COVID-19) immunization. Ongoing medical history included attention deficit disorder and anxiety, both from 2018. Ongoing concomitant medications included lisdexamfetamine mesilate (VYVANSE) for attention deficit hyperactivity disorder (ADHD) from 2018, paracetamol (TYLENOL) and ibuprofen both for fever and pain from 20Jan2021 and ketorolac tromethamine (TORADOL) for pain from 23Jan2021. The subject had no concomitant vaccines administered on same date of the investigational vaccine or prior vaccines within 4 weeks. The subject experienced generalized functional neurological disorder on 21Jan2021 which required a visit to emergency room and resulted in hospitalization. Clinical course was reported as follows: subject was with history only significant for well-controlled ADHD. The subject did not have any history of abdominal pain/complaints. She received the second vaccine on 20Jan2021. Her reactogenicity symptoms included fever to 101.4 degrees Fahrenheit (F) on day 2 with severe chills, myalgia, arthralgia, fatigue and headache. Her fever resolved. She remained with moderate to severe fatigue, headache, chills, myalgia and arthralgia which were present on day 7. She also developed mild diarrhea on day 7. She presented to the emergency department on 21Jan2021 with severe abdominal and flank pain, myalgia and headache. COVID-19 polymerase chain reaction (PCR)/ COVID-19 nucleic acid amplification test (NAAT) was negative (manufactured by COPAN and distributed by CLIA certified lab). She was well-appearing, well-hydrated, with stable vital signs. Abdominal ultrasound (ultrasound right lower quadrant (RLQ)) done on 21Jan2021 to rule out (r/o) appendicitis. Appendix not visualized, but there were no secondary signs; no ultrasound findings to support diagnosis of appendicitis. Her urinalysis showed moderate blood without red blood cells (RBC) so she was screened for rhabdomyolysis,

Medical Summary

Case Number: 2021101980

which was negative. Urine culture was negative. She improved with intravenous fluids and paracetamol/ibuprofen and was discharged home. She returned to the emergency department on 23Jan2021 with continued severe abdominal pain and headache; also with lower back, neck pan and chest pain. Computerized tomogram (CT) abdomen/pelvis was normal, noncontrast CT of the abdomen and pelvis; no urinary tract calculi. Ultrasound RLQ with pelvis/doppler was normal pelvic ultrasound. Electrocardiogram (ECG) did not demonstrate significant cardiac pathology. She improved with intravenous fluids and ketorolac tromethamine. Subject was discharged to home. After 1 to 2 days, the pain progressively returned. The subject again returned to the emergency department on 30Jan2021 with worsening fatigue, abdominal pain (generalized), tenderness to touch of her neck, back, chest and bilateral legs. Her vital signs were stable. Physical examination (PE) significant for pain to light-moderate palpation over lower back, bilateral buttocks, posterior neck and bilateral scapular regions. Her neurological exam was normal. Complete blood count (CBC) with hemoglobin (Hgb) 14.1 g/dL (normal: 12.0 to 16.0), hematocrit (Hct) 41.3 % (normal: 36.0 to 46.0), platelets 471 x10 3/mm3 (normal: 135 to 466), sedimentation rate 9, lipase 39.0 iu/L (normal: 12.0 to 50.0), blood urea nitrogen (BUN) 25 mg/dL (normal 8.0 to 18.0), BUN 13, creatinine 0.43 mg/dl (range 0.42-0.71), alanine aminotransferase (ALT) 22, aspartate aminotransferase (AST) 21, total bilirubin 0.2, and C-reactive protein (CRP) less than 0.40 mg/dL (normal: less than or equal to 0.40), white blood cell count (WBC) 8.82 x10 3/mm3 (normal: 4.5 to 13.5) and creatine phosphokinase (CPK) 123 iu/L (normal: 31 to 145). Urinalysis (UA) was normal without blood. Although stable, the subject was hospitalized for observation. During admission, her exam, test results and imaging were reassuring against neurologic or anatomical causes for pain. The focus of admission was pain control and a developing psychiatric network to provide support. The pain team was consulted who prescribed gabapentin with uptitration over the following weeks (200 mg daily orally for 1 week, then increase to 200 mg twice daily (BID) orally for 1 week then increase to 200 mg twice daily (TID) orally). She was also prescribed naproxen 375 mg BID for 5 days (followed by as needed (PRN)), paracetamol every 6 hours while awake and methocarbamol (ROBAXIN) 750 mg PRN. She was referred to psychology and physical therapy. Her symptoms were gradually improving. The subject also endorsed constipation during her admission. She was prescribed macrogol 3350 (MIRALAX) 1 capsule (cap) BID. She also started on famotidine 20 mg BID due to symptoms of gastritis secondary to prolonged ibuprofen use. It was also noted that the subject was seen as an outpatient by her primary care provider on 24Jan2021 for a very small boil (erythema measuring less than 0.25 cm with small white tip in the center) on her left inferior labia majora. She was prescribed topical clindamycin 1% gel for 7 days and warm compress. The boil drained at home and resolved on 26Jan2021. The assessment of the cause for the vulvar boil was done per site investigator; upon further discussion, the etiology of methicillin-resistant staphylococcus aureus (MRSA) had been revised to probable staph infection. The boil drained at home after warm compresses without incision and drainage by a medical provider. Therefore, no culture was done. The subject had no known history of MRSA exposure or prior risk factor for MRSA. This was not thought to be the cause of her fever or abdominal pain. The subject had not onset of menses so the conditions were not related. Abdominal examination findings at each of the three emergency room (ER) visits as below: On 21Jan2021, emergency department (ED) abdominal physical examination (PE) findings: Soft, tender to palpation over bilateral lower quadrants, bilateral costovertebral angle (CVA), no rebound or guarding, +BS, no hepatosplenomegaly. On 23Jan2021, ED abdominal PE findings: Soft, non-distended, pain and guarding in the Image result for right lower quadrant (RLQ), no rebound or guarding, +BS, no hepatosplenomegaly. On 30Jan2021, ED abdominal PE findings: NABS. Guarding present initially, but then tolerates exam. TIP across all quadrants. ND with no organomegaly. The subject's diagnose updated to generalized functional neurologic disorder on 09Apr2021 and functional abdominal pain. It was reported that subject had functional abdominal pain from 28Feb2021, constipation from 28Feb2021, and gastritis from 30Jan2021, all ongoing. On 24Mar2021, the subject had worsening of event. The subject had multiple life stressors in the months preceding her diagnosis of functional neurologic disorder. Since that time, the subject continued with diffuse myalgia, dizziness, headaches, decreasing strength in her lower extremities, abdominal pain, vomiting, poor appetite, constipation, and intermittent rash on upper extremities. In addition, the subject had "passed out twice" between 19Feb2021 and 20Feb2021. Her work-up included psychology, medical pain consult, gastrointestinal (GI) consult for abdominal pain and poor oral intake status post (S/p) esophagogastroduodenoscopy (EGD) with normal biopsies, neurology consult with normal MRI spine, initiation of escitalopram oxalate for anxiety. Since her hospital discharge on 13Mar2021, the subject continued with lower extremity weakness and numbness progressing to inability to walk, emesis and regurgitation of most oral (PO), word finding difficulties, moodiness, longer "spells" consisting of falling down/over, both arms shaking, eyes rolling back and unresponsiveness lasting up to 6 minutes, as well as more frequent "zoning out" episodes. The subject weight had decreased from 57. 1 kg on 06Mar2021 to 52.6 kg on 09Apr2021. The subject presented to the emergency department on 09Apr2021 due to the worsening symptoms above. The subject was well-appearing and interactive with stable vital signs. Neurological exam consistent with functional signs. Reflexes were normal. The subject was confined to a wheelchair with reports of lower extremity paralysis but was able to lift her leg onto the wheelchair at one point. Her abdomen was soft, nontender without masses or organomegaly. The subject labs were significant for glucose of 47 (asymptomatic). The subject received D25 intravenous bolus with resolution

Medical Summary

Case Number: 2021101980

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of hypoglycemia. The subject was admitted for observation and management of symptoms. The "spells" observed in the hospital were less likely consistent with seizure given distractibility, variability of episodes, and lack of postictal phase. It was reported that her neurologic examination was consistent with a functional neurological disorder. The subject was evaluated by speech therapy who recommended Videofluoroscopic Swallow Study/ fiberoptic endoscopic evaluation of swallowing (VSS/FEES) for further evaluation of oral-motor dysfunction. VSS showed functional oral motors skills and adequate airway protection but severe gagging and emesis with all PO. The UES appeared to be functioning on VSS. The subject did not initiate swallowing. The subject was evaluated by physical therapist/occupational therapist (PT/OT) who recommended an inpatient rehabilitation stay, However, a direct inpatient admit was not possible. The subject was discharged to home on 14Apr2021 with the plan for outpatient rehabilitation to include OT/PT/Speech therapy, as well as psychotherapy. The subject was discharged from the hospital on 14Apr2021; however, she was then transferred to the inpatient pediatric rehabilitation unit where she remained. Her rehabilitation had included physical therapy, occupational therapy, speech therapy, therapeutic recreation, and psychosocial services. Subject remained with moderate pain requiring paracetamol, ibuprofen, and cyclobenzaprine hydrochloride (FLEXERIL) as previously prescribed. She had made progress in her ability to walk. She continued with gagging and was requiring nasogastric tube feedings, but she was eating small amounts of soft foods. She was receiving psychotherapy and remained on escitalopram oxalate (LEXAPRO). Relevant laboratory information included: Liver function test (LFT) was last drawn on 30Jan2021 which showed within normal limits (WNL). However, the subject did not have LFT's drawn during this admission. Furthermore, the subject has not had toxicology or ceruloplasmin screening. Other laboratory tests on 09Apr2021 included: sodium which showed 135 mmol/L (normal range: 136-145), potassium 3.4 mmol/L (normal range 3.3- 4.7), chloride 102 mmol/L (normal range: 100-112), Carbon dioxide (CO2) 16 mg/dl (normal range: 17 to 31), BUN 6 mg/dl (normal range: 8 to 18), creatinine 0.43mg/dl (normal range: 0.42 to 0.71), glucose 47 mg/dl (normal range: 65 to 106) and rapid glucose 213 mg/dl (normal range: 65 to 106) following D25. COVID testing was not performed. The subject remained in inpatient rehabilitation until 01Jun2021. She continued to demonstrate functional weakness and abnormal movements of her legs with slow improvement. She was able to progress and use her legs for more functional activities such as walking with a walker. She was not able to progress to walking without assistive device. She had one episode of functional episode of shaking her bilateral upper extremities and right upper extremity during her rehabilitation which resolved within 24 hours. She continued with anxiety which was being treated with escitalopram oxalate from 13Mar2021 and ongoing and alprazolam (ATARAX) from Feb2021 and ongoing. Her generalized pain was slowly improving on cyclobenzaprine hydrochloride. She was voiding independently during her rehabilitation stay but did require occasional urinary catherization for elevated bladder volumes. This was believed to be functional withholding. She continued with constipation treated with macrogol 3350 from 28Feb2021 and ongoing and senna (SENOKOT) from 27May2021 and ongoing. She was requiring nasogastric tube feedings for nutrition. She had very limited oral intake. Her swallow study and speech evaluation were consistent with oral aversion. Due to insurance issues, subject was discharged from inpatient rehabilitation on 01Jun201 and transferred to an inpatient psychiatric facility. The parents decided to take subject out of the psychiatric facility against medical advice. She was discharged to home on 01Jun2021. It was reported that subject had the following medications: bisacodyl suppository for constipation from 27Apr2021, paracetamol from 21Jan2021 for generalized functional neurologic pain, paracetamol from 21Jan2021 and cyclobenzaprine hydrochloride from 25Feb2021, both for generalized functional neurologic pain, ibuprofen from 19Mar2021 for functional generalized neurologic pain, and lansoprazole (PREVACID) from 14Mar2021 for functional abdominal pain, all ongoing, famotidine (PEPCID) from 30Jan2021 to Apr2021 for gastritis and pregabalin (LYRICA) from 25Feb2021 to 28Mar2021 for generalized functional neurologic pain. The action taken in response to the event for blinded study vaccine was not applicable. Outcome of the event was not recovered.

The investigator considered there was not a reasonable possibility that the event generalized functional neurological disorder was related to blinded study vaccine, concomitant drugs or clinical trial procedure. The PI did not feel that the subject's symptology was consistent with a vaccine related adverse event.

Follow-up (10Feb2021): New information reported includes: lab data (abdominal PE), event data (SAE updated form functional neurologic pain to generalized functional neurologic pain, onset date) and clinical course (no history of abdominal pain).

Follow-up (02Apr2021): New reported information includes: reporter information.

Follow-up (20Apr2021): New information reported includes: SAE term updated from generalized functional neurologic pain to generalized functional neurological disorder.

Medical Summary

Case Number: 2021101980

Follow-up (17May2021): New information reported includes: medical history.

Follow-up (08Jun2021): This is a follow-up report combining information from duplicate reports 2021101980 and 2021418472. The current and all subsequent follow-up information will be reported under manufacturer report number 2021101980. New information reported includes: lab data, reaction data (treatment), outcome (updated to not recovered) and clinical course (worsening of event, hospitalization information and subject status).

Case Comment

Based on the information available and on the pathophysiology of the event company does not reasonably attribute the reported event as related to study vaccine, concomitant drugs, or clinical trial procedure. The event was likely due to subject underlying contributory factors

PSUR/Line Listing Comment

This case is cross-referenced to case 2021291329: same patient, same study, different event.

Case Serious	Listedness Determination	Case Causality	Case Outcome
Yes	Unlisted	No	Not recovered/Not resolved

Medications - Suspect

#	Product Name Generic Name	Reported Indication	Duration of Administration	Total Dosage Total Dose to Primary Event / Units	Product Event Delay Product Event Latency	Action Taken	Dechallenge Results Rechallenge Results
1	BNT162;PLACEBO BNT162;PLACEBO	COVID-19 immunization(COVID-19 immunisation)		Blinded Blinded	7 hrs 30 min 7 hrs 30 min	Not Applicable	N/A N/A

Dosage Regimens

#	Start Date/Time	Stop Date/Time	Dose	Frequency	Patient Route of Administration
1	20-JAN-2021 16:30:00	20-JAN-2021 16:30:00	Blinded	Blinded	Blinded

Medications - Concomitant

#	Product Name	Generic Name	Reported Indication	Duration of Administration
1	TYLENOL	PARACETAMOL	fever(Pyrexia) pain(Pain)	

Dosage Regimens

#	Dose
1	

Medical Summary

Case Number: **2021101980**

#	Product Name	Generic Name	Reported Indication	Duration of Administration
2	IBUPROFEN	IBUPROFEN	fever(Pyrexia) pain(Pain)	
	Dosage Regimens **#** **Dose** 1			
3	TORADOL	KETOROLAC TROMETHAMINE	Pain(Pain)	
	Dosage Regimens **#** **Dose** 1			
4	VYVANSE	LISDEXAMFETAMINE MESILATE	ADHD(Attention deficit hyperactivity disorder)	
	Dosage Regimens **#** **Dose** 1			

Devices

No information present

Events

#	Description as Reported	Preferred Term Lower Level Term	Onset Date/Time Stop Date/Time	Duration	Onset Latency Onset From Last Dose		Seriousness Criteria	Outcome of Event
1	generalized functional neurological disorder	Conversion disorder Functional neurological symptom disorder	21-JAN-2021		7 hrs 30 min 7 hrs 30 min		Yes Hospitalized	Not recovered/Not resolved

Event Assessment

No information present

Medical Summary

Case Number: **2021101980**

Hospitalization Information

Description as Reported	Hospitalization Start Date	Hospitalization End Date	Duration of Hospitalization	Event Caused Hospitalization	Hospitalization Prolonged	Hospital Discharge Summary Available
generalized functional neurological disorder		14-APR-2021		Yes	No	No

Patient Relevant History

#	Start	Stop Date	Ongoing	Condition Type	Coded PT
1	30-DEC-2020	30-DEC-2020		Historical Vaccine	BNT162;PLACEBO (BLINDED THERAPY)(Drug Indication: COVID-19 immunisation)
	Notes: Dose 1 at 10:26, IM in the left deltoid at single dose				
2	2018		Yes	Relevant Med History	attention deficit disorder (Attention deficit hyperactivity disorder)
	Notes: well-controlled				
3	2018		Yes	Relevant Med History	anxiety (Anxiety)

Patient Lab Tests

#	Date	Test Name	Results	Norm High	Norm Low	Assessment
1	30-JAN-2021	Alanine aminotransferase	22			
2	30-JAN-2021	Aspartate aminotransferase	21			
3		Barium swallow	functional oral motors skills and adequate airway			
4		Biopsy	normal			
5	30-JAN-2021	Blood bilirubin	0.2			
6	09-APR-2021	Blood chloride	102 mmol/L	112	100	
7	30-JAN-2021	Blood creatine phosphokinase	123 IU/l	145	31	
8	30-JAN-2021	Blood creatinine	0.43 mg/dl	0.71	0.42	
9	09-APR-2021	Blood creatinine	0.43 mg/dl	0.71	0.42	
10	09-APR-2021	Blood glucose	47 mg/dl	106	65	
11	09-APR-2021	Blood glucose	213 mg/dl	106	65	
12	09-APR-2021	Blood potassium	3.4 mmol/L	4.7	3.3	

Medical Summary

Case Number: **2021101980**

#	Date	Test Name	Results	Norm High	Norm Low	Assessment
13	09-APR-2021	Blood sodium	135 mmol/L	145	136	
14	30-JAN-2021	Blood urea	25 mg/dl	18.0	8.0	
15	30-JAN-2021	Blood urea	13 mg/dl	18.0	8.0	
16	09-APR-2021	Blood urea	6 mg/dl	18.0	8.0	
17		Body temperature	101.4 Fahrenheit			
18	09-APR-2021	Carbon dioxide	16 mmol/L	31	17	
19	23-JAN-2021	Computerised tomogram abdomen	normal noncontrast CT of the abdomen and pelvis.			
20	23-JAN-2021	Computerised tomogram pelvis	normal noncontrast CT of the abdomen and pelvis.			
21	30-JAN-2021	C-reactive protein	0.40 mg/dl			
22	21-JAN-2021	Culture urine	negative			Negative
23	23-JAN-2021	Electrocardiogram	did not demonstrate significant cardiac pathology			
24	30-JAN-2021	Haematocrit	41.3 %	46.0	36.0	
25	30-JAN-2021	Haemoglobin	14.1 g/dl	16.0	12.0	
26	21-JAN-2021	Investigation	negative			Negative
27	30-JAN-2021	Lipase	39.0 IU/l	50.0	12.0	
28	30-JAN-2021	Liver function test	within normal limits (WNL)			
29		Magnetic resonance imaging spinal	normal			
30	30-JAN-2021	Neurological examination	normal			
31	09-APR-2021	Neurological examination	consistent with functional signs			
32	21-JAN-2021	Physical examination	Soft, tender to palpation over bilateral lower			
33	23-JAN-2021	Physical examination	Soft, non-distended, pain and guarding in the RLQ,			
34	30-JAN-2021	Physical examination	NABS. Guarding present initially, but then			
35	30-JAN-2021	Physical examination	significant for pain to light-moderate palpation			
36	30-JAN-2021	Platelet count	471 x10 3/mm3	466	135	
37	30-JAN-2021	Red blood cell sedimentation	9			

Medical Summary

Case Number: **2021101980**

		rate				
#	Date	Test Name	Results	Norm High	Norm Low	Assessment
38	21-JAN-2021	SARS-CoV-2 test	negative			Negative
39	23-JAN-2021	Ultrasound Doppler	normal pelvic ultrasound			
40	21-JAN-2021	Ultrasound scan	appendix not visualized; no ultrasound findings to			
41	21-JAN-2021	Urine analysis	moderate blood without RBC			
42	30-JAN-2021	Urine analysis	normal without blood			
43	21-JAN-2021	Vital signs measurement	stable			
44	30-JAN-2021	Vital signs measurement	stable			
45	09-APR-2021	Weight	52.6 kg			
46	30-JAN-2021	White blood cell count	8.82 x10 3/mm3	13.5	4.5	

Relevant Tests

From: Fink, Doran [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B3BFBF3E7BEA40B1B726937796EBA4E8-FINKDO]
Sent: 6/30/2021 10:56:54 AM
To: Boyce, Donna (b) (6) @pfizer.com]; Gurtman, Alejandra C [Alejandra.Gurtman@pfizer.com]
CC: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Thanks Donna,

I think this detailed summary will go a long way toward bringing Peter Marks and Janet Woodcock up to speed on the case, and will let you know if we need additional information from Pfizer or from the PI.

Best,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna < (b) (6) @pfizer.com>
Sent: Wednesday, June 30, 2021 10:44 AM
To: Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>; Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Doran,
The PI is willing to discuss this case directly with CBER to provide more background and context. Please let us know if this would be helpful.
Kind regards,
Donna

-----Original Message-----
From: Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Sent: Wednesday, June 30, 2021 10:30 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Boyce, Donna < (b) (6) @pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran,
Attached please find the updated narrative for this participant. Please note that it has been downloaded from our system and an official CIOMS form will follow but we wanted you to have the information.
I have been in regular contact with the Principal Investigator as well and his assessment remains that the events described are not related to the vaccine Please let me know if you have any questions.
Best regards
Alejandra

-----Original Message-----
From: Gurtman, Alejandra C
Sent: Tuesday, June 29, 2021 11:11 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Boyce, Donna < (b) (6) @pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran
We are putting together a comprehensive narrative of the case for your review.
Hope to have it ready for you within the next day or so Best regards, Alejandra

Alejandra Gurtman, MD
Vice President
Pfizer Vaccine Clinical Research and Development Tel (b) (6) Cel (b) (6) Fax 845 474 3219
Email: alejandra.gurtman@pfizer.com

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 10:57 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Donna,

Thanks for the update. Just to be clear, the narrative provided with the EUA submission (attached) was pretty scant on details, and no additional details were available from Pfizer when we asked during the review. I appreciated that Pfizer may not have had access to any additional details at the time, so it will be very helpful to have the more detailed follow-up that is forthcoming.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Tuesday, June 29, 2021 9:49 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Dear Doran,
My apologies. I thought this message had been sent to you last week. You are correct and this is participant 10071620. This case from the COVID-19 C4591001 study was reported in the EUA with a narrative. It was also presented to the ACIP working group and many other recommending bodies. We are collating the SAEs follow up and will send to you shortly. In the meantime, Dr Alejandra Gurtman spoke with Dr Frenck who is the Principal Investigator at Cincinnati's Children today and confirmed that this case is not related to the vaccine and that the participant has had extensive work up with consultations with various specialties including pulmonary, neurology, pain management and psychiatry with no findings of anything organic.
We will include all pertinent data in the follow up.
Best Regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 9:32 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Hi Donna,

Please update us on where things stand with this request so that we can get back to Peter Marks and Janet Woodcock.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Thursday, June 24, 2021 9:22 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Doran,
Thanks for reaching out. I will look into this and get back to you as soon as possible.
Kind regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, June 24, 2021 8:23 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Importance: High

Good morning Donna,

Janet Woodcock received the email below, and we are trying to gather more information so that she can respond quickly. Can Pfizer provide any information to clarify details of this purported adverse event (participant's name is in the email subject line)? We have reviewed again the information submitted with the adolescent EUA amendment, and the only SAE that could potentially fit the description is for the participant with Unique Subject ID: C4591001 1007 10071620, described as follows:

"The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

Could Pfizer please also provide any available update on this participant?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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do you know the story of this girl? She was in the Pfizer trial.

She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

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Sent: 6/30/2021 1:38:10 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Attachments: 2021101980 medical summary.pdf

Dear Peter,

Pfizer has provided the attached updated narrative on this study participant, which provides a more detailed account of her illness and diagnosis of a functional neurologic disorder based on extensive specialist evaluation and consistent exam, labs, and imaging. This illness is considered not due to an organic process, and while temporally associated with vaccination it is difficult to explain a physiologically causal association.

Thanks,
Doran

Doran L. Fink, MD, PhD
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Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
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Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Boyce, Donna <(b) (6)@pfizer.com>
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Alejandra Gurtman, MD
Vice President
Pfizer Vaccine Clinical Research and Development Tel (b) (6) Cel (b) (6) Fax 845 474 3219
Email: alejandra.gurtman@pfizer.com

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Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
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Importance: High

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Could Pfizer please also provide any available update on this participant?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

Medical Summary

Case Number: **2021101980**

General Case Information

Report Type	Pfizer Spons Interv Study
Initial Receipt Date	01-Feb-2021
Case Creation Time	02-Feb-2021 06:00
Country of Incidence	UNITED STATES
Health Care Professional	Yes

Study Information

Study Project ID	PF-07302048
Study ID	C4591001
Study Center ID	1007
Pat. ID	10071620

Patient Information

Age	12 Years
Date of Birth	22-MAY-2008
Weight	57.100 kg
Patient Height in.	155.500 cm
Race Information	Caucasian
Gender	Female
Pregnant	

Reporter Information

Reporter Type	Physician	**Country**	UNITED STATES	**Email Address**	IN CONFIDENCE
Reporter Name	Dr. Robert Frenck				

Narrative / Comment

Narrative

A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's behalf.

A 12-year-old female subject received blinded study vaccine (BNT162; PLACEBO), first dose on 30Dec2020 at 10:26 and second dose on 20Jan2021 at 16:30, both intramuscularly on left deltoid at single doses for coronavirus disease 2019 (COVID-19) immunization. Ongoing medical history included attention deficit disorder and anxiety, both from 2018. Ongoing concomitant medications included lisdexamfetamine mesilate (VYVANSE) for attention deficit hyperactivity disorder (ADHD) from 2018, paracetamol (TYLENOL) and ibuprofen both for fever and pain from 20Jan2021 and ketorolac tromethamine (TORADOL) for pain from 23Jan2021. The subject had no concomitant vaccines administered on same date of the investigational vaccine or prior vaccines within 4 weeks. The subject experienced generalized functional neurological disorder on 21Jan2021 which required a visit to emergency room and resulted in hospitalization. Clinical course was reported as follows: subject was with history only significant for well-controlled ADHD. The subject did not have any history of abdominal pain/complaints. She received the second vaccine on 20Jan2021. Her reactogenicity symptoms included fever to 101.4 degrees Fahrenheit (F) on day 2 with severe chills, myalgia, arthralgia, fatigue and headache. Her fever resolved. She remained with moderate to severe fatigue, headache, chills, myalgia and arthralgia which were present on day 7. She also developed mild diarrhea on day 7. She presented to the emergency department on 21Jan2021 with severe abdominal and flank pain, myalgia and headache. COVID-19 polymerase chain reaction (PCR)/ COVID-19 nucleic acid amplification test (NAAT) was negative (manufactured by COPAN and distributed by CLIA certified lab). She was well-appearing, well-hydrated, with stable vital signs. Abdominal ultrasound (ultrasound right lower quadrant (RLQ)) done on 21Jan2021 to rule out (r/o) appendicitis. Appendix not visualized, but there were no secondary signs; no ultrasound findings to support diagnosis of appendicitis. Her urinalysis showed moderate blood without red blood cells (RBC) so she was screened for rhabdomyolysis,

Medical Summary

Case Number: 2021101980

which was negative. Urine culture was negative. She improved with intravenous fluids and paracetamol/ibuprofen and was discharged home. She returned to the emergency department on 23Jan2021 with continued severe abdominal pain and headache; also with lower back, neck pan and chest pain. Computerized tomogram (CT) abdomen/pelvis was normal, noncontrast CT of the abdomen and pelvis; no urinary tract calculi. Ultrasound RLQ with pelvis/doppler was normal pelvic ultrasound. Electrocardiogram (ECG) did not demonstrate significant cardiac pathology. She improved with intravenous fluids and ketorolac tromethamine. Subject was discharged to home. After 1 to 2 days, the pain progressively returned. The subject again returned to the emergency department on 30Jan2021 with worsening fatigue, abdominal pain (generalized), tenderness to touch of her neck, back, chest and bilateral legs. Her vital signs were stable. Physical examination (PE) significant for pain to light-moderate palpation over lower back, bilateral buttocks, posterior neck and bilateral scapular regions. Her neurological exam was normal. Complete blood count (CBC) with hemoglobin (Hgb) 14.1 g/dL (normal: 12.0 to 16.0), hematocrit (Hct) 41.3 % (normal: 36.0 to 46.0), platelets 471 x10 3/mm3 (normal: 135 to 466), sedimentation rate 9, lipase 39.0 iu/L (normal: 12.0 to 50.0), blood urea nitrogen (BUN) 25 mg/dL (normal 8.0 to 18.0), BUN 13, creatinine 0.43 mg/dl (range 0.42-0.71), alanine aminotransferase (ALT) 22, aspartate aminotransferase (AST) 21, total bilirubin 0.2, and C-reactive protein (CRP) less than 0.40 mg/dL (normal: less than or equal to 0.40), white blood cell count (WBC) 8.82 x10 3/mm3 (normal: 4.5 to 13.5) and creatine phosphokinase (CPK) 123 iu/L (normal: 31 to 145). Urinalysis (UA) was normal without blood. Although stable, the subject was hospitalized for observation. During admission, her exam, test results and imaging were reassuring against neurologic or anatomical causes for pain. The focus of admission was pain control and a developing psychiatric network to provide support. The pain team was consulted who prescribed gabapentin with uptitration over the following weeks (200 mg daily orally for 1 week, then increase to 200 mg twice daily (BID) orally for 1 week then increase to 200 mg twice daily (TID) orally). She was also prescribed naproxen 375 mg BID for 5 days (followed by as needed (PRN)), paracetamol every 6 hours while awake and methocarbamol (ROBAXIN) 750 mg PRN. She was referred to psychology and physical therapy. Her symptoms were gradually improving. The subject also endorsed constipation during her admission. She was prescribed macrogol 3350 (MIRALAX) 1 capsule (cap) BID. She also started on famotidine 20 mg BID due to symptoms of gastritis secondary to prolonged ibuprofen use. It was also noted that the subject was seen as an outpatient by her primary care provider on 24Jan2021 for a very small boil (erythema measuring less than 0.25 cm with small white tip in the center) on her left inferior labia majora. She was prescribed topical clindamycin 1% gel for 7 days and warm compress. The boil drained at home and resolved on 26Jan2021. The assessment of the cause for the vulvar boil was done per site investigator; upon further discussion, the etiology of methicillin-resistant staphylococcus aureus (MRSA) had been revised to probable staph infection. The boil drained at home after warm compresses without incision and drainage by a medical provider. Therefore, no culture was done. The subject had no known history of MRSA exposure or prior risk factor for MRSA. This was not thought to be the cause of her fever or abdominal pain. The subject had not onset of menses so the conditions were not related. Abdominal examination findings at each of the three emergency room (ER) visits as below: On 21Jan2021, emergency department (ED) abdominal physical examination (PE) findings: Soft, tender to palpation over bilateral lower quadrants, bilateral costovertebral angle (CVA), no rebound or guarding, +BS, no hepatosplenomegaly. On 23Jan2021, ED abdominal PE findings: Soft, non-distended, pain and guarding in the Image result for right lower quadrant (RLQ), no rebound or guarding, +BS, no hepatosplenomegaly. On 30Jan2021, ED abdominal PE findings: NABS. Guarding present initially, but then tolerates exam. TIP across all quadrants. ND with no organomegaly. The subject's diagnose updated to generalized functional neurologic disorder on 09Apr2021 and functional abdominal pain. It was reported that subject had functional abdominal pain from 28Feb2021, constipation from 28Feb2021, and gastritis from 30Jan2021, all ongoing. On 24Mar2021, the subject had worsening of event. The subject had multiple life stressors in the months preceding her diagnosis of functional neurologic disorder. Since that time, the subject continued with diffuse myalgia, dizziness, headaches, decreasing strength in her lower extremities, abdominal pain, vomiting, poor appetite, constipation, and intermittent rash on upper extremities. In addition, the subject had "passed out twice" between 19Feb2021 and 20Feb2021. Her work-up included psychology, medical pain consult, gastrointestinal (GI) consult for abdominal pain and poor oral intake status post (S/p) esophagogastroduodenoscopy (EGD) with normal biopsies, neurology consult with normal MRI spine, initiation of escitalopram oxalate for anxiety. Since her hospital discharge on 13Mar2021, the subject continued with lower extremity weakness and numbness progressing to inability to walk, emesis and regurgitation of most oral (PO), word finding difficulties, moodiness, longer "spells" consisting of falling down/over, both arms shaking, eyes rolling back and unresponsiveness lasting up to 6 minutes, as well as more frequent "zoning out" episodes. The subject weight had decreased from 57. 1 kg on 06Mar2021 to 52.6 kg on 09Apr2021. The subject presented to the emergency department on 09Apr2021 due to the worsening symptoms above. The subject was well-appearing and interactive with stable vital signs. Neurological exam consistent with functional signs. Reflexes were normal. The subject was confined to a wheelchair with reports of lower extremity paralysis but was able to lift her leg onto the wheelchair at one point. Her abdomen was soft, nontender without masses or organomegaly. The subject labs were significant for glucose of 47 (asymptomatic). The subject received D25 intravenous bolus with resolution

of hypoglycemia. The subject was admitted for observation and management of symptoms. The "spells" observed in the hospital were less likely consistent with seizure given distractibility, variability of episodes, and lack of postictal phase. It was reported that her neurologic examination was consistent with a functional neurological disorder. The subject was evaluated by speech therapy who recommended Videofluoroscopic Swallow Study/ fiberoptic endoscopic evaluation of swallowing (VSS/FEES) for further evaluation of oral-motor dysfunction. VSS showed functional oral motors skills and adequate airway protection but severe gagging and emesis with all PO. The UES appeared to be functioning on VSS. The subject did not initiate swallowing. The subject was evaluated by physical therapist/occupational therapist (PT/OT) who recommended an inpatient rehabilitation stay, However, a direct inpatient admit was not possible. The subject was discharged to home on 14Apr2021 with the plan for outpatient rehabilitation to include OT/PT/Speech therapy, as well as psychotherapy. The subject was discharged from the hospital on 14Apr2021; however, she was then transferred to the inpatient pediatric rehabilitation unit where she remained. Her rehabilitation had included physical therapy, occupational therapy, speech therapy, therapeutic recreation, and psychosocial services. Subject remained with moderate pain requiring paracetamol, ibuprofen, and cyclobenzaprine hydrochloride (FLEXERIL) as previously prescribed. She had made progress in her ability to walk. She continued with gagging and was requiring nasogastric tube feedings, but she was eating small amounts of soft foods. She was receiving psychotherapy and remained on escitalopram oxalate (LEXAPRO). Relevant laboratory information included: Liver function test (LFT) was last drawn on 30Jan2021 which showed within normal limits (WNL). However, the subject did not have LFT's drawn during this admission. Furthermore, the subject has not had toxicology or ceruloplasmin screening. Other laboratory tests on 09Apr2021 included: sodium which showed 135 mmol/L (normal range: 136-145), potassium 3.4 mmol/L (normal range 3.3- 4.7), chloride 102 mmol/L (normal range: 100-112), Carbon dioxide (CO2) 16 mg/dl (normal range: 17 to 31), BUN 6 mg/dl (normal range: 8 to 18), creatinine 0.43mg/dl (normal range: 0.42 to 0.71), glucose 47 mg/dl (normal range: 65 to 106) and rapid glucose 213 mg/dl (normal range: 65 to 106) following D25. COVID testing was not performed. The subject remained in inpatient rehabilitation until 01Jun2021. She continued to demonstrate functional weakness and abnormal movements of her legs with slow improvement. She was able to progress and use her legs for more functional activities such as walking with a walker. She was not able to progress to walking without assistive device. She had one episode of functional episode of shaking her bilateral upper extremities and right upper extremity during her rehabilitation which resolved within 24 hours. She continued with anxiety which was being treated with escitalopram oxalate from 13Mar2021 and ongoing and alprazolam (ATARAX) from Feb2021 and ongoing. Her generalized pain was slowly improving on cyclobenzaprine hydrochloride. She was voiding independently during her rehabilitation stay but did require occasional urinary catherization for elevated bladder volumes. This was believed to be functional withholding. She continued with constipation treated with macrogol 3350 from 28Feb2021 and ongoing and senna (SENOKOT) from 27May2021 and ongoing. She was requiring nasogastric tube feedings for nutrition. She had very limited oral intake. Her swallow study and speech evaluation were consistent with oral aversion. Due to insurance issues, subject was discharged from inpatient rehabilitation on 01Jun201 and transferred to an inpatient psychiatric facility. The parents decided to take subject out of the psychiatric facility against medical advice. She was discharged to home on 01Jun2021. It was reported that subject had the following medications: bisacodyl suppository for constipation from 27Apr2021, paracetamol from 21Jan2021 for generalized functional neurologic pain, paracetamol from 21Jan2021 and cyclobenzaprine hydrochloride from 25Feb2021, both for generalized functional neurologic pain, ibuprofen from 19Mar2021 for functional generalized neurologic pain, and lansoprazole (PREVACID) from 14Mar2021 for functional abdominal pain, all ongoing, famotidine (PEPCID) from 30Jan2021 to Apr2021 for gastritis and pregabalin (LYRICA) from 25Feb2021 to 28Mar2021 for generalized functional neurologic pain. The action taken in response to the event for blinded study vaccine was not applicable. Outcome of the event was not recovered.

The investigator considered there was not a reasonable possibility that the event generalized functional neurological disorder was related to blinded study vaccine, concomitant drugs or clinical trial procedure. The PI did not feel that the subject's symptology was consistent with a vaccine related adverse event.

Follow-up (10Feb2021): New information reported includes: lab data (abdominal PE), event data (SAE updated form functional neurologic pain to generalized functional neurologic pain, onset date) and clinical course (no history of abdominal pain).

Follow-up (02Apr2021): New reported information includes: reporter information.

Follow-up (20Apr2021): New information reported includes: SAE term updated from generalized functional neurologic pain to generalized functional neurological disorder.

Medical Summary

Case Number: 2021101980

Follow-up (17May2021): New information reported includes: medical history.

Follow-up (08Jun2021): This is a follow-up report combining information from duplicate reports 2021101980 and 2021418472. The current and all subsequent follow-up information will be reported under manufacturer report number 2021101980. New information reported includes: lab data, reaction data (treatment), outcome (updated to not recovered) and clinical course (worsening of event, hospitalization information and subject status).

Case Comment

Based on the information available and on the pathophysiology of the event company does not reasonably attribute the reported event as related to study vaccine, concomitant drugs, or clinical trial procedure. The event was likely due to subject underlying contributory factors

PSUR/Line Listing Comment

This case is cross-referenced to case 2021291329: same patient, same study, different event.

Case Serious	Listedness Determination	Case Causality	Case Outcome
Yes	Unlisted	No	Not recovered/Not resolved

Medications - Suspect

#	Product Name Generic Name	Reported Indication	Duration of Administration	Total Dosage Total Dose to Primary Event / Units	Product Event Delay Product Event Latency	Action Taken	Dechallenge Results Rechallenge Results
1	BNT162;PLACEBO BNT162;PLACEBO	COVID-19 immunization(COVID-19 immunisation)		Blinded Blinded	7 hrs 30 min 7 hrs 30 min	Not Applicable	N/A N/A

Dosage Regimens

#	Start Date/Time	Stop Date/Time	Dose	Frequency	Patient Route of Administration
1	20-JAN-2021 16:30:00	20-JAN-2021 16:30:00	Blinded	Blinded	Blinded

Medications - Concomitant

#	Product Name	Generic Name	Reported Indication	Duration of Administration
1	TYLENOL	PARACETAMOL	fever(Pyrexia) pain(Pain)	

Dosage Regimens

#	Dose
1	

Medical Summary

Case Number: **2021101980**

#	Product Name	Generic Name	Reported Indication	Duration of Administration
2	IBUPROFEN	IBUPROFEN	fever(Pyrexia) pain(Pain)	
	Dosage Regimens **#** **Dose** 1			
3	TORADOL	KETOROLAC TROMETHAMINE	Pain(Pain)	
	Dosage Regimens **#** **Dose** 1			
4	VYVANSE	LISDEXAMFETAMINE MESILATE	ADHD(Attention deficit hyperactivity disorder)	
	Dosage Regimens **#** **Dose** 1			

Devices

No information present

Events

#	Description as Reported	Preferred Term Lower Level Term	Onset Date/Time Stop Date/Time	Duration	Onset Latency Onset From Last Dose		Seriousness Criteria	Outcome of Event
1	generalized functional neurological disorder	Conversion disorder Functional neurological symptom disorder	21-JAN-2021		7 hrs 30 min 7 hrs 30 min		Yes Hospitalized	Not recovered/Not resolved

Event Assessment

No information present

Medical Summary

Case Number: **2021101980**

Hospitalization Information

Description as Reported	Hospitalization Start Date	Hospitalization End Date	Duration of Hospitalization	Event Caused Hospitalization	Hospitalization Prolonged	Hospital Discharge Summary Available
generalized functional neurological disorder		14-APR-2021		Yes	No	No

Patient Relevant History

#	Start	Stop Date	Ongoing	Condition Type	Coded PT
1	30-DEC-2020	30-DEC-2020		Historical Vaccine	BNT162;PLACEBO (BLINDED THERAPY)(Drug Indication: COVID-19 immunisation)
	Notes: Dose 1 at 10:26, IM in the left deltoid at single dose				
2	2018		Yes	Relevant Med History	attention deficit disorder (Attention deficit hyperactivity disorder)
	Notes: well-controlled				
3	2018		Yes	Relevant Med History	anxiety (Anxiety)

Patient Lab Tests

#	Date	Test Name	Results	Norm High	Norm Low	Assessment
1	30-JAN-2021	Alanine aminotransferase	22			
2	30-JAN-2021	Aspartate aminotransferase	21			
3		Barium swallow	functional oral motors skills and adequate airway			
4		Biopsy	normal			
5	30-JAN-2021	Blood bilirubin	0.2			
6	09-APR-2021	Blood chloride	102 mmol/L	112	100	
7	30-JAN-2021	Blood creatine phosphokinase	123 IU/l	145	31	
8	30-JAN-2021	Blood creatinine	0.43 mg/dl	0.71	0.42	
9	09-APR-2021	Blood creatinine	0.43 mg/dl	0.71	0.42	
10	09-APR-2021	Blood glucose	47 mg/dl	106	65	
11	09-APR-2021	Blood glucose	213 mg/dl	106	65	
12	09-APR-2021	Blood potassium	3.4 mmol/L	4.7	3.3	

Medical Summary

Case Number: **2021101980**

#	Date	Test Name	Results	Norm High	Norm Low	Assessment
13	09-APR-2021	Blood sodium	135 mmol/L	145	136	
14	30-JAN-2021	Blood urea	25 mg/dl	18.0	8.0	
15	30-JAN-2021	Blood urea	13 mg/dl	18.0	8.0	
16	09-APR-2021	Blood urea	6 mg/dl	18.0	8.0	
17		Body temperature	101.4 Fahrenheit			
18	09-APR-2021	Carbon dioxide	16 mmol/L	31	17	
19	23-JAN-2021	Computerised tomogram abdomen	normal noncontrast CT of the abdomen and pelvis.			
20	23-JAN-2021	Computerised tomogram pelvis	normal noncontrast CT of the abdomen and pelvis.			
21	30-JAN-2021	C-reactive protein	0.40 mg/dl			
22	21-JAN-2021	Culture urine	negative			Negative
23	23-JAN-2021	Electrocardiogram	did not demonstrate significant cardiac pathology			
24	30-JAN-2021	Haematocrit	41.3 %	46.0	36.0	
25	30-JAN-2021	Haemoglobin	14.1 g/dl	16.0	12.0	
26	21-JAN-2021	Investigation	negative			Negative
27	30-JAN-2021	Lipase	39.0 IU/l	50.0	12.0	
28	30-JAN-2021	Liver function test	within normal limits (WNL)			
29		Magnetic resonance imaging spinal	normal			
30	30-JAN-2021	Neurological examination	normal			
31	09-APR-2021	Neurological examination	consistent with functional signs			
32	21-JAN-2021	Physical examination	Soft, tender to palpation over bilateral lower			
33	23-JAN-2021	Physical examination	Soft, non-distended, pain and guarding in the RLQ,			
34	30-JAN-2021	Physical examination	NABS. Guarding present initially, but then			
35	30-JAN-2021	Physical examination	significant for pain to light-moderate palpation			
36	30-JAN-2021	Platelet count	471 x10 3/mm3	466	135	
37	30-JAN-2021	Red blood cell sedimentation	9			

Medical Summary

Case Number: **2021101980**

		rate				
#	Date	Test Name	Results	Norm High	Norm Low	Assessment
38	21-JAN-2021	SARS-CoV-2 test	negative			Negative
39	23-JAN-2021	Ultrasound Doppler	normal pelvic ultrasound			
40	21-JAN-2021	Ultrasound scan	appendix not visualized; no ultrasound findings to			
41	21-JAN-2021	Urine analysis	moderate blood without RBC			
42	30-JAN-2021	Urine analysis	normal without blood			
43	21-JAN-2021	Vital signs measurement	stable			
44	30-JAN-2021	Vital signs measurement	stable			
45	09-APR-2021	Weight	52.6 kg			
46	30-JAN-2021	White blood cell count	8.82 x10 3/mm3	13.5	4.5	

Relevant Tests

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 6/30/2021 1:49:33 PM
To: Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]
CC: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran,

Thank you so much for this follow-up. It is incredibly helpful.

Best Regards,
Peter

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Wednesday, June 30, 2021 1:38 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Peter,

Pfizer has provided the attached updated narrative on this study participant, which provides a more detailed account of her illness and diagnosis of a functional neurologic disorder based on extensive specialist evaluation and consistent exam, labs, and imaging. This illness is considered not due to an organic process, and while temporally associated with vaccination it is difficult to explain a physiologically causal association.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Sent: Wednesday, June 30, 2021 10:30 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Boyce, Donna <(b) (6)@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Doran,
Attached please find the updated narrative for this participant. Please note that it has been downloaded from our system and an official CIOMS form will follow but we wanted you to have the information.
I have been in regular contact with the Principal Investigator as well and his assessment remains that the events described are not related to the vaccine Please let me know if you have any questions.
Best regards
Alejandra

-----Original Message-----
From: Gurtman, Alejandra C
Sent: Tuesday, June 29, 2021 11:11 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Doran
We are putting together a comprehensive narrative of the case for your review.
Hope to have it ready for you within the next day or so Best regards, Alejandra

Alejandra Gurtman, MD
Vice President
Pfizer Vaccine Clinical Research and Development Tel (b) (6) Cel (b) (6) Fax 845 474 3219
Email: alejandra.gurtman@pfizer.com

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 10:57 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Dear Donna,

Thanks for the update. Just to be clear, the narrative provided with the EUA submission (attached) was pretty scant on details, and no additional details were available from Pfizer when we asked during the review. I appreciated that Pfizer may not have had access to any additional details at the time, so it will be very helpful to have the more detailed follow-up that is forthcoming.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Tuesday, June 29, 2021 9:49 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Dear Doran,
My apologies. I thought this message had been sent to you last week. You are correct and this is participant 10071620. This case from the COVID-19 C4591001 study was reported in the EUA with a narrative. It was also presented to the ACIP working group and many other recommending bodies. We are collating the SAEs follow up and will send to you shortly. In the meantime, Dr Alejandra Gurtman spoke with Dr Frenck who is the Principal Investigator at Cincinnati's Children today and confirmed that this case is not related to the vaccine and that the participant has had extensive work up with consultations with various specialties including pulmonary, neurology, pain management and psychiatry with no findings of anything organic.
We will include all pertinent data in the follow up.
Best Regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Tuesday, June 29, 2021 9:32 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Hi Donna,

Please update us on where things stand with this request so that we can get back to Peter Marks and Janet Woodcock.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Thursday, June 24, 2021 9:22 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>

Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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Doran,
Thanks for reaching out. I will look into this and get back to you as soon as possible.
Kind regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, June 24, 2021 8:23 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Importance: High

Good morning Donna,

Janet Woodcock received the email below, and we are trying to gather more information so that she can respond quickly. Can Pfizer provide any information to clarify details of this purported adverse event (participant's name is in the email subject line)? We have reviewed again the information submitted with the adolescent EUA amendment, and the only SAE that could potentially fit the description is for the participant with Unique Subject ID: C4591001 1007 10071620, described as follows:

"The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

Could Pfizer please also provide any available update on this participant?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

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do you know the story of this girl? She was in the Pfizer trial.

She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

From: Gurtman, Alejandra C [Alejandra.Gurtman@pfizer.com]
Sent: 7/1/2021 7:18:37 PM
To: Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]
CC: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Boyce, Donna [(b) (6)@pfizer.com]
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Attachments: 2021101980 medical summary - updated.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Doran
Attached please see an update from with information received on June 29
Again, please let me know if you have any questions
Best
Alejandra

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Wednesday, June 30, 2021 10:44 AM
To: Gurtman, Alejandra C <Alejandra.Gurtman@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Boyce, Donna <(b) (6)@pfizer.com>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

Thanks Alejandra, much appreciated. We understand and acknowledge the basis for the assessment of causality.

Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
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Alejandra Gurtman, MD
Vice President

Pfizer Vaccine Clinical Research and Development Tel (b) (6) Cel (b) (6) Fax 845 474 3219
Email: alejandra.gurtman@pfizer.com

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Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

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To: Fink, Doran <Doran.Fink@fda.hhs.gov>
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Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Boyce, Donna <(b) (6)@pfizer.com>
Sent: Thursday, June 24, 2021 9:22 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Doran,
Thanks for reaching out. I will look into this and get back to you as soon as possible.
Kind regards,
Donna

-----Original Message-----
From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Thursday, June 24, 2021 8:23 AM
To: Boyce, Donna <(b) (6)@pfizer.com>
Cc: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: FW: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial
Importance: High

Good morning Donna,

Janet Woodcock received the email below, and we are trying to gather more information so that she can respond quickly. Can Pfizer provide any information to clarify details of this purported adverse event (participant's name is in the email subject line)? We have reviewed again the information submitted with the adolescent EUA amendment, and the only SAE that could potentially fit the description is for the participant with Unique Subject ID: C4591001 1007 10071620, described as follows:

"The SAE of neuralgia was reported in 1 female participant 12 years of age who had 3 emergency room visits beginning 1 day after the second dose. She reported concurrent non-serious AEs of vulvar abscess, gastritis, and contact dermatitis. She subsequently had SAEs of abdominal pain and constipation. She had an extensive work-up including serial physical and laboratory examinations and was diagnosed with functional abdominal pain; she was referred to psychology and physical therapy, after which symptoms were reported as gradually improving."

Could Pfizer please also provide any available update on this participant?

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines and Related Products Applications FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

-----Original Message-----
From: Steve Kirsch <stk@m10.io>
Sent: Wednesday, June 23, 2021 11:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Maddie de Garay (12 years old) victim of the Pfizer trial

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

do you know the story of this girl? She was in the Pfizer trial.

She is now permanently disabled. She has NO FEELING FROM WAIST DOWN. She has to be fed through a feeding tube.

Pfizer never reported this in their trial results.

How can you allow these trials to continue? Has anyone at FDA or CDC investigated?

-steve

Medical Summary

Case Number: 2021101980

General Case Information

Report Type	Pfizer Spons Interv Study
Initial Receipt Date	01-Feb-2021
Case Creation Time	02-Feb-2021 06:00
Country of Incidence	UNITED STATES
Health Care Professional	Yes

Study Information

Study Project ID	PF-07302048
Study ID	C4591001
Study Center ID	1007
Pat. ID	10071620

Patient Information

Age	12 Years
Date of Birth	22-MAY-2008
Weight	57.100 kg
Patient Height in.	155.500 cm
Race Information	Caucasian
Gender	Female
Pregnant	

Reporter Information

Reporter Type	Physician	**Country**	UNITED STATES	**Email Address**	IN CONFIDENCE
Reporter Name	Dr. Robert Frenck				

Narrative / Comment

Narrative

A PHASE 1/2/3, PLACEBO-CONTROLLED, RANDOMIZED, OBSERVER-BLIND, DOSE-FINDING STUDY TO EVALUATE THE SAFETY, TOLERABILITY, IMMUNOGENICITY, AND EFFICACY OF SARS-COV-2 RNA VACCINE CANDIDATES AGAINST COVID-19 IN HEALTHY INDIVIDUALS

This is a report from an interventional study source for Protocol C4591001 sponsored by BioNTech, managed and reported by Pfizer on the sponsor's behalf.

A 12-year-old female subject received blinded study vaccine (BNT162; PLACEBO), first dose on 30Dec2020 at 10:26 and second dose on 20Jan2021 at 16:30, both intramuscularly on left deltoid at single doses for coronavirus disease 2019 (COVID-19) immunization. Ongoing medical history included attention deficit disorder and anxiety, both from 2018. Ongoing concomitant medications included lisdexamfetamine mesilate (VYVANSE) for attention deficit hyperactivity disorder (ADHD) from 2018, paracetamol (TYLENOL) and ibuprofen both for fever and pain from 20Jan2021. The subject had no concomitant vaccines administered on same date of the investigational vaccine or prior vaccines within 4 weeks. The subject experienced generalized functional neurologic disorder on 21Jan2021 which required a visit to emergency room and resulted in hospitalization. Clinical course was reported as follows: subject was with history only significant for well-controlled ADHD. The subject did not have any history of abdominal pain/complaints. She received the second vaccine on 20Jan2021. Her reactogenicity symptoms included fever to 101.4 degrees Fahrenheit (F) on day 2 with severe chills, myalgia, arthralgia, fatigue and headache. Her fever resolved. She remained with moderate to severe fatigue, headache, chills, myalgia and arthralgia which were present on day 7. She also developed mild diarrhea on day 7. She presented to the emergency department on 21Jan2021 with severe abdominal and flank pain, myalgia and headache. COVID-19 polymerase chain reaction (PCR)/ COVID-19 nucleic acid amplification test (NAAT) was negative (manufactured by COPAN and distributed by CLIA certified lab). She was well-appearing, well-hydrated, with stable vital signs. Abdominal ultrasound (ultrasound right lower quadrant (RLQ)) done on 21Jan2021 to rule out (r/o) appendicitis. Appendix not visualized, but there were no secondary signs; no ultrasound findings to support diagnosis of appendicitis. Her urinalysis showed moderate blood without red blood cells (RBC) so she was screened for rhabdomyolysis, which was negative. Urine culture was negative. She improved

with intravenous fluids and paracetamol/ibuprofen and was discharged home. She returned to the emergency department on 23Jan2021 with continued severe abdominal pain and headache; also with lower back, neck pan and chest pain. The subject took ketorolac tromethamine (TORADOL) for pain from 23Jan2021. Computerized tomogram (CT) abdomen/pelvis was normal, noncontrast CT of the abdomen and pelvis; no urinary tract calculi. Ultrasound RLQ with pelvis/doppler was normal pelvic ultrasound. Electrocardiogram (ECG) did not demonstrate significant cardiac pathology. She improved with intravenous fluids and ketorolac tromethamine. Subject was discharged to home. After 1 to 2 days, the pain progressively returned. The subject again returned to the emergency department on 30Jan2021 with worsening fatigue, abdominal pain (generalized), tenderness to touch of her neck, back, chest and bilateral legs. Her vital signs were stable. Physical examination (PE) significant for pain to light-moderate palpation over lower back, bilateral buttocks, posterior neck and bilateral scapular regions. Her neurological exam was normal. Complete blood count (CBC) with hemoglobin (Hgb) 14.1 g/dL (normal: 12.0 to 16.0), hematocrit (Hct) 41.3 % (normal: 36.0 to 46.0), platelets 471 x10 3/mm3 (normal: 135 to 466), sedimentation rate 9, lipase 39.0 iu/L (normal: 12.0 to 50.0), blood urea nitrogen (BUN) 25 mg/dL (normal 8.0 to 18.0), BUN 13, creatinine 0.43 mg/dl (range 0.42-0.71), alanine aminotransferase (ALT) 22, aspartate aminotransferase (AST) 21, total bilirubin 0.2, and C-reactive protein (CRP) less than 0.40 mg/dL (normal: less than or equal to 0.40), white blood cell count (WBC) 8.82 x10 3/mm3 (normal: 4.5 to 13.5) and creatine phosphokinase (CPK) 123 iu/L (normal: 31 to 145). Urinalysis (UA) was normal without blood. Although stable, the subject was hospitalized for observation. During admission, her exam, test results and imaging were reassuring against neurologic or anatomical causes for pain. The focus of admission was pain control and a developing psychiatric network to provide support. The pain team was consulted who prescribed gabapentin with uptitration over the following weeks (200 mg daily orally for 1 week, then increase to 200 mg twice daily (BID) orally for 1 week then increase to 200 mg twice daily (TID) orally). She was also prescribed naproxen 375 mg BID for 5 days (followed by as needed (PRN)), paracetamol every 6 hours while awake and methocarbamol (ROBAXIN) 750 mg PRN. She was referred to psychology and physical therapy. Her symptoms were gradually improving. The subject also endorsed constipation during her admission. She was prescribed macrogol 3350 (MIRALAX) 1 capsule (cap) BID. She also started on famotidine 20 mg BID due to symptoms of gastritis secondary to prolonged ibuprofen use. It was also noted that the subject was seen as an outpatient by her primary care provider on 24Jan2021 for a very small boil (erythema measuring less than 0.25 cm with small white tip in the center) on her left inferior labia majora. She was prescribed topical clindamycin 1% gel for 7 days and warm compress. The boil drained at home and resolved on 26Jan2021. The assessment of the cause for the vulvar boil was done per site investigator; upon further discussion, the etiology of methicillin-resistant staphylococcus aureus (MRSA) had been revised to probable staph infection. The boil drained at home after warm compresses without incision and drainage by a medical provider. Therefore, no culture was done. The subject had no known history of MRSA exposure or prior risk factor for MRSA. This was not thought to be the cause of her fever or abdominal pain. The subject had not onset of menses so the conditions were not related. Abdominal examination findings at each of the three emergency room (ER) visits as below: On 21Jan2021, emergency department (ED) abdominal physical examination (PE) findings: Soft, tender to palpation over bilateral lower quadrants, bilateral costovertebral angle (CVA), no rebound or guarding, +BS, no hepatosplenomegaly. On 23Jan2021, ED abdominal PE findings: Soft, non-distended, pain and guarding in the Image result for right lower quadrant (RLQ), no rebound or guarding, +BS, no hepatosplenomegaly. On 30Jan2021, ED abdominal PE findings: NABS. Guarding present initially, but then tolerates exam. TIP across all quadrants. ND with no organomegaly. The subject's diagnose updated to generalized functional neurologic disorder on 09Apr2021 and functional abdominal pain. It was reported that subject had functional abdominal pain from 28Feb2021, constipation from 28Feb2021, and gastritis from 30Jan2021, all ongoing. On 24Mar2021, the subject had worsening of event. The subject had multiple life stressors in the months preceding her diagnosis of functional neurologic disorder. Since that time, the subject continued with diffuse myalgia, dizziness, headaches, decreasing strength in her lower extremities, abdominal pain, vomiting, poor appetite, constipation, and intermittent rash on upper extremities. In addition, the subject had "passed out twice" between 19Feb2021 and 20Feb2021. Her work-up included psychology, medical pain consult, gastrointestinal (GI) consult for abdominal pain and poor oral intake status post (S/p) esophagogastroduodenoscopy (EGD) with normal biopsies, neurology consult with normal MRI spine, initiation of escitalopram oxalate for anxiety. Since her hospital discharge on 13Mar2021, the subject continued with lower extremity weakness and numbness progressing to inability to walk, emesis and regurgitation of most oral (PO), word finding difficulties, moodiness, longer "spells" consisting of falling down/over, both arms shaking, eyes rolling back and unresponsiveness lasting up to 6 minutes, as well as more frequent "zoning out" episodes. The subject weight had decreased from 57. 1 kg on 06Mar2021 to 52.6 kg on 09Apr2021. The subject presented to the emergency department on 09Apr2021 due to the worsening symptoms above. The subject was well-appearing and interactive with stable vital signs. Neurological exam consistent with functional signs. Reflexes were normal. The subject was confined to a wheelchair with reports of lower extremity paralysis but was able to lift her leg onto the wheelchair at one point. Her abdomen was soft, nontender without masses or organomegaly. The subject labs were significant for glucose of 47 (asymptomatic). The subject received D25 intravenous bolus with resolution

of hypoglycemia. The subject was admitted for observation and management of symptoms. The "spells" observed in the hospital were less likely consistent with seizure given distractibility, variability of episodes, and lack of postictal phase. It was reported that her neurologic examination was consistent with a functional neurological disorder. The subject was evaluated by speech therapy who recommended Videofluoroscopic Swallow Study/ fiberoptic endoscopic evaluation of swallowing (VSS/FEES) for further evaluation of oral-motor dysfunction. VSS showed functional oral motors skills and adequate airway protection but severe gagging and emesis with all PO. The UES appeared to be functioning on VSS. The subject did not initiate swallowing. The subject was evaluated by physical therapist/occupational therapist (PT/OT) who recommended an inpatient rehabilitation stay, However, a direct inpatient admit was not possible. The subject was discharged to home on 14Apr2021 with the plan for outpatient rehabilitation to include OT/PT/Speech therapy, as well as psychotherapy. The subject was discharged from the hospital on 14Apr2021; however, she was then transferred to the inpatient pediatric rehabilitation unit where she remained. Her rehabilitation had included physical therapy, occupational therapy, speech therapy, therapeutic recreation, and psychosocial services. Subject remained with moderate pain requiring paracetamol, ibuprofen, and cyclobenzaprine hydrochloride (FLEXERIL) as previously prescribed. She had made progress in her ability to walk. She continued with gagging and was requiring nasogastric tube feedings, but she was eating small amounts of soft foods. She was receiving psychotherapy and remained on escitalopram oxalate (LEXAPRO). Relevant laboratory information included: Liver function test (LFT) was last drawn on 30Jan2021 which showed within normal limits (WNL). However, the subject did not have LFT's drawn during this admission. Furthermore, the subject has not had toxicology or ceruloplasmin screening. Other laboratory tests on 09Apr2021 included: sodium which showed 135 mmol/L (normal range: 136-145), potassium 3.4 mmol/L (normal range 3.3- 4.7), chloride 102 mmol/L (normal range: 100-112), Carbon dioxide (CO2) 16 mg/dl (normal range: 17 to 31), BUN 6 mg/dl (normal range: 8 to 18), creatinine 0.43mg/dl (normal range: 0.42 to 0.71), glucose 47 mg/dl (normal range: 65 to 106) and rapid glucose 213 mg/dl (normal range: 65 to 106) following D25. COVID testing was not performed. The subject remained in inpatient rehabilitation until 01Jun2021. She continued to demonstrate functional weakness and abnormal movements of her legs with slow improvement. She was able to progress and use her legs for more functional activities such as walking with a walker. She was not able to progress to walking without assistive device. She had one episode of functional episode of shaking her bilateral upper extremities and right upper extremity during her rehabilitation which resolved within 24 hours. She continued with anxiety which was being treated with escitalopram oxalate from 13Mar2021 and ongoing and alprazolam (ATARAX) from Feb2021 and ongoing. Her generalized pain was slowly improving on cyclobenzaprine hydrochloride. She was voiding independently during her rehabilitation stay but did require occasional urinary catherization for elevated bladder volumes. This was believed to be functional withholding. She continued with constipation treated with macrogol 3350 from 28Feb2021 and ongoing and senna (SENOKOT) from 27May2021 and ongoing. She was requiring nasogastric tube feedings for nutrition. She had very limited oral intake. Her swallow study and speech evaluation were consistent with oral aversion. Due to insurance issues, subject was discharged from inpatient rehabilitation on 01Jun201 and transferred to an inpatient psychiatric facility. The parents decided to take subject out of the psychiatric facility against medical advice. She was discharged to home on 01Jun2021. It was reported that subject had the following medications: bisacodyl suppository for constipation from 27Apr2021, paracetamol from 21Jan2021 for generalized functional neurologic pain, paracetamol from 21Jan2021 and cyclobenzaprine hydrochloride from 25Feb2021, both for generalized functional neurologic pain, ibuprofen from 19Mar2021 for functional generalized neurologic pain, and lansoprazole (PREVACID) from 14Mar2021 for functional abdominal pain, all ongoing, famotidine (PEPCID) from 30Jan2021 to Apr2021 for gastritis and pregabalin (LYRICA) from 25Feb2021 to 28Mar2021 for generalized functional neurologic pain. On 10Jun2021, the subject was seen by neurology for follow-up of her generalized functional neurologic disorder. Neuro: Subject was ambulating with walker; able to do activities of daily living (ADL's) and continues with physical therapy. On 22Jun2021, a MRI/MRV Brain (with and without contrast) showed: normal MRI of the brain with and without contrast, normal MR venography of the brain. Her exam findings were as follows: Her exam was variable and inconsistent with itself and for her level of functioning. Mental Status: awake, alert; normal processing; able to answer questions and describe symptoms on her own. Language: age appropriate. Cranial nerves: Pupils equal, round & reactive to light & accommodation (PERRL); extra ocular movement intact (EOMI); facial features symmetric; hearing symmetric bilaterally; oropharynx elevates symmetrically; shoulder shrug 5/5 bilaterally; tongue protrudes in the midline. Motor: Muscle bulk: normal; Deep tendon reflexes (DTR's) - normal (1 in upper extremity (UE) and lower extremity (LE)); tone - normal; strength - give away weakness in UE deltoid, BC and TCI; opposing muscles contraction was palpated in some trials. Sensory: normal light touch in UE; temperature sensation-decreased left forehead; chest symmetric, UE proximal colder on left; distal UE colder on left; No sensation in LE to proprioception, temperature, light touch or vibration. Coordination: variable amp and high frequent (freq.) tremor RUE with motor movement, left upper extremity (LUE) same with FN; no trouble with tremor when texting (mom reports the things she does without thinking could be done without tremor, once asked to do something on command the tremor was noted); when asked to put her UE out in front, she was only able to get to a few inches off her lap; when assisting to get them higher, she pulled back and

Medical Summary

Case Number: 2021101980

resisted. Gait: with walker; high freq. shaking of legs; stands and sits without troubles. Pain: subject continued to required paracetamol and cyclobenzaprine hydrochloride for management of back pain. Feeding intolerance: Subject continued with feeding intolerance and requires nasogastric tube feedings. She had been unable to tolerate oral intake. She had chewed on food but spits it out, consistent with rumination. Bowel movements: She continued to require macrogol and senna for constipation. Genitourinary: She had experienced functional withholding of urine; she empties large volumes twice daily and had required occasional catherization for elevated bladder volumes; she states she did not feel sensation that her bladder was full. Anxiety: Continued to manage anxiety with escitalopram oxalate and alprazolam; she does describe improvement in her symptoms when she is not hospitalized. She was currently at home. The action taken in response to the event for blinded study vaccine was not applicable. Outcome of the event was not recovered.

The investigator considered there was not a reasonable possibility that the event generalized functional neurologic disorder was related to blinded study vaccine, concomitant drugs or clinical trial procedure. The PI did not feel that the subject's symptology was consistent with a vaccine related adverse event.

Follow-up (10Feb2021): New information reported includes: lab data (abdominal PE), event data (SAE updated form functional neurologic pain to generalized functional neurologic pain, onset date) and clinical course (no history of abdominal pain).

Follow-up (02Apr2021): New reported information includes: reporter information.

Follow-up (20Apr2021): New information reported includes: SAE term updated from generalized functional neurologic pain to generalized functional neurological disorder.

Follow-up (17May2021): New information reported includes: medical history.

Follow-up (08Jun2021): This is a follow-up report combining information from duplicate reports 2021101980 and 2021418472. The current and all subsequent follow-up information will be reported under manufacturer report number 2021101980. New information reported includes: lab data, reaction data (treatment), outcome (updated to not recovered) and clinical course (worsening of event, hospitalization information and subject status).

Follow-up (29Jun2021): New information reported includes: SAE term updated to "generalized functional neurologic disorder", lab test and clinical course (current status).

Case Comment

The company reasonably does not attribute the case to blinded study vaccine, (BNT162;PLACEBO) or clinical trial procedure based on the known adverse event profile of the suspect product and on the lack of a plausible pathophysiological mechanism for the event. The medical history, clinical description and laboratory data reported are more in favor of a functional disorder.

PSUR/Line Listing Comment

This case is cross-referenced to case 2021291329: same patient, same study, different event.

Case Serious	Listedness Determination	Case Causality	Case Outcome
Yes	Unlisted	No	Not recovered/Not resolved

Medications - Suspect

Medical Summary

Case Number: **2021101980**

#	Product Name Generic Name	Reported Indication	Duration of Administration	Total Dosage Total Dose to Primary Event / Units	Product Event Delay Product Event Latency	Action Taken	Dechallenge Results Rechallenge Results
1	BNT162;PLACEBO BNT162;PLACEBO	COVID-19 immunization(COVID-19 immunisation)		Blinded Blinded	7 hrs 30 min 7 hrs 30 min	Not Applicable	N/A N/A

Dosage Regimens

#	Start Date/Time	Stop Date/Time	Dose	Frequency	Patient Route of Administration
1	20-JAN-2021 16:30:00	20-JAN-2021 16:30:00	Blinded	Blinded	Blinded

Medications - Concomitant

#	Product Name	Generic Name	Reported Indication	Duration of Administration
1	TYLENOL	PARACETAMOL	fever(Pyrexia) pain(Pain)	

Dosage Regimens

#	Dose
1	

#	Product Name	Generic Name	Reported Indication	Duration of Administration
2	IBUPROFEN	IBUPROFEN	fever(Pyrexia) pain(Pain)	

Dosage Regimens

#	Dose
1	

#	Product Name	Generic Name	Reported Indication	Duration of Administration
3	VYVANSE	LISDEXAMFETAMINE MESILATE	ADHD(Attention deficit hyperactivity disorder)	

Dosage Regimens

#	Dose
1	

Devices

No information present

Medical Summary

Case Number: **2021101980**

Events

#	Description as Reported	Preferred Term Lower Level Term	Onset Date/Time Stop Date/Time	Duration	Onset Latency Onset From Last Dose		Seriousness Criteria	Outcome of Event
1	generalized functional neurologic disorder	Conversion disorder Functional neurological symptom disorder	21-JAN-2021		7 hrs 30 min 7 hrs 30 min		Yes Hospitalized	Not recovered/Not resolved

Event Assessment

No information present

Hospitalization Information

Description as Reported	Hospitalization Start Date	Hospitalization End Date	Duration of Hospitalization	Event Caused Hospitalization	Hospitalization Prolonged	Hospital Discharge Summary Available
generalized functional neurologic disorder		14-APR-2021		Yes	No	No

Patient Relevant History

#	Start	Stop Date	Ongoing	Condition Type	Coded PT
1	30-DEC-2020	30-DEC-2020		Historical Vaccine	BNT162;PLACEBO (BLINDED THERAPY)(Drug Indication: COVID-19 immunisation)
	Notes: 1ST DOSE, SINGLE, at 10:26, IM in the left deltoid at single dose				
2	2018		Yes	Relevant Med History	attention deficit disorder (Attention deficit hyperactivity disorder)
	Notes: well-controlled				
3	2018		Yes	Relevant Med History	anxiety (Anxiety)

Medical Summary

Case Number: **2021101980**

Patient Lab Tests

#	Date	Test Name	Results	Norm High	Norm Low	Assessment
1	30-JAN-2021	Alanine aminotransferase	22			
2	30-JAN-2021	Aspartate aminotransferase	21			
3		Barium swallow	functional oral motors skills and adequate airway			
4		Biopsy	normal			
5	30-JAN-2021	Blood bilirubin	0.2			
6	09-APR-2021	Blood chloride	102 mmol/L	112	100	
7	30-JAN-2021	Blood creatine phosphokinase	123 IU/l	145	31	
8	30-JAN-2021	Blood creatinine	0.43 mg/dl	0.71	0.42	
9	09-APR-2021	Blood creatinine	0.43 mg/dl	0.71	0.42	
10	09-APR-2021	Blood glucose	47 mg/dl	106	65	
11	09-APR-2021	Blood glucose	213 mg/dl	106	65	
12	09-APR-2021	Blood potassium	3.4 mmol/L	4.7	3.3	
13	09-APR-2021	Blood sodium	135 mmol/L	145	136	
14	30-JAN-2021	Blood urea	25 mg/dl	18.0	8.0	
15	30-JAN-2021	Blood urea	13 mg/dl	18.0	8.0	
16	09-APR-2021	Blood urea	6 mg/dl	18.0	8.0	
17		Body temperature	101.4 Fahrenheit			
18	09-APR-2021	Carbon dioxide	16 mmol/L	31	17	
19	23-JAN-2021	Computerised tomogram abdomen	normal noncontrast CT of the abdomen and pelvis.			
20	23-JAN-2021	Computerised tomogram pelvis	normal noncontrast CT of the abdomen and pelvis.			
21	30-JAN-2021	C-reactive protein	0.40 mg/dl			
22	21-JAN-2021	Culture urine	negative			Negative
23	23-JAN-2021	Electrocardiogram	did not demonstrate significant cardiac pathology			
24	30-JAN-2021	Haematocrit	41.3 %	46.0	36.0	
25	30-JAN-2021	Haemoglobin	14.1 g/dl	16.0	12.0	
26		Investigation	awake, alert; normal processing; able to answer			
27		Investigation	Muscle bulk: normal; DTR's - normal			

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#	Date	Test Name	Results	Norm High	Norm Low	Assessment
28	21-JAN-2021	Investigation	negative			Negative
29	30-JAN-2021	Lipase	39.0 IU/l	50.0	12.0	
30	30-JAN-2021	Liver function test	within normal limits (WNL)			
31	22-JUN-2021	Magnetic resonance imaging head	Normal MRI of the brain with and without contrast			
32		Magnetic resonance imaging spinal	normal			
33		Neurological examination	variable amp and high freq tremor RUE with motor			
34		Neurological examination	PERRL; EOMI; facial features symmetric; hearing			
35		Neurological examination	with walker; high freq shaking of legs; stands			
36	30-JAN-2021	Neurological examination	normal			
37	09-APR-2021	Neurological examination	consistent with functional signs			
38		Neurological examination	normal light touch in UE; temperature sensation -			
39	21-JAN-2021	Physical examination	Soft, tender to palpation over bilateral lower			
40	23-JAN-2021	Physical examination	Soft, non-distended, pain and guarding in the RLQ,			
41	30-JAN-2021	Physical examination	NABS. Guarding present initially, but then			
42		Physical examination	age appropriate			
43	30-JAN-2021	Physical examination	significant for pain to light-moderate palpation			
44	30-JAN-2021	Platelet count	471 x10 3/mm3	466	135	
45	30-JAN-2021	Red blood cell sedimentation rate	9			
46	21-JAN-2021	SARS-CoV-2 test	negative			Negative
47	23-JAN-2021	Ultrasound Doppler	normal pelvic ultrasound			
48	21-JAN-2021	Ultrasound scan	appendix not visualized; no ultrasound findings to			
49	21-JAN-2021	Urine analysis	moderate blood without			

Medical Summary

Case Number: **2021101980**

			RBC			
#	Date	Test Name	Results	Norm High	Norm Low	Assessment
50	30-JAN-2021	Urine analysis	normal without blood			
51	21-JAN-2021	Vital signs measurement	stable			
52	30-JAN-2021	Vital signs measurement	stable			
53	09-APR-2021	Weight	52.6 kg			
54	30-JAN-2021	White blood cell count	8.82 x10 3/mm3	13.5	4.5	

Relevant Tests

Sent: 8/20/2021 6:19:44 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]
Subject: RE: [EXTERNAL] No evidence of all cause mortality benefit for Pfizer vaccine

Dear Janet,

Thanks for forwarding. We are aware. However, this is a standard anti-vaccine

-----Original Message-----
From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Friday, August 20, 2021 6:16 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Anderson, Steven <Steven.Anderson@fda.hhs.gov>
Subject: FW: [EXTERNAL] No evidence of all cause mortality benefit for Pfizer vaccine
Importance: High

Fyi jw

-----Original Message-----
From: Steve Kirsch <stk@skirsch.com>
Sent: Friday, August 20, 2021 6:02 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Stein, Peter <Peter.Stein@fda.hhs.gov>
Cc: (b) (6)
(b) (6)
Subject: [EXTERNAL] No evidence of all cause mortality benefit for Pfizer vaccine
Importance: High

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Janet,

We couldn't find any evidence of an all cause mortality benefit from the vaccines.

The vaccines do save covid deaths, but they elevate other death causes, so there is NET LOSS OF LIFE. Nobody is warned of this. It won't be on the label I'm sure.

this is very easy to see in the Pfizer 6 month study.

I'm sure your team will argue the numbers are too small to be meaningful.

But 4 cardiac arrests vs. 1 in placebo? Surely that raises some eyebrows. bottom line: 20 people who got the drug died vs. 14 who got the placebo. At a minimum giving the drug the benefit of the doubt, there was a 12.5% increase in mortality.

And the causes of death were different in the two groups, with the causes in the vaccine group just coincidentally corresponding to symptoms elevated by the vaccine. Bad luck? VERY unlikely.

The the drug kills more people than it saves is confirmed in the VAERS data which is VERY CLEAR on this. That's impossible to dispute. But your CBER team and the ACIP team at the CDC will *not* look at our VAERS analysis or examine the VAERS data themselves.

And of course nobody investigated the fraud in the Phase 3 trial of Pfizer. Maddie de Garay is likely paralyzed for life and nobody from the FDA or CDC called. I am baffled by this. She was paralyzed less than 24 hours after the second shot and people act like it didn't happen. There probably won't even be a warning on this.

And finally, Mathew Crawford did a brilliant analysis of the death data from the vaccines and found 411 deaths per million doses. 4 other researchers confirmed this using different methods. We have 20 different ways to get to approximately the same number. Even with a $1M reward, no academic could find an error in the paper. The CDC and FDA won't look at it. No interest. This was a GLOBAL analysis with 1/4 of the world's total population. Perhaps you'd want to find the hole in this study before you approve a vaccine which is this dangerous??

We have no complete study on pregnancy.

We don't know if ADE is a problem still. And linked-epitope suppression (also known as original antigenic sin) we don't know about either. We know spike creates Lewy bodies which are associated with prion diseases. And you're approving this without knowing any of this??

If the FDA approves this on Monday, It will set a new low point since the evidence was in front of the FDA the entire time and nobody was interested in looking at it.

-steve

P.S. I made a list of over 100 problems with the current vaccines and it shows the adverse event rates, analysis of the 13 kids who died, analysis of the Pfizer 6 month study, etc. Let me know if anyone wants to chat about it. Lots of doctors and nurses have read it and write me that they agree with everything there. It's worth a look. Here is the URL: https://bit.ly/3AiOTt8 Happy to discuss any parts of this to defend the analysis.

Sent: 9/1/2021 2:48:12 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Frantz-Bohn, Susan [Susan.Frantzbohn@fda.hhs.gov]
CC: Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]
Subject: FW: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP
Attachments: ACIP comment 8-30-21.pdf

Dear Lorrie,

See below. We may need to object to this.

Best Regards,
Peter

-----Original Message-----
From: Steve Kirsch <stk@skirsch.com>
Sent: Wednesday, September 1, 2021 2:35 PM
To: Su, John (CDC) <ezu2@cdc.gov>; (b) (6)
Cc: Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6)
(b) (6)
Subject: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello,

Attached is an updated public comment I submitted at the ACIP meeting. Since you are both mentioned by name in the comment, I would like to give you an opportunity to respond before I publish this on TrialSiteNews.

To the CBER team members on the Cc: line, you should take a very close look at this. If you can find an error please let me know. If I don't hear from you, I will assume you have no objections to the methods and the conclusions.

I worked with a team of 20 scientists in putting this together... VAERS experts, statisticians, physicians, one Medical Examiner, multiple pathologists, and the inventor of the mRNA vaccine.

Thanks!

-steve

Comment to ACIP meeting of August 30, 2021 submitted by

Steve Kirsch

Executive Director of the COVID-19 Early Treatment Fund
stk@treatearly.org

September 1, 2021

NOTE:

1. This document is an updated version of the original August 29, 2021 filing.
2. If you are viewing a PDF version of this document, the most up-to-date version is here.

ABOUT ME

I am the founder of the COVID-19 Early Treatment Fund (www.treatearly.org). Our work in funding early treatments for COVID was featured on *60 Minutes*.

I have been vaccinated and my entire family has been vaccinated.

However, shortly after I was fully vaccinated, I began to hear stories from my friends that were very troubling. For example, one friend had three relatives who were formerly healthy die after getting the vaccine. Another friend had a heart attack 2 minutes after the injection and is now disabled, apparently for life.

I assembled a team of over 19 doctors and scientists listed at the end of this comment to investigate the available evidence.

OUR FINDINGS

Using the VAERS database and other official government data sources from the US and around the world (covering 35% of the world's population), we found evidence that clearly demonstrates that the current vaccines are significantly more dangerous than has been previously believed.

Our most important findings include:

1. The "real world" fatality data from VAERS does not match the fatality data from the Phase 3 trials. They aren't even close. Using multiple independent methods from independent researchers, we show that it is extremely likely that **over 150,000 Americans** have already been killed (see Attachment 2). Even with a $1M reward to academics to spot an error in the analysis, there were no takers. It is urgent to resolve

this discrepancy as soon as possible as we strongly believe that the real world data is right and the vaccines should be immediately stopped because they kill more people than they save. Even Pfizer's own 6 month study failed to show any evidence of a net mortality benefit either before or after unblinding. And all three vaccines showed they significantly increase morbidity.

2. The vaccines should be stopped immediately based on the 150,000 Americans killed alone. Arguing about myocarditis cases and morbidity tradeoffs is like re-arranging deck chairs on the Titanic. We have never had a vaccine that has killed 150,000 Americans.
3. None of the COVID vaccines reduce all-cause morbidity. It's the opposite: they all significantly increase all-cause morbidity by as much as 4.2 times baseline ($p<=0.00001$). The CDC must know this since this information is hiding in plain sight in the published literature. What is the point of offering an optional medical intervention which significantly increases all-cause morbidity when safer alternatives such as early treatment are available?
4. There is an error in the adverse event detection formula used by the CDC that appears to have prevented the CDC from seeing the safety signals that were obvious to our VAERS experts.
5. Early treatment and prophylaxis protocols are a superior option to the current vaccines on every single meaningful metric:
    a. Higher relative risk reduction (over 99%)
    b. Simple prophylaxis protocols be used to prevent infection with up to 100% success without the use of any drugs whatsoever
    c. Greater safety (minor temporary side effects, known safety profile)
    d. They lower both all-cause mortality and all-cause morbidity
    e. They work equally well on all variants
    f. They do not promote escape variants
    g. They do not cause vaccine enhanced infectivity/replication
    h. They do not cause prion diseases
    i. They prevent long-haul COVID syndrome nearly 100% of the time
    j. They enable people to acquire recovered immunity which is both 13 times stronger and more durable than vaccine-induced immunity
6. Because of all of these advantages, all early treatment methods are being deliberately sabotaged by the NIH so that people will believe that the vaccines are the only option. Even when drugs are proven in high quality large Phase 3 trials, or when there is a published peer-reviewed systematic review and meta-analysis, the NIH and medical community ignores these treatments and rates them as NEUTRAL which doctors all take as a sign to avoid.
7. Nobody of any stature in the medical world will agree to publicly debate our team on any of the issues raised in this document, even with huge financial incentives to do so. People at the NIH, FDA, and CDC refuse to comment or respond to any of the issues raised in this document. Censorship is used on all social media platforms to keep this information out of public view. Reporters who attempt to write stories find that they will not be published. Fact checkers will not reply to corrections on their fact checks. Top academic scientists who seek to challenge the narrative with peer-reviewed papers find

that the papers never make it into the journal. This is not how science is supposed to work but no one in the mainstream academic community (except for Peter Doshi of the BMJ and even he has to be very careful) is speaking out about this.

8. Experts like Geert Vanden Bossche, Dr. Robert Malone, Dr. Peter McCullough, and others have been right about these issues since they started speaking out, but they are being ignored or censored by the mainstream media.
9. It is insulting to us for the ACIP committee to ask for comments before the meeting and then vote on approving the vaccine before reading the comments. The ACIP committee is sending a very clear message to the public that any comments made will be ignored.

We recommend the committee take the following actions:

1. Require autopsies for all deaths within 4 weeks of any COVID19 vaccination so that data is available to compute an estimate of the true all-cause mortality.
2. Make available the analysis of the 11,000 deaths investigation in VAERS for public inspection. It's important for the public to understand why the CDC couldn't attribute a single death to the vaccine whereas one of the world's top pathologists ascribed at least 30% of all deaths to the vaccine.
3. Explain publicly why there is a death peak on the second day after vaccination if the vaccinations are perfectly safe and not causing deaths.
4. Explain publicly why the severe adverse side effects are dose dependent
5. Publish the proper elevated event table (see Attachment 2. Page 17)
6. Publish your analysis of the VAERS data including the propensity to report factor and the under reporting factor for fatalities or serious events. Please show us the correct analysis showing that there are no excess deaths this year as has been claimed.
7. Meet with our team as soon as possible to assess the validity of the points above.
8. Fix the adverse event signal detection system so it can at least recognize all the serious adverse events identified in Attachment 2, page 17.
9. Review the VAERS multiplier used in the myocarditis analysis. It appears to be 1. That makes absolutely no sense to us. How was that justified?
10. Recommend that vaccine mandates should not be issued without evidence of a statistically significant all-cause morbidity decrease (which there is not in this case).
11. Define a COVID vaccine stopping condition after which that vaccine should be halted until the stopping issues are addressed. In 1976, the stopping threshold was 35 deaths.
12. Ask the CDC to engage with us in a public discussion on vaccination issues so the public can hear first hand from qualified experts on both sides. This is a more effective way to combat vaccine hesitancy than censorship.

If the meetings with our team result in the validation of our assertions, then the following actions should be considered:

1. Recommend that at least three classes of people should not be vaccinated and should use early treatment if infected:
    a. Previously infected
    b. Women who are pregnant or might soon become pregnant

   c. Anyone under age 50
2. Inform the public of the complete list of elevated risks and their rates for the COVID vaccines.

THE MECHANISM OF ACTION OF THE COVID VACCINES IS DIFFERENT FROM THAT OF TRADITIONAL VACCINES

Dr. Robert Malone has described the vaccine as causing a cytotoxic spike protein to be produced throughout the body for up to 48 hours, with the potential to cause blood clots, inflammation, and permanent scarring. In addition, the spike protein (particularly the S1 segment) could break free of the cell and freely circulate, causing damage which could lead to a very wide range of pulmonary, cardiovascular, and neurological events.

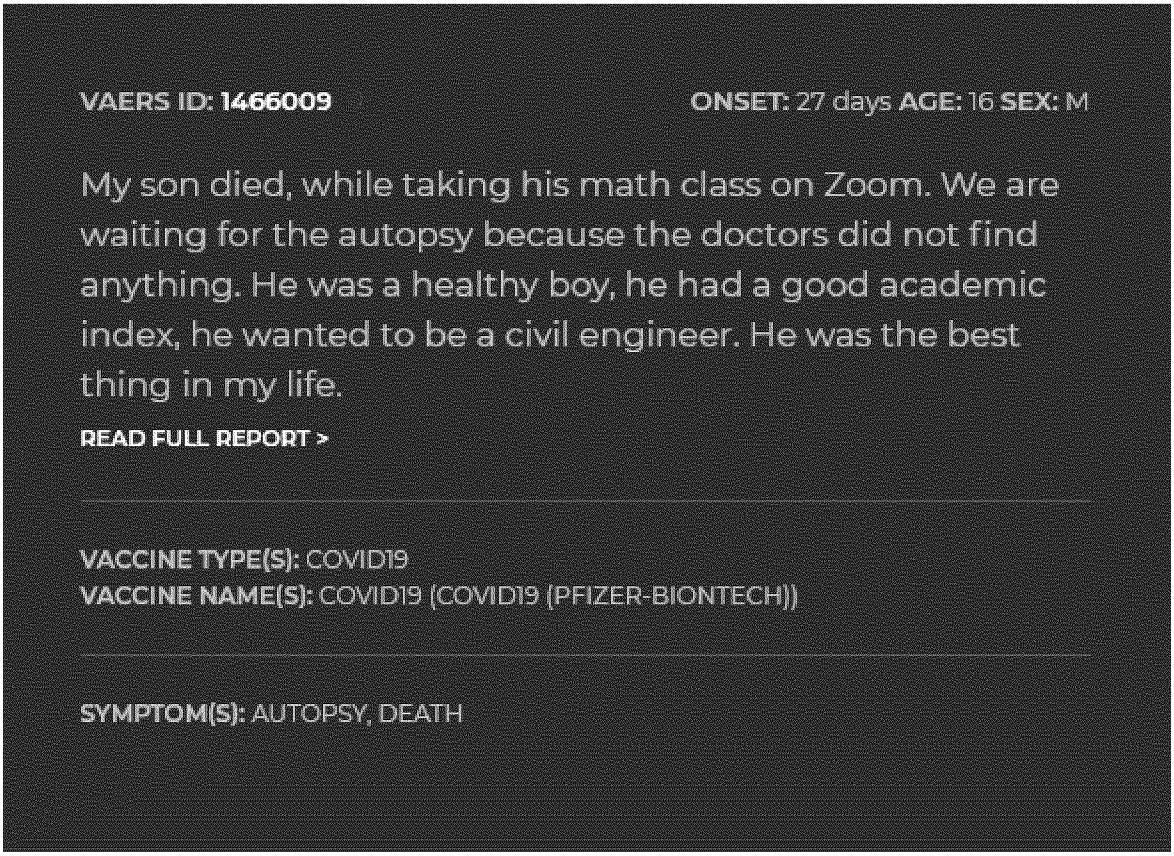
The gene-based vaccines (i.e., the 3 vaccines used in the US today) work in a completely different way than classical vaccines. With the latter, a fixed dose of killed or weakened pathogen or a toxin from the pathogen is injected and this sets a precise upper limit on how much foreign material is administered. In the former, while a fixed dose is also given, the upper limit of how much antigen is expressed depends on a series of steps each with substantial variability. This unavoidably greatly widens the range of amounts and concentrations of toxic spike protein in the body. Compounding this is the variability in anatomical distribution of the product with some body parts more prone to injury than others.

This built-in variability means that gene-based vaccines will likely always be much less safe than a classical vaccine. While the majority of people have no serious adverse events whatsoever, a significant number of people, perhaps in the millions, can be profoundly affected with one or more of a wide range of serious symptoms. Females are nearly 2.5 times as likely to be affected as males.

In particular, the VAERS data shows these symptoms include brain hemorrhages, strokes, heart attacks, multiple organ failure, pulmonary embolisms, and even sudden unexpected death.

A person can be perfectly normal and then just drop dead unexpectedly as the ACIP team already knows through their recent examination of the VAERS records of children 12-17 who died. For example, a 16 year old California student died unexpectedly in the middle of a Zoom math class. He had no prior health problems and appeared completely normal 20 minutes before his death.

If he didn't die from the vaccine, what did he die from? Can we see the autopsy report or is there a reason to keep it secret? Did the committee see the autopsy report? Did the mom ever get the autopsy report or was she denied?



There is a partial list of the elevated symptoms identified by VAERS analysis in Attachment2, page 17.

Nearly every cardiovascular and neurological event occurred at a rate that was 10X or more than would be expected to be reported in a typical year by all of the vaccines in that year.

IT IS VITALLY IMPORTANT THAT ALL PHYSICIANS BE EDUCATED ON BOTH THE MECHANISM OF ACTION OF THE VACCINE AND THE RANGE OF SYMPTOMS THAT ARE BEING CAUSED ASAP BECAUSE IT IS COMPROMISING PATIENT CARE

Today, most doctors believe the vaccines are completely safe. There is virtually no knowledge of vaccine symptoms. This causes physicians to treat these symptoms as if they are caused by something other than the vaccine which results in treatments that are ineffective since they are not treating the underlying cause.

Maddie de Garay is a perfect example of this. She will pay the price of preventable misdiagnosis for the rest of her life because physicians were never informed that the vaccines could be causal for her symptoms; the doctors treated Maddie as if symptoms were all in her head.

Angela Wulbrecht who has been a nurse for 23 years in Northern California is another example. She was misdiagnosed by the world's best experts because the CDC never disclosed to anyone that the vaccines are super dangerous and how the vaccines can disable or kill people. She

only found relief when she consulted Dr. Bruce Patterson who understood that the vaccines are deadly. She was able to get relief from her symptoms only when she was given drugs that targeted the vaccine damage.

Both of these people are public figures and are willing to speak out if you want to talk to them.

THE PROPER SAFETY TESTS WERE NEVER DONE

The FDA made the mistake of regulating the three COVID vaccines as a vaccine exclusively. As a result, the dose, duration, and amount of spike protein produced by these vaccines were never measured in advance of approval by the FDA.

Today, despite the evidence of unforeseen and unprecedented harm, these three critical parameters are still completely unknown.

Why haven't these tests been done in non-human primates with the actual vaccine?

THE D-DIMER AND CRP BIOMARKERS ARE A SMOKING GUN THAT THESE VACCINES ARE NOT SAFE

Even more concerning is that there has been no attempt to measure biomarkers that could clearly show that these vaccines are causing unexpected harm.

For example, measuring C-Reactive Protein and D-dimer of people before and after vaccination is a very simple experiment to show that the vaccines are causing problems.

Multiple researchers (contact us for the details) have done such a study in hundreds of patients and found that both biomarkers are elevated above normal levels for around three months in over 60% of patients.

This is very serious. It is a smoking gun that indicates that something is very wrong with these vaccines. For example, a 73 year-old female on her second dose had a D-dimer of 1186 ng/mL (normally it is less than 250 ng/mL) two weeks after the shot. **It remained above normal for three months.**

AN OVER-RELIANCE ON DELEGATED TRUST HAS MAGNIFIED SMALL ERRORS INTO LARGER ERRORS

We live in a world of delegated trust. But if the root of that trust makes a mistake, it creates a ripple effect where the consequences are magnified exponentially.

Our first example of amplified errors due to delegated trust is the safety signal detection of the VAERS database that John Su at the CDC has been monitoring.

The ACIP committee trusts the CDC staff to monitor VAERS. If there is a bug in the monitoring algorithm used by the CDC, the CDC will miss the critical safety signals and the ACIP committee will not be alerted. ACIP members do not have the time or expertise to analyze the VAERS data themselves, as it is not a simple task, requiring many months of dedicated effort using specialized tools. If such a critical safety signal is missed by the CDC, there are immeasurable consequences and harm to the public.

When we looked at the VAERS database, we found dozens of very serious safety signals that the CDC failed to detect.

The attached analysis (see Attachment 2, page 17) shows that every neurological and cardiovascular event that we investigated was strongly elevated as compared to previous vaccines, most by at least 10X and some by as much as 473 times higher than what is normally expected in a typical year across all vaccines. This is impossible to explain if the COVID vaccines are perfectly safe.

We just received a similar analysis from Professor Josh Guetzkow which can be viewed at Attachment 3. In Table 1, for example, death is happening at a rate 91X higher than normal. That sort of increase cannot possibly be explained by "stimulated reporting" or "more people got vaccinations." This is again independent confirmation that the explanation from the CDC and FDA does not match reality. The ACIP committee is also clueless and apparently lacks basic critical thinking skills. All the evidence is in plain sight that this is a disaster and has been in plain sight since January 2021, not just in VAERS, but to those practicing doctors, neurologists, and pathologists who were seeing a huge spike in adverse events and deaths and were willing to consider the possibility that the vaccines were not as safe as had been claimed by the CDC and FDA.

In addition, all of the neurological and cardiovascular symptoms with elevated event counts were consistent with the mechanism of action described at the start of this comment. Each and every symptom we looked at satisfies all the traditional Bradford-Hill causality criteria using both absolute rate elevation compared to baseline rates as well as Dose 1 vs. Dose 2 response disparities.

A BUG IN THE SAFETY SIGNAL ALGORITHM ALLOWS SAFETY SIGNALS TO ESCAPE DETECTION

Why was the CDC oblivious to these same signals? The answer: a bug in the algorithm used by the CDC. This bug only manifests itself when the vaccine being monitored produces a wider than normal range of side effects. This has not been the case with earlier vaccines which is why it wasn't detected earlier.

The bug in the safety signal algorithm is documented in this post: https://roundingtheearth.substack.com/p/defining-away-vaccine-safety-signals-572 (this is Part

III, which contains links to Parts I and II). We would be happy to meet with CDC staff to go over this in detail.

WHY ARE YOU IGNORING PEOPLE WHO ARE TRYING TO HELP YOU SPOT SAFETY SIGNALS?

Repeated attempts to inform any ACIP committee member of this anomaly were unsuccessful. Considering that the ACIP committee is tasked with the critical monitoring of safety in the world's single most important drug, we are puzzled by the lack of interest in receiving safety information from qualified researchers. We were directed to submit comments to a non-existent docket number.

Failing to get anyone on the ACIP committee to respond, we next attempted to communicate the signal error to the CBER group at the FDA. Not one person responded, including Dr. Steven A. Anderson and his staff, despite multiple emails and phone calls. Again, we are puzzled by the lack of interest in receiving safety information from qualified researchers. Dr. Anderson had said in a video call that he was the main person responsible for the safety monitoring.

Emails to both John Su and Anne M. Hause were also not responded to.

Perhaps the FDA and CDC should simply let people know that "**if you find an urgent safety problem, don't bother to contact us because we aren't interested in hearing what you have to say.**"

If this were more well known, it would have saved our time and yours.

MYTH BUSTED: "VAERS CANNOT BE USED TO SHOW CAUSALITY"

For the current COVID vaccines, our team is extremely confident that we can meet all the Bradford-Hill criteria for causality using VAERS analysis alone. Will our statisticians and VAERS experts be permitted to meet with any ACIP members to discuss the data?

For example, it is well established that a clear dose dependency relationship can be used to satisfy one of the Bradford-Hill criteria. Because two of the vaccines are multi-dose vaccines, a Dose 1/Dose 2 ratio analysis shows a very clear signal. Sadly, this type of analysis is currently being completely ignored by the CDC.

THE FDA HAS ASSUMED THAT VAERS WAS JUST OVER-REPORTED THIS YEAR

Our second example of amplified errors due to delegated trust is the calculation of the VAERS event counts.

A detailed analysis of the VAERS data (Attachment2 and Attachment3) both show that the FDA has made a very serious error in assuming (without any evidence whatsoever as far as we've

been able to determine) that the propensity to report to VAERS is much higher this year and that these are simply all background events that can safely be ignored. The two analyses found the same thing and were done by different people, in different countries, who never met. The results were the same.

If the propensity to report is drastically increased, then it should be easy to prove. Randomly survey 100 neurologists and ask them the number of reportable events vs. reports last year vs. this year.

YOU CAN LEARN A LOT BY TALKING TO A NEUROLOGIST

Some of the things we learned by talking to a neurologist with over 15 years of experience and a 20,000 patient practice are worth keeping in mind:

1. They can't reveal their identity publicly or they would lose their license
2. They can't speak out against the vaccine to their patients or risk loss of license
3. Patient load went up 20X during the vaccine rollout. Never saw anything like it in her career.
4. Over 2,000 patients had serious side effects from the vaccine
5. They only reported 2 to VAERS: it was too frustrating to use; it would crash every 2 minutes and you'd have to start over from scratch.
6. Only the doctor doing the injection must report to VAERS, so they don't have to, so they stopped doing it since it was so cumbersome.
7. Has always known about VAERS, but never need to use it before since never had to report an adverse event!!! This year would have reported all 2,000 patients if VAERS was easier to use. Instead, made just 2 reports (1 of 1,000)
8. Neurologists are now booked up for 3-4 months is typical. At Stanford is 6 months.
9. Most neurologists are clueless on how to treat vax events. Most neurologists don't associate the vax as the cause of the problem. Treatments are useless. When patient goes on Patterson treatment protocol, they can recover back to "normal" in 8 weeks. However, they get no medical training at all on this (because doing so would be an admission that the vaccines aren't safe) so most people who are vaccine injured remain disabled.
10. At UC Davis, 40% of staff is unvaxed. They have to wait in line twice a week and come in 2.5 hours early to get in line for COVID testing. They endure that because they've seen first hand how bad the vax reactions can be.
11. Long-term impact of the vaccination program: Increase in multiple neurological conditions.
12. For the vaccine injured, the standard blood tests (including all extended testing such as CRP, D-dimer, etc) can all show completely normal. Angela Wulbrecht was given every test under the sun and they were all normal. It was only when she took Patterson's cytokine panel and S-protein tests that showed she was clearly very sick.

FDA FALSE STATEMENT: "DEATHS CAUSED BY THE VACCINE ARE EXTREMELY RARE"

In a letter dated August 23, 2021, Janet Woodcock writes to Senator Johnson, “Reports of death after COVID-19 vaccination that are found to be related, or even possibly related, to vaccination with COVID-19 vaccines have been extremely rare.”

Where are the 249 autopsies on which that statement was made? Has the committee reviewed all 249 autopsy reports?

We were able to prove causality using the Bradford-Hill criteria from just the VAERS data alone. We didn’t need the autopsies.

It was shocking to us that the CDC and FDA couldn’t find these signals despite access to 249 autopsy reports.

There is something seriously wrong here. You cannot have a few excess deaths from the vaccine when both the VAERS database itself and the data from other countries shows that there have to be 150,000 deaths. They both cannot be right. We think the CDC is mistaken because the death data we used to compute the 150,000 deaths comes from 35% of the world’s population. This error needs to be corrected as soon as possible.

SYMPTOM CODE FOR A VACCINE DEATH

What is the SYMPTOM code for a vaccine death? We looked at all the VAERS records with autopsies and we couldn’t find a single record with a coding for a COVID VACCINE DEATH.

OUR ANALYSIS SHOWS THAT IT IS HIGHLY LIKELY THAT OVER 150,000 PREVIOUSLY HEALTHY AMERICANS HAVE BEEN KILLED BY THE COVID VACCINES IN 2021

The analysis in Attachment 2 shows that 150,000 previously healthy vaccinated Americans have had their lives cut short prematurely due to the vaccines. We confirmed this number using independent methods from independent researchers. We used both US data and data from other countries. Our analysis used data from over 35% of the world’s population.

Our results are also consistent with reports from doctors we know who report that they have lost more patients to the vaccine than to COVID. For example, one doctor with 700 patients lost 2 patients to the vaccine and no patients to COVID. These doctors are special because they are “vaccine aware” and understand the mechanisms of action. In another case, one nursing home with 132 beds lost two patients within hours after vaccination.

Unfortunately, most doctors are blind to the association between the COVID vaccines and deaths and if asked, always report 0 vaccine deaths because they believe the narrative that the vaccines are “safe and effective.” Any deaths would be anecdotes and ascribed to some other cause. For example, when the fetus of a recently vaccinated pregnant woman had a massive

brain hemorrhage, the doctor considered the event caused by a "genetic defect." The vaccine is never even considered as a possible cause.

As far as we know, not a single doctor in the US has determined that any deaths were caused by the COVID vaccines. There isn't even a column in the CDC weekly report for deaths from the COVID vaccine. Apparently, it is impossible to die from the COVID vaccines if you live in the US.

However, a methodology based on excess death analysis (as detailed in Attachment 2) and autopsy results in other countries of people who died after getting the vaccine tells a completely different story: a story of a very deadly vaccine that has likely killed over 150,000 Americans so far.

It has been enormously frustrating to us that the CDC and FDA look the other way and have ignored all our attempts to share our analysis. That is not a good safety practice to ignore qualified people who disagree with you, especially when 150,000 lives are at stake. This is not serving the public interest. Safety must be a top priority at these agencies but when there are deaths from the vaccine, people are simply looking the other way and don't want to hear it. This is why all our attempts to contact people were ignored.

If the CDC or FDA engages with us and finds an error in our analysis and can show evidence that no lives have been lost to the vaccine, then this would do wonders for reducing vaccine hesitancy. Conversely, if the CDC or FDA confirms we are correct, we can immediately stop future loss of life by aborting the vaccination campaign.

Whichever way it ends up, the clarity that happens when both sides engage in an open public discussion of the methods and evidence used will benefit all parties and the public.

THERE IS NO EVIDENCE ANYWHERE OF AN ALL-CAUSE MORBIDITY BENEFIT. WITHOUT THAT, DEPLOYING THESE VACCINES MAKES NO SENSE, ESPECIALLY SINCE SUPERIOR ALTERNATIVES ARE AVAILABLE

When a vaccine class is generating a huge number of adverse events in 8 months that are more than the events from all 70 vaccines over the past 30 years, it is reasonable to assume that there might be a significant safety problem with the vaccine.

In such a case, rather than focusing on the reduction of relative and absolute risk provided by the vaccine, it is instead more important to focus on whether there is a significant reduction in all-cause morbidity.

For the three vaccines, using data from the original clinical trials, it has been shown that in all cases, **the all-cause morbidity is significantly elevated by all the vaccines**. The elevation ranges from 1.5X to 4.2X. That is a **large move in the wrong direction.** It is **highly statistically significant** for all three vaccines. This of course is consistent with what we find in VAERS.

With respect to efficacy, nobody argues that the vaccines have saved people from dying from COVID. But the problem is that this benefit comes at a steep cost: an increase in death from other causes that completely negates the benefit of the reduction in COVID-related deaths.

But could an all-cause mortality benefit compensate for the higher all-cause morbidity? Our best data on that is the Pfizer 6-month study. A 50% reduction in COVID deaths was more than offset by a four times higher rate of cardiac arrest. As a result, the all cause mortality rate was higher in the treatment group than in the placebo group. This was true in **both** the pre-unblinding and post-unblinding phases. **The numbers were small but the point is that there is no demonstrable all-cause mortality benefit. Zero. If anything it was the other way around.**

As evidenced by the high number of reported deaths to the VAERS system, it is the all-cause morbidity statistic that is the new elephant in the room. If you can't show a lower all-cause morbidity, there is no reason to vaccinate.

We also have troubling anecdotes like the Sunnycrest nursing home in Ontario, Canada with 136 beds where all the residents were given the booster and 4 of them are dead and 7 hospitalized. **This is a 3% death rate from the vaccine that we'd guess is pretty common everywhere but nobody will talk**. We only found out about this through an insider. The media never covers this because they don't want to panic the public reporting on an anecdote that would dissuade people from taking the safe and effective vaccine.

Or the Hawaii nursing homes with 32 vaccine deaths vs. 16 COVID deaths. If it wasn't for one whistleblower, Abrien Aguirre, we'd never have known this because **all the nursing homes keep all this information secret so the public never knows about it**. Each nursing home thinks they are simply an unfortunate anecdote, where the reality is that their numbers are normal for this vaccine. If you try to call the homes directly, they won't talk. **So nobody ever finds out.**

What makes those two anecdotes interesting is that the reporters understand how the vaccines kill. **Most other nursing homes don't make the connection and will tell you that no one has died from the vaccine**. Since the vaccine can kill you over a 3 month period, they simply assume that the patient died from natural causes (like a massive heart attack or just "died") and it just "happened" that a lot of deaths coincidentally happened around vaccination time, but nobody is doing the statistical calculation. And since most nursing homes are small, a 3% death rate looks like "natural causes."

The Hawaii data, if confirmed, shows that the vaccines caused twice as many deaths as could have possibly been prevented even with a perfect vaccine.

Was he lying? What was his motivation? Aguirre basically put all his income on the line. For what? His reward: Aguirre was fired for telling the truth. This is exactly why people at nursing homes will not say anything. There is only punishment if you tell the truth. This is why the Sunnycrest whistleblower isn't identifying himself/herself.

The nursing homes aren't talking about the correct data. Why wouldn't they correct the data if it is wrong.

For the three vaccines, using data from the original clinical trials, it has been shown in the peer-reviewed literature that in all cases, the all-cause morbidity is significantly elevated. The elevation ranges from 1.5X to 4.2X. That is a large move in the wrong direction. It is highly statistically significant for all three vaccines. This of course is consistent with what we find in VAERS.

NOBODY WANTS TO TALK ON THE RECORD FOR FEAR OF LOSING THEIR JOB

One of my vaccine injured friends said the head anaesthesiologist at one of the world's top medical schools said "he wasn't willing to put it in writing" that it was caused by the vaccine because it would affect his reputation. However, his medical assistant was willing to put it in writing and sacrifice her career. My friend was told his symptoms would get worse over time. He's 39 years old and his life was ruined by the vaccine and nobody wants to end their career to speak out.

One of the top neurologists in my area (over 20,000 patients) won't talk publicly.

I talked to a medical examiner who didn't even feel comfortable sharing her name with me, but revealed autopsies are useless.

Basically everyone who could talk won't. They can't speak out publicly or they will lose their license.

They could speak to a reporter and talk without their names being disclosed, but no mainstream media would run the story, so there is no point. Reporters at top newspapers cannot get their stories run. *60 Minutes* won't touch the story either.

MEDICAL EXAMINER SAYS AUTOPSIES ARE USELESS, VAERS IS THE GOLD STANDARD FOR CAUSALITY

We were only able to find one medical examiner who would talk to us. Even then, she wouldn't reveal her last name or state.

Here are the key points:

- She is the only ME in her state looking at vaccine-related deaths. The other ME's all assume the vaccines are safe so never will implicate the vaccine.
- The ME's in general don't have the skills, they don't have the proper tests to determine causality for deaths caused by this vaccine (they don't exist in the post-mortem setting), they don't have the time, they don't have the medical records, and they get the body too late. They can see large blood clots of course
- THEY CAN'T EVEN ORDER A D-DIMER because they are told "well that's not generally done" so unless they fight for it, they simply give up.
- They even get a huge push back when asking for the medical records.
- Often, they don't even know the vax status or when the patient was vaccinated.
- She had to personally make a call to the family to determine whether a patient got vaccinated.
- THIS IS WHY the ME's cannot make the connection in the autopsy setting.
- She trusts VAERS way more than autopsy....says **NOBODY** is going to find this post-mortem
- She never had time to report any of her deaths in VAERS.... the ME's are overloaded with some cases from 6 months ago still not completed.
- She was operating today on 3 hours sleep. They are understaffed and overworked. It's exhausting.
- For vax deaths, she said autopsies are NOT the gold standard. It is VAERS.

CALCULATION OF REDUCED LIFESPAN

It is difficult to make a tradeoff between the elevated morbidity that reduces lifespan and the number of COVID deaths saved.

The COVID vaccines introduce both morbidity and mortality risks.

What ACIP has done is compare morbidity due to the vaccine vs. the same morbidity from COVID. That can be problematic if some some morbidities are improved and some are made worse. We'd have to look at all morbidities, something that ACIP hasn't done since they haven't seen the safety signals.

We believe that if we just look at the increased mortality due to the 1) direct deaths caused by the vaccine and 2) the reduction in total lifespan from all serious adverse events elevated by the vaccine, it would be clear that there is no mortality benefit.

We can see that from the Pfizer Phase 3 6 month study where more people in the treatment group died both pre- and post-unblinding. The Hawaii nursing home data is consistent: there was a 2:1 vaccine caused death:max possible vaccine saved death ratio which also supports stopping the vaccine.

Therefore, it seems likely to us that not only is there no morbidity benefit from the vaccines, but there is no all-cause mortality benefit from the vaccines either.

This makes the vaccines very hard to justify.

If we are wrong, we'd like to see the analysis.

WE ESTIMATE THAT APPROXIMATELY 574 KIDS HAVE BEEN KILLED BY THE VACCINE SO FAR; THAT'S MORE THAN HAVE DIED FROM COVID. WE ARE MAKING A HUGE MISTAKE. WE ARE KILLING OUR KIDS, NOT SAVING THEM.

The ACIP committee recently analyzed the cause of death of the 14 kids (aged 12 to 17) whose fatalities were recorded in the VAERS system. Had they had the table in the attached document, they would have realized that in every case (where there was sufficient symptom detail), the main cause of death was consistent with a symptom that was strongly elevated by the COVID19 vaccines. This should have led to a different outcome Mortality Among Teenagers Aged 12-19 Years: United States, 1999-2006 than simply listing the causes of death of the kids with no further discussion. No concern over the lack of autopsies was noted in the meeting notes. It is very likely that none of the kids had an autopsy done. There was no mention of this in the report.

We believe the lack of autopsies is a huge oversight for a vaccine that is generating so many legitimate adverse events. We believe it is imperative for the ACIP committee to immediately demand that autopsies be done. How many more kids must die before we look to find the real cause of death?

These children are dead now and their lives can never be recovered. But we can learn from their death if the ACIP committee members would simply read the 14 VAERS reports on each child and compare the cause of death with the symptoms listed in the table in the attached paper.

Five kids dying from cardiac arrest is not normal. Kids between 12 and 17 are twice as likely to die from cancer (6%) as from heart disease (3%). In this case, 38% died from heart disease and 0% died from cancer. That's statistically very unlikely. It points to the undeniable fact that these kids did not die of natural causes. Therefore, the hypothesis that the vaccines are safe seems highly unlikely. How does the ACIP panel explain this?

One of the children died with an intracranial hemorrhage. How could that have not raised a huge red flag. Kids that age never die from an intracranial hemorrhage.

We did a search in VAERS searching every record, over 70 vaccines over the last 30 years. There were only two deaths of kids aged 12-17 with "HAEMORRHAGE INTRACRANIAL" in the history of VAERS and both were associated with the recently approved Pfizer vaccine. There

weren't any deaths caused by an intracranial hemorrhage in the entire history of VAERS in that age range until the COVID vaccines arrived on the scene. One event could be written off as a fluke--- very bad luck. But two events are a complete train wreck. How this didn't raise any red flags in the ACIP committee is a mystery to us.

As this note is being written the BBC News just reported that BBC presenter Lisa Shaw died of a brain haemorrhage. The coroner determined the cause was the COVID vaccine. All of the causal factors in her death were consistent with the elevated symptoms we found in VAERS. Note that the Astra-Zeneca vaccine has a nearly identical mechanism of action as the mRNA vaccines.

Each of the 14 children who died in the CDC study represents 41*14=574 real deaths (as noted in the attached paper). Thus, more American kids have already been killed by the COVID vaccines than have been killed in the entire history of COVID to date (361). That's tragic.

Two of the kids died from a pulmonary embolism, a symptom that is very strongly caused by the vaccines. Over 5 years in VAERS, you'll find just one PE death in that age range. So to get one PE death in a year, that's bad luck. To get two, you have to at least say that it's more likely than not that it wasn't just random. Yet the CDC report dismissed it without comment.

AN ACCURATE MYOCARDITIS COST-BENEFIT ANALYSIS IS MISSING

The CDC myocarditis cost-benefit analysis omitted the determination of the VAERS under-reporting factor for "mild" events.

While we think myocarditis is a serious event, the CDC characterizes these events as "mild" and thus would be less likely to be reported than something "severe" like death.

Therefore, we'd estimate that the VAERS under-reporting of such an event might be somewhere around a factor of 100.

My question to the panel is whether **a 100 times greater rate than the rate reported in the report would make a difference in the recommendation of the ACIP panel?** We would be very surprised if this doesn't change the recommendation.

Also, as a sanity check on our results, please refer to Table 1 in Attachment3 which is Joshua Guetzkow's analysis showing a 91-fold increase over baseline myocarditis rates.

Also, it would be good to estimate the effect of this heart damage **(and all other conditions elevated by the vaccines)** on expected lifespan so it is clear that the shortened lifespan is worth the savings in the amount of deaths. This way, we can do a pure mortality tradeoff.

For a lot of AEs, the quality adjusted life years (QALYs) is not significant. For young people, myocarditis represents an enormous QALY calculation. This will include some deaths, but most of a lifetime of a large range of reduction of life value.

For public health officials to discard the data without acknowledging something like a QALY comparison (and the deaths) is inappropriate.

TRUSTING THE PHASE 3 TRIAL RESULTS AS THE "GOLD STANDARD" IS NOT A GOOD IDEA

When there is a disagreement between real-world results and the Phase 3 clinical trial, we think it is better to trust reality. Here are some of our reasons:

1. The paralysis of Maddie de Garay was not reported in the Pfizer 12-15 year old clinical trial, and the FDA failed to investigate this case even though they knew about it. This is serious misconduct happening and nobody is holding the FDA accountable.
2. Adverse events were difficult to impossible to report (and Facebook conveniently removed the evidence of people complaining about that)
3. At least one death that happened didn't show up. Who knows how many more?
4. The cohorts were not representative of the population as a whole (they were much healthier, e.g., rate of heart attacks was 10X lower than the overall population rate)
5. Five times as many people were disqualified from the treatment arm (311) compared to the control arm (61) for protocol violations even though the trial was supposed to be double blind.
6. Read this article on the Pfizer consent form. The consent form allows for participants who need emergency care and go straight to their doctor or hospital to be ejected from the study. But that's hardly the only problem.
7. Pfizer paid one of the largest criminal fines ever imposed on a drug company for the arthritis drug Bextra.
8. The company can't seem to find any safety signals even though it is obvious in VAERS.
9. **No autopsies to determine cause of death done in the treatment group**. This was a **very serious** oversight in our opinion.
10. The death rates make no sense. We know of a 132 bed nursing home that had 2 deaths within hours of getting the vaccine. And a larger nursing home in Hawaii with over 500 beds had 32 deaths after vaccination. The numbers don't match each other, but they are nowhere close to what was reported in the clinical trials which again suggests the cohorts were not representative of the population or that the company didn't find the deaths or both.

THE LACK OF AUTOPSIES IS INEXPLICABLE

Autopsies are the gold standard for determining causality.

How can the CDC say confidently that there have only been a few deaths? May we see the 249 autopsies? If not, why not?

In Germany, soon after the vaccines rolled out and deaths after vaccination started happening, the Federal Association of German Pathologists called upon the German authorities to require autopsies to validate the cause. Their requests were ignored presumably because nobody wants to know the answer.

In America, few people are asking for autopsies. And when they do, they are being denied

If we had the autopsies available, we wouldn't have to debate whether we are right or wrong about the numbers of deaths -- we'd have the data.

The Norwegian Medicines Agency linked 13 deaths to vaccine side effects. At the time that article was published, there were only 13 assessments completed. So in 100% of the cases, the deaths were deemed to be caused by the vaccine by the official government agency.

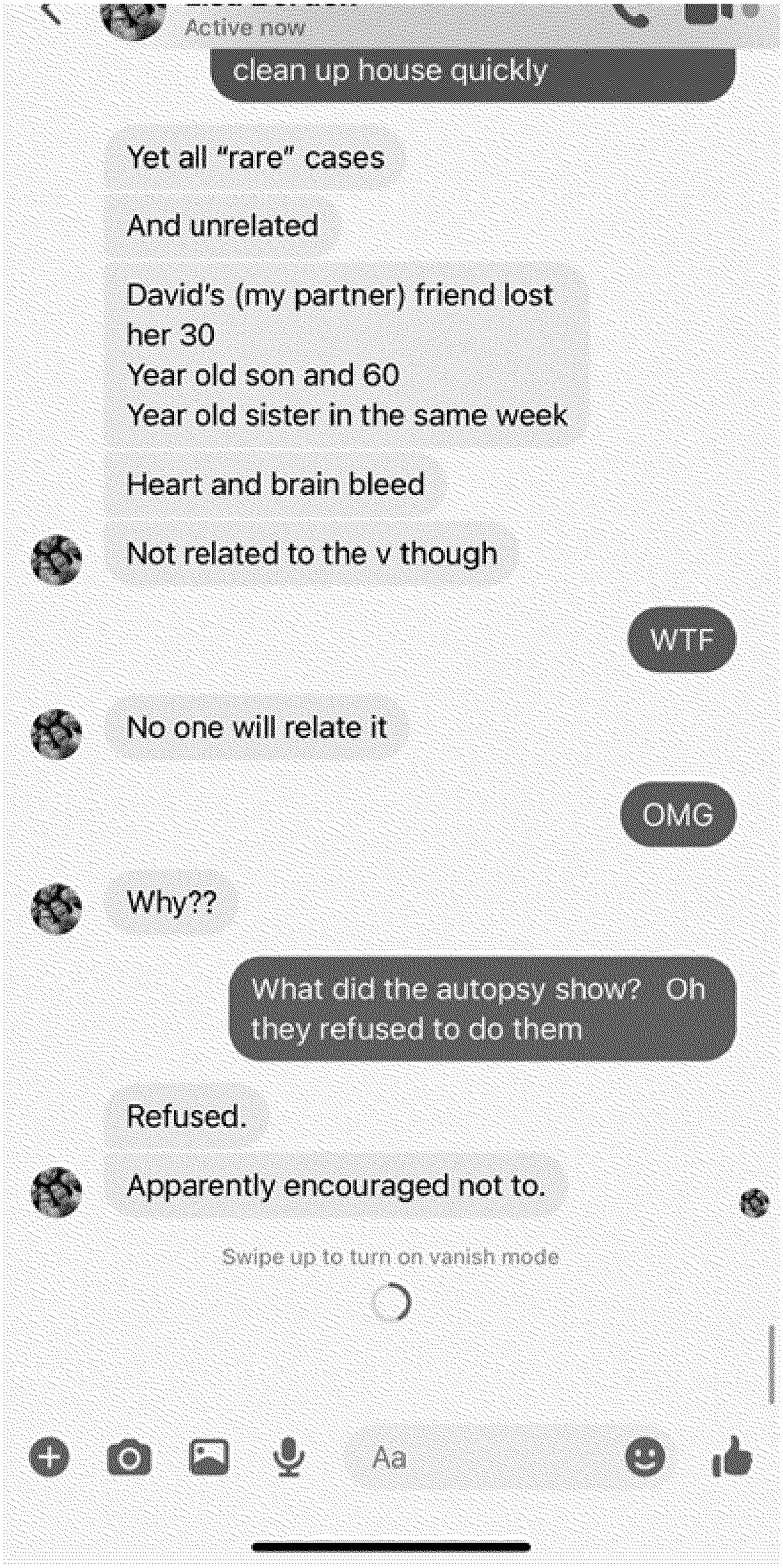
In Germany, they actually did autopsies of 40 people who died within 2 weeks after vaccination. They determined that at least 30% to 40% really did die from the vaccine. From Media Blackout: Renowned German Pathologist's Vaccine Autopsy Data is Shocking... and Being Censored:

> Dr. Peter Schirmacher is not just an average pathologist. The German doctor is world-renowned in his field, honored by The Pathologist as one of the 100 most influential in the world. He is the acting chairman of the German Society of Pathology, director of the Institute of Pathology at Heidelberg University Hospital, and president of the German Association for the Study of the Liver. Bottom line, this professor and doctor understands pathology like very few on the planet.

It is puzzling to us that nobody on the ACIP committee is calling for mandatory autopsies. Only 249 have been done on the 11,000 people who have died. It would be nice to know what they said.

Does ACIP think we should not have autopsies? I think it is important to clarify the committee's opinion on whether we should have the data on why people are dying after the vaccine or whether ACIP would rather have coroners look the other way.

Right now, it seems to be difficult to have an autopsy done, so if you want to gather the data, I think it is important to say something rather than remain silent on this issue.



IT IS BECOMING CLEAR THAT THE VACCINES ARE RAPIDLY BECOMING LESS EFFECTIVE

As far as effectiveness, we believe the recent paper from a team of Japanese researchers, "The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines" shows that the vaccines we received will soon become completely useless to protect us and, to make matters worse, are already enhancing the ability of current variants to infect us through **vaccine enhanced infection and/or replication** (rather than "classical ADE" which so far appears not to be happening).

From the abstract:

> Although Pfizer-BioNTech BNT162b2-immune sera neutralized the Delta variant, when four common mutations were introduced into the receptor binding domain (RBD) of the Delta variant (Delta 4+), some BNT162b2-immune sera lost neutralizing activity and **enhanced the infectivity.**

In short, even if the vaccine were perfectly safe and killed no one, vaccinating with a non-sterilizing vaccine in the middle of a pandemic is going to have a net negative benefit, exactly as Geert Vanden Bossche has been trying to tell the world since shortly after the vaccination program began. He called it a very serious mistake. Nobody in power listened.

The latest UK government data (Briefing #20), shows you are 57% more likely to die if you get delta and you are vaccinated than if you are unvaccinated. The computation for age<50 and fully vaxed vs. unvaxed is 13/48*147612/25536=1.57 which is consistent with the Japanese paper.

Therefore, not only are the vaccines not safe, but they are quickly becoming useless and may shortly be a liability as far as effectiveness is concerned.

EARLY TREATMENTS HAVE ALWAYS BEEN THE SAFER, MORE EFFECTIVE OPTION

Meanwhile, early treatments have been virtually ignored by mainstream academia and the NIH. Lack of suitable guidance from the NIH has caused the entire world to avoid early treatments. These treatments are both extremely safe and very effective. They work against all variants as well. For example, the protocols used by George Fareed and Bryan Tyson against COVID continue to work well against COVID and with over 6,000 patients treated in an area with one of the highest CFRs in the country, it is very rare for a patient to be hospitalized for COVID in their clinic; it only happens if the patient presents late. They have more than a 99% relative risk reduction against all COVID variants if the patients get treated early. The NIH has expressed no interest in trying to replicate this success despite the tremendous lifesaving potential and negligible risk. They are more interested in waiting for a new, unproven drug from Merck for treatment.

EARLY TREATMENTS HAVE BEEN CENSORED. NOBODY IN MEDICINE SEEMS TO MIND.

One of the earliest pioneers of early treatment, George Fareed, is banned for life from YouTube for trying to spread life-saving treatment protocols that work..

The Nobel Prize winning inventor of ivermectin, Dr. Satoshi Omura, had his video on ivermectin for COVID blocked on YouTube.

Ivermectin has a peer-reviewed systematic review and meta-analysis, the highest level of evidence in evidence based medicine.

We find it troubling that so few in the medical community are speaking out about such abuses.

These individuals are giving life-saving advice and have been censored and there are dozens of examples of many others that have been censored, banned for life, and/or demonetized.

It would be interesting to hear the ACIP members speak out on this subject, either endorsing the censorship or condemning it. Remaining silent on such an important issue will not help advance science and save lives. Normally, ACIP shouldn't have to do this, but everyone else is remaining silent.

THE UK SAID THE VACCINE IS NOT RECOMMENDED FOR THOSE < 18 YEARS OLD

The UK panel said the data doesn't justify vaccination of those under 18

Jul 19: UK opts not to vaccinate most under 18 against COVID-19

Then they changed their minds just 2 weeks later:

Aug 4: UK to roll out COVID-19 vaccines to 16 and 17-year-olds

Did the science really change that quickly? What new things were learned? Or is science being driven by politics which would be a new low point. If there was new science, it would be useful for everyone to know what it was.

16% NEVER CAME BACK FOR A SECOND SHOT. WHY?

62% of Americans are vaccinated vs. 52% who are fully vaccinated. So that's 16% (52/62=.84) that never came back for a second shot

Why is there such a large gap when in order to do anything (like keep your job, go to school, etc) you need to be fully vaccinated?

We understand why people don't get vaccinated at all (they are well informed). But what's the reason for the 16% gap?

We know from user surveys that 3% of people who took the vaccine required treatment by a doctor. And 5% are still suffering from side effects. So that explains half of the gap. Basically 8% of people who got the vaccine had a large enough bad first experience, they aren't going back for a second shot. This leaves 8% unexplained, but likely due to a bad first reaction.

We think that 12M injured Americans is a lot of people especially in light of the lack of an all cause mortality benefit and a clear lack of all-cause morbidity benefit. That's a lot of people who have been injured for no proven net benefit (yes, COVID lives were saved, but it was an overall cost of lives). But that's just our opinion.

SUMMARY

Analysis of multiple researchers using different sources confirms that the current COVID vaccines are very dangerous and are significantly increasing all-cause morbidity. The vaccines can trigger a wide range of serious neurological and cardiovascular symptoms, re-activate latent viruses, trigger flare-ups in people with cancer, and more. Multiple studies show 60% of patients have elevated D-dimers that persist for 3 months after vaccination. These vaccines should be immediately halted. If they cannot be halted, then it is imperative that we inform the American public of the risks. Children, pregnant women, and previously infected people should be instructed to avoid vaccination. All vaccine mandates should end immediately until there is scientific proof of an all-cause morbidity benefit.

Early treatment has always been a superior strategy for treating COVID: it is safer, more effective, and has a number of other important benefits.

Virtually none of the people diagnosed with COVID in the hospital today were treated early. That is the message we should be sending to America.

A FINAL NOTE OF ACIP COMMITTEE WAS 14-0 IN FAVOR OF APPROVAL

They said they are there to protect the health of the public.

As far as we can tell, no member of the ACIP committee read this note or any of the other public comments submitted prior to the vote. So this comment didn't matter. The public comments portal is just to placate the public.

There was no mention of early treatment as an alternative to vaccination.

This suggests to us that the committee is not interested in hearing from qualified people who disagree.

The data they presented was just one side of the story.

I loved how the slides showing bad data were left on the screen for like 2 seconds. And when the rate of severe adverse events was 10% vs. 2% for placebo, they just didn't discuss that at all!

My favorite was Dr. Lee's presentation (VaST). Look at slide 18. It showed that the vaccines reduce your risk for pulmonary embolisms. Which is very interesting because our VAERS analysis showed the PE rates were off the charts.

First of all two of the 14 kids (12-17 year old) died from PE. That can't happen. How do they explain that? But our chart showed PE rates were elevated by 473 times. It was the most extreme event we saw in VAERS that was elevated. So this is a stunning divergence of reality vs. data presented to ACIP. This is an objective example of how the data that they used to make the recommendation diverges from VAERS and nobody was interested in resolving the inconsistency.

From OpenVAERS, we got 5164 events so 1411 events per million with 41X underreporting. The normal rate of PE is 0.39 per million. So this is an elevation of **3,617X from normal** if we compare with the baseline incidence rate. And it is likely more than that since 41X is likely a lower-bound on the reporting rate factor.

But our opinions don't matter.

Science is supposed to matter though. The science says only one hypothesis fits the facts: the vax is safe or it isn't.

Here's a table pulmonary embolism to help you decide:

	Safe	Not safe
Mechanism of action	x	✔
VAERS data is elevated by 473	x	✔
VAERS data is 3,617 above normal	x	✔
2 of the 14 kids died from PE	x	✔

The point is that if you look for the hypothesis that is consistent with what is measured and observed, there is only one hypothesis that fits the data. That's how science is supposed to work.

Today, science is about dropping critical thinking on the floor, censoring or ignoring qualified experts who disagree, and finding ways to support the mainstream political narrative.

If ivermectin has a systematic review and meta-analysis published in a peer-reviewed journal, the NIH simply ignores the recommendation. If NAC has caused no harm over 60 years, the FDA pulls it from the shelves and makes it prescription only while at the same time taking a vaccine which has killed over 200,000 people and making it available without a prescription and without warnings of just how deadly and/or disabling it is.

It's very sad how quickly the wheels have come off the science bus.

OUR TEAM OF EXPERTS

1. **Dr. Robert Malone**, widely recognized as the inventor of the mRNA vaccine. He immediately recognized the dangers of the current vaccines when the biodistribution data was revealed after a FOIA request. He was one of the first people to go on record warning the world about vaccine enhanced infection and replication.
2. **Dr. Geert Vanden Bossche**, one of the few virologists in the world to warn the world about vaccinating with a non-sterilizing vaccine against a virus capable of mutation in the middle of a pandemic.
3. **Dr. Byram Bridle,** a highly respected viral immunologist at University of Guelph, did the FOIA request that exposed the biodistribution data showing the vaccines do not stay at the injection site like people thought, but instead cause the production of a toxin in all parts of the body including the brain.
4. **Dr. Peter McCullough**, Professor of Medicine, is the author of over 1,000 peer reviewed publications, He serves as editor of two journals and sits on the editorial boards of multiple specialty journals.
5. **Dr. Ryan Cole,** one of the few pathologists who has been unafraid to speak out.
6. **Dr. Bret Weinstein** host of the DarkHorse podcast, expert in evolutionary biology.
7. **Dr. Chris Martenson,** pathologist and host of Peak Prosperity on YouTube. Chris's videos on YouTube are the most insightful videos about the virus and the vaccines.
8. **Dr. Pierre Kory** is our ivermectin expert, and one of our experts on early treatment.
9. **Dr. Paul Alexander** has expertise in the teaching of epidemiology (clinical epidemiology), evidence-based medicine, and research methodology. He is a former professor at McMaster University in evidence-based medicine; former COVID pandemic advisor to WHO-PAHO in Washington, D.C. (2020); and a former senior advisor on COVID pandemic policy at the U.S. government's Department of Health and Human Services (HHS) in Washington, D.C.
10. **Dr. Ira Bernstein**, a physician in Canada. Bernstein replicated Hoffe's D-dimer test which is extremely frightening.
11. **Dr. Jessica Rose** is an expert on the VAERS system. Her YouTube video on VAERS have never been challenged. She has a published paper on VAERS with several more on the way.
12. **Dr. Meryl Nass,** is a physician and VAERS expert.
13. **Dr. Sin Hang Lee,** an expert on DNA sequencing.
14. **Mathew Crawford**, is a mathematician and statistician who writes frequently about the pandemic including two articles on a serious CDC math error that no other person had noticed (Part I and Part II)
15. **Dr. Charles Hoffe**, is a physician in Canada.
16. **Marc Girardot**, is a member of PANDA. https://www.pandata.org/team/. PANDA is a politically and economically independent organization, focused on science-based explanations and tests them against international data. Marc has published extensively on the pandemic.

17. **Dr. George Fareed,** a physician in southern California who developed an extremely effective protocol for treating COVID-19 infections with a 99.76% risk reduction which is far more effective and safer than any vaccine
18. **Tyson Gabriel** is our mask expert. He produced this 1 hour instructional video. Nobody wants to challenge him to a debate on mask wearing.
19. **Stephanie Seneff**, senior research scientist at MIT. Although her field is computer science, she has an amazing breadth of knowledge in biology.

Attachments

Estimating the number of COVID vaccine deaths in America
This document uses VAERS to estimate the total number of excess deaths caused by the vaccines. This estimate is validated using multiple other methods.

There is also a table of elevated adverse events showing the pulmonary embolism is elevated by 473 times above baseline (typical VAERS year).

Adverse Events Reported Following COVID-19 Vaccinations
This research by Professor Josh Guetzkow is an independent confirmation of two of the factors we found in our analysis:

1. VAERS isn't being "over reported" this year as the FDA and CDC have falsely claimed due to greater "awareness" and propensity to report
2. VAERS isn't be over-reported this year due to the number of vaccinations

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 9/1/2021 2:51:36 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; 'Frantz-Bohn, Susan (Susan.Frantzbohn@fda.hhs.gov)' [Susan.Frantzbohn@fda.hhs.gov]
CC: Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]
Subject: FW: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP
Attachments: ACIP comment 8-30-21.pdf

Dear Lorrie,

See below. We may need to object to this. Or thoughts?

Best Regards,
Peter

-----Original Message-----
From: Steve Kirsch <stk@skirsch.com>
Sent: Wednesday, September 1, 2021 2:35 PM
To: Su, John (CDC) <ezu2@cdc.gov>; (b) (6)
Cc: Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6)
(b) (6)
Subject: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello,

Attached is an updated public comment I submitted at the ACIP meeting. Since you are both mentioned by name in the comment, I would like to give you an opportunity to respond before I publish this on TrialSiteNews.

To the CBER team members on the Cc: line, you should take a very close look at this. If you can find an error please let me know. If I don't hear from you, I will assume you have no objections to the methods and the conclusions.

I worked with a team of 20 scientists in putting this together... VAERS experts, statisticians, physicians, one Medical Examiner, multiple pathologists, and the inventor of the mRNA vaccine.

Thanks!

-steve

Comment to ACIP meeting of August 30, 2021 submitted by

Steve Kirsch

Executive Director of the COVID-19 Early Treatment Fund
stk@treatearly.org

September 1, 2021

NOTE:

1. This document is an updated version of the original August 29, 2021 filing.
2. If you are viewing a PDF version of this document, the most up-to-date version is here.

ABOUT ME

I am the founder of the COVID-19 Early Treatment Fund (www.treatearly.org). Our work in funding early treatments for COVID was featured on *60 Minutes*.

I have been vaccinated and my entire family has been vaccinated.

However, shortly after I was fully vaccinated, I began to hear stories from my friends that were very troubling. For example, one friend had three relatives who were formerly healthy die after getting the vaccine. Another friend had a heart attack 2 minutes after the injection and is now disabled, apparently for life.

I assembled a team of over 19 doctors and scientists listed at the end of this comment to investigate the available evidence.

OUR FINDINGS

Using the VAERS database and other official government data sources from the US and around the world (covering 35% of the world's population), we found evidence that clearly demonstrates that the current vaccines are significantly more dangerous than has been previously believed.

Our most important findings include:

1. The "real world" fatality data from VAERS does not match the fatality data from the Phase 3 trials. They aren't even close. Using multiple independent methods from independent researchers, we show that it is extremely likely that **over 150,000 Americans** have already been killed (see Attachment 2). Even with a $1M reward to academics to spot an error in the analysis, there were no takers. It is urgent to resolve

this discrepancy as soon as possible as we strongly believe that the real world data is right and the vaccines should be immediately stopped because they kill more people than they save. Even Pfizer's own 6 month study failed to show any evidence of a net mortality benefit either before or after unblinding. And all three vaccines showed they significantly increase morbidity.

2. The vaccines should be stopped immediately based on the 150,000 Americans killed alone. Arguing about myocarditis cases and morbidity tradeoffs is like re-arranging deck chairs on the Titanic. We have never had a vaccine that has killed 150,000 Americans.
3. None of the COVID vaccines reduce all-cause morbidity. It's the opposite: they all significantly increase all-cause morbidity by as much as 4.2 times baseline ($p<=0.00001$). The CDC must know this since this information is hiding in plain sight in the published literature. What is the point of offering an optional medical intervention which significantly increases all-cause morbidity when safer alternatives such as early treatment are available?
4. There is an error in the adverse event detection formula used by the CDC that appears to have prevented the CDC from seeing the safety signals that were obvious to our VAERS experts.
5. Early treatment and prophylaxis protocols are a superior option to the current vaccines on every single meaningful metric:
    a. Higher relative risk reduction (over 99%)
    b. Simple prophylaxis protocols be used to prevent infection with up to 100% success without the use of any drugs whatsoever
    c. Greater safety (minor temporary side effects, known safety profile)
    d. They lower both all-cause mortality and all-cause morbidity
    e. They work equally well on all variants
    f. They do not promote escape variants
    g. They do not cause vaccine enhanced infectivity/replication
    h. They do not cause prion diseases
    i. They prevent long-haul COVID syndrome nearly 100% of the time
    j. They enable people to acquire recovered immunity which is both 13 times stronger and more durable than vaccine-induced immunity
6. Because of all of these advantages, all early treatment methods are being deliberately sabotaged by the NIH so that people will believe that the vaccines are the only option. Even when drugs are proven in high quality large Phase 3 trials, or when there is a published peer-reviewed systematic review and meta-analysis, the NIH and medical community ignores these treatments and rates them as NEUTRAL which doctors all take as a sign to avoid.
7. Nobody of any stature in the medical world will agree to publicly debate our team on any of the issues raised in this document, even with huge financial incentives to do so. People at the NIH, FDA, and CDC refuse to comment or respond to any of the issues raised in this document. Censorship is used on all social media platforms to keep this information out of public view. Reporters who attempt to write stories find that they will not be published. Fact checkers will not reply to corrections on their fact checks. Top academic scientists who seek to challenge the narrative with peer-reviewed papers find

that the papers never make it into the journal. This is not how science is supposed to work but no one in the mainstream academic community (except for Peter Doshi of the BMJ and even he has to be very careful) is speaking out about this.

8. Experts like Geert Vanden Bossche, Dr. Robert Malone, Dr. Peter McCullough, and others have been right about these issues since they started speaking out, but they are being ignored or censored by the mainstream media.
9. It is insulting to us for the ACIP committee to ask for comments before the meeting and then vote on approving the vaccine before reading the comments. The ACIP committee is sending a very clear message to the public that any comments made will be ignored.

We recommend the committee take the following actions:

1. Require autopsies for all deaths within 4 weeks of any COVID19 vaccination so that data is available to compute an estimate of the true all-cause mortality.
2. Make available the analysis of the 11,000 deaths investigation in VAERS for public inspection. It's important for the public to understand why the CDC couldn't attribute a single death to the vaccine whereas one of the world's top pathologists ascribed at least 30% of all deaths to the vaccine.
3. Explain publicly why there is a death peak on the second day after vaccination if the vaccinations are perfectly safe and not causing deaths.
4. Explain publicly why the severe adverse side effects are dose dependent
5. Publish the proper elevated event table (see Attachment 2. Page 17)
6. Publish your analysis of the VAERS data including the propensity to report factor and the under reporting factor for fatalities or serious events. Please show us the correct analysis showing that there are no excess deaths this year as has been claimed.
7. Meet with our team as soon as possible to assess the validity of the points above.
8. Fix the adverse event signal detection system so it can at least recognize all the serious adverse events identified in Attachment 2, page 17.
9. Review the VAERS multiplier used in the myocarditis analysis. It appears to be 1. That makes absolutely no sense to us. How was that justified?
10. Recommend that vaccine mandates should not be issued without evidence of a statistically significant all-cause morbidity decrease (which there is not in this case).
11. Define a COVID vaccine stopping condition after which that vaccine should be halted until the stopping issues are addressed. In 1976, the stopping threshold was 35 deaths.
12. Ask the CDC to engage with us in a public discussion on vaccination issues so the public can hear first hand from qualified experts on both sides. This is a more effective way to combat vaccine hesitancy than censorship.

If the meetings with our team result in the validation of our assertions, then the following actions should be considered:

1. Recommend that at least three classes of people should not be vaccinated and should use early treatment if infected:
    a. Previously infected
    b. Women who are pregnant or might soon become pregnant

   c. Anyone under age 50
2. Inform the public of the complete list of elevated risks and their rates for the COVID vaccines.

THE MECHANISM OF ACTION OF THE COVID VACCINES IS DIFFERENT FROM THAT OF TRADITIONAL VACCINES

Dr. Robert Malone has described the vaccine as causing a cytotoxic spike protein to be produced throughout the body for up to 48 hours, with the potential to cause blood clots, inflammation, and permanent scarring. In addition, the spike protein (particularly the S1 segment) could break free of the cell and freely circulate, causing damage which could lead to a very wide range of pulmonary, cardiovascular, and neurological events.

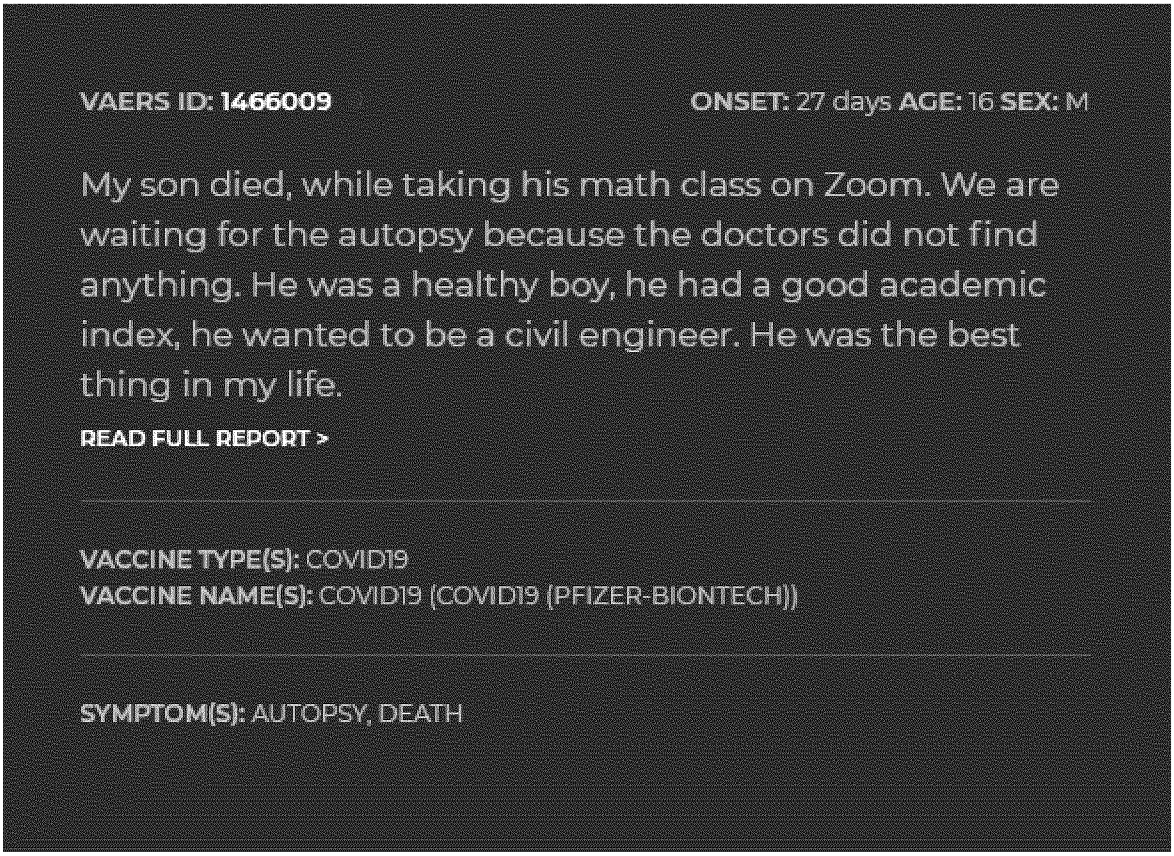
The gene-based vaccines (i.e., the 3 vaccines used in the US today) work in a completely different way than classical vaccines. With the latter, a fixed dose of killed or weakened pathogen or a toxin from the pathogen is injected and this sets a precise upper limit on how much foreign material is administered. In the former, while a fixed dose is also given, the upper limit of how much antigen is expressed depends on a series of steps each with substantial variability. This unavoidably greatly widens the range of amounts and concentrations of toxic spike protein in the body. Compounding this is the variability in anatomical distribution of the product with some body parts more prone to injury than others.

This built-in variability means that gene-based vaccines will likely always be much less safe than a classical vaccine. While the majority of people have no serious adverse events whatsoever, a significant number of people, perhaps in the millions, can be profoundly affected with one or more of a wide range of serious symptoms. Females are nearly 2.5 times as likely to be affected as males.

In particular, the VAERS data shows these symptoms include brain hemorrhages, strokes, heart attacks, multiple organ failure, pulmonary embolisms, and even sudden unexpected death.

A person can be perfectly normal and then just drop dead unexpectedly as the ACIP team already knows through their recent examination of the VAERS records of children 12-17 who died. For example, a 16 year old California student died unexpectedly in the middle of a Zoom math class. He had no prior health problems and appeared completely normal 20 minutes before his death.

If he didn't die from the vaccine, what did he die from? Can we see the autopsy report or is there a reason to keep it secret? Did the committee see the autopsy report? Did the mom ever get the autopsy report or was she denied?



There is a partial list of the elevated symptoms identified by VAERS analysis in Attachment2, page 17.

Nearly every cardiovascular and neurological event occurred at a rate that was 10X or more than would be expected to be reported in a typical year by all of the vaccines in that year.

IT IS VITALLY IMPORTANT THAT ALL PHYSICIANS BE EDUCATED ON BOTH THE MECHANISM OF ACTION OF THE VACCINE AND THE RANGE OF SYMPTOMS THAT ARE BEING CAUSED ASAP BECAUSE IT IS COMPROMISING PATIENT CARE

Today, most doctors believe the vaccines are completely safe. There is virtually no knowledge of vaccine symptoms. This causes physicians to treat these symptoms as if they are caused by something other than the vaccine which results in treatments that are ineffective since they are not treating the underlying cause.

Maddie de Garay is a perfect example of this. She will pay the price of preventable misdiagnosis for the rest of her life because physicians were never informed that the vaccines could be causal for her symptoms; the doctors treated Maddie as if symptoms were all in her head.

Angela Wulbrecht who has been a nurse for 23 years in Northern California is another example. She was misdiagnosed by the world's best experts because the CDC never disclosed to anyone that the vaccines are super dangerous and how the vaccines can disable or kill people. She

only found relief when she consulted Dr. Bruce Patterson who understood that the vaccines are deadly. She was able to get relief from her symptoms only when she was given drugs that targeted the vaccine damage.

Both of these people are public figures and are willing to speak out if you want to talk to them.

THE PROPER SAFETY TESTS WERE NEVER DONE

The FDA made the mistake of regulating the three COVID vaccines as a vaccine exclusively. As a result, the dose, duration, and amount of spike protein produced by these vaccines were never measured in advance of approval by the FDA.

Today, despite the evidence of unforeseen and unprecedented harm, these three critical parameters are still completely unknown.

Why haven't these tests been done in non-human primates with the actual vaccine?

THE D-DIMER AND CRP BIOMARKERS ARE A SMOKING GUN THAT THESE VACCINES ARE NOT SAFE

Even more concerning is that there has been no attempt to measure biomarkers that could clearly show that these vaccines are causing unexpected harm.

For example, measuring C-Reactive Protein and D-dimer of people before and after vaccination is a very simple experiment to show that the vaccines are causing problems.

Multiple researchers (contact us for the details) have done such a study in hundreds of patients and found that both biomarkers are elevated above normal levels for around three months in over 60% of patients.

This is very serious. It is a smoking gun that indicates that something is very wrong with these vaccines. For example, a 73 year-old female on her second dose had a D-dimer of 1186 ng/mL (normally it is less than 250 ng/mL) two weeks after the shot. **It remained above normal for three months.**

AN OVER-RELIANCE ON DELEGATED TRUST HAS MAGNIFIED SMALL ERRORS INTO LARGER ERRORS

We live in a world of delegated trust. But if the root of that trust makes a mistake, it creates a ripple effect where the consequences are magnified exponentially.

Our first example of amplified errors due to delegated trust is the safety signal detection of the VAERS database that John Su at the CDC has been monitoring.

The ACIP committee trusts the CDC staff to monitor VAERS. If there is a bug in the monitoring algorithm used by the CDC, the CDC will miss the critical safety signals and the ACIP committee will not be alerted. ACIP members do not have the time or expertise to analyze the VAERS data themselves, as it is not a simple task, requiring many months of dedicated effort using specialized tools. If such a critical safety signal is missed by the CDC, there are immeasurable consequences and harm to the public.

When we looked at the VAERS database, we found dozens of very serious safety signals that the CDC failed to detect.

The attached analysis (see Attachment 2, page 17) shows that every neurological and cardiovascular event that we investigated was strongly elevated as compared to previous vaccines, most by at least 10X and some by as much as 473 times higher than what is normally expected in a typical year across all vaccines. This is impossible to explain if the COVID vaccines are perfectly safe.

We just received a similar analysis from Professor Josh Guetzkow which can be viewed at Attachment 3. In Table 1, for example, death is happening at a rate 91X higher than normal. That sort of increase cannot possibly be explained by "stimulated reporting" or "more people got vaccinations." This is again independent confirmation that the explanation from the CDC and FDA does not match reality. The ACIP committee is also clueless and apparently lacks basic critical thinking skills. All the evidence is in plain sight that this is a disaster and has been in plain sight since January 2021, not just in VAERS, but to those practicing doctors, neurologists, and pathologists who were seeing a huge spike in adverse events and deaths and were willing to consider the possibility that the vaccines were not as safe as had been claimed by the CDC and FDA.

In addition, all of the neurological and cardiovascular symptoms with elevated event counts were consistent with the mechanism of action described at the start of this comment. Each and every symptom we looked at satisfies all the traditional Bradford-Hill causality criteria using both absolute rate elevation compared to baseline rates as well as Dose 1 vs. Dose 2 response disparities.

A BUG IN THE SAFETY SIGNAL ALGORITHM ALLOWS SAFETY SIGNALS TO ESCAPE DETECTION

Why was the CDC oblivious to these same signals? The answer: a bug in the algorithm used by the CDC. This bug only manifests itself when the vaccine being monitored produces a wider than normal range of side effects. This has not been the case with earlier vaccines which is why it wasn't detected earlier.

The bug in the safety signal algorithm is documented in this post: https://roundingtheearth.substack.com/p/defining-away-vaccine-safety-signals-572 (this is Part

III, which contains links to Parts I and II). We would be happy to meet with CDC staff to go over this in detail.

WHY ARE YOU IGNORING PEOPLE WHO ARE TRYING TO HELP YOU SPOT SAFETY SIGNALS?

Repeated attempts to inform any ACIP committee member of this anomaly were unsuccessful. Considering that the ACIP committee is tasked with the critical monitoring of safety in the world's single most important drug, we are puzzled by the lack of interest in receiving safety information from qualified researchers. We were directed to submit comments to a non-existent docket number.

Failing to get anyone on the ACIP committee to respond, we next attempted to communicate the signal error to the CBER group at the FDA. Not one person responded, including Dr. Steven A. Anderson and his staff, despite multiple emails and phone calls. Again, we are puzzled by the lack of interest in receiving safety information from qualified researchers. Dr. Anderson had said in a video call that he was the main person responsible for the safety monitoring.

Emails to both John Su and Anne M. Hause were also not responded to.

Perhaps the FDA and CDC should simply let people know that "**if you find an urgent safety problem, don't bother to contact us because we aren't interested in hearing what you have to say.**"

If this were more well known, it would have saved our time and yours.

MYTH BUSTED: "VAERS CANNOT BE USED TO SHOW CAUSALITY"

For the current COVID vaccines, our team is extremely confident that we can meet all the Bradford-Hill criteria for causality using VAERS analysis alone. Will our statisticians and VAERS experts be permitted to meet with any ACIP members to discuss the data?

For example, it is well established that a clear dose dependency relationship can be used to satisfy one of the Bradford-Hill criteria. Because two of the vaccines are multi-dose vaccines, a Dose 1/Dose 2 ratio analysis shows a very clear signal. Sadly, this type of analysis is currently being completely ignored by the CDC.

THE FDA HAS ASSUMED THAT VAERS WAS JUST OVER-REPORTED THIS YEAR

Our second example of amplified errors due to delegated trust is the calculation of the VAERS event counts.

A detailed analysis of the VAERS data (Attachment2 and Attachment3) both show that the FDA has made a very serious error in assuming (without any evidence whatsoever as far as we've

been able to determine) that the propensity to report to VAERS is much higher this year and that these are simply all background events that can safely be ignored. The two analyses found the same thing and were done by different people, in different countries, who never met. The results were the same.

If the propensity to report is drastically increased, then it should be easy to prove. Randomly survey 100 neurologists and ask them the number of reportable events vs. reports last year vs. this year.

YOU CAN LEARN A LOT BY TALKING TO A NEUROLOGIST

Some of the things we learned by talking to a neurologist with over 15 years of experience and a 20,000 patient practice are worth keeping in mind:

1. They can't reveal their identity publicly or they would lose their license
2. They can't speak out against the vaccine to their patients or risk loss of license
3. Patient load went up 20X during the vaccine rollout. Never saw anything like it in her career.
4. Over 2,000 patients had serious side effects from the vaccine
5. They only reported 2 to VAERS: it was too frustrating to use; it would crash every 2 minutes and you'd have to start over from scratch.
6. Only the doctor doing the injection must report to VAERS, so they don't have to, so they stopped doing it since it was so cumbersome.
7. Has always known about VAERS, but never need to use it before since never had to report an adverse event!!! This year would have reported all 2,000 patients if VAERS was easier to use. Instead, made just 2 reports (1 of 1,000)
8. Neurologists are now booked up for 3-4 months is typical. At Stanford is 6 months.
9. Most neurologists are clueless on how to treat vax events. Most neurologists don't associate the vax as the cause of the problem. Treatments are useless. When patient goes on Patterson treatment protocol, they can recover back to "normal" in 8 weeks. However, they get no medical training at all on this (because doing so would be an admission that the vaccines aren't safe) so most people who are vaccine injured remain disabled.
10. At UC Davis, 40% of staff is unvaxed. They have to wait in line twice a week and come in 2.5 hours early to get in line for COVID testing. They endure that because they've seen first hand how bad the vax reactions can be.
11. Long-term impact of the vaccination program: Increase in multiple neurological conditions.
12. For the vaccine injured, the standard blood tests (including all extended testing such as CRP, D-dimer, etc) can all show completely normal. Angela Wulbrecht was given every test under the sun and they were all normal. It was only when she took Patterson's cytokine panel and S-protein tests that showed she was clearly very sick.

FDA FALSE STATEMENT: "DEATHS CAUSED BY THE VACCINE ARE EXTREMELY RARE"

In a letter dated August 23, 2021, Janet Woodcock writes to Senator Johnson, “Reports of death after COVID-19 vaccination that are found to be related, or even possibly related, to vaccination with COVID-19 vaccines have been extremely rare.”

Where are the 249 autopsies on which that statement was made? Has the committee reviewed all 249 autopsy reports?

We were able to prove causality using the Bradford-Hill criteria from just the VAERS data alone. We didn’t need the autopsies.

It was shocking to us that the CDC and FDA couldn’t find these signals despite access to 249 autopsy reports.

There is something seriously wrong here. You cannot have a few excess deaths from the vaccine when both the VAERS database itself and the data from other countries shows that there have to be 150,000 deaths. They both cannot be right. We think the CDC is mistaken because the death data we used to compute the 150,000 deaths comes from 35% of the world’s population. This error needs to be corrected as soon as possible.

SYMPTOM CODE FOR A VACCINE DEATH

What is the SYMPTOM code for a vaccine death? We looked at all the VAERS records with autopsies and we couldn’t find a single record with a coding for a COVID VACCINE DEATH.

OUR ANALYSIS SHOWS THAT IT IS HIGHLY LIKELY THAT OVER 150,000 PREVIOUSLY HEALTHY AMERICANS HAVE BEEN KILLED BY THE COVID VACCINES IN 2021

The analysis in Attachment 2 shows that 150,000 previously healthy vaccinated Americans have had their lives cut short prematurely due to the vaccines. We confirmed this number using independent methods from independent researchers. We used both US data and data from other countries. Our analysis used data from over 35% of the world’s population.

Our results are also consistent with reports from doctors we know who report that they have lost more patients to the vaccine than to COVID. For example, one doctor with 700 patients lost 2 patients to the vaccine and no patients to COVID. These doctors are special because they are “vaccine aware” and understand the mechanisms of action. In another case, one nursing home with 132 beds lost two patients within hours after vaccination.

Unfortunately, most doctors are blind to the association between the COVID vaccines and deaths and if asked, always report 0 vaccine deaths because they believe the narrative that the vaccines are “safe and effective.” Any deaths would be anecdotes and ascribed to some other cause. For example, when the fetus of a recently vaccinated pregnant woman had a massive

brain hemorrhage, the doctor considered the event caused by a "genetic defect." The vaccine is never even considered as a possible cause.

As far as we know, not a single doctor in the US has determined that any deaths were caused by the COVID vaccines. There isn't even a column in the CDC weekly report for deaths from the COVID vaccine. Apparently, it is impossible to die from the COVID vaccines if you live in the US.

However, a methodology based on excess death analysis (as detailed in Attachment 2) and autopsy results in other countries of people who died after getting the vaccine tells a completely different story: a story of a very deadly vaccine that has likely killed over 150,000 Americans so far.

It has been enormously frustrating to us that the CDC and FDA look the other way and have ignored all our attempts to share our analysis. That is not a good safety practice to ignore qualified people who disagree with you, especially when 150,000 lives are at stake. This is not serving the public interest. Safety must be a top priority at these agencies but when there are deaths from the vaccine, people are simply looking the other way and don't want to hear it. This is why all our attempts to contact people were ignored.

If the CDC or FDA engages with us and finds an error in our analysis and can show evidence that no lives have been lost to the vaccine, then this would do wonders for reducing vaccine hesitancy. Conversely, if the CDC or FDA confirms we are correct, we can immediately stop future loss of life by aborting the vaccination campaign.

Whichever way it ends up, the clarity that happens when both sides engage in an open public discussion of the methods and evidence used will benefit all parties and the public.

THERE IS NO EVIDENCE ANYWHERE OF AN ALL-CAUSE MORBIDITY BENEFIT. WITHOUT THAT, DEPLOYING THESE VACCINES MAKES NO SENSE, ESPECIALLY SINCE SUPERIOR ALTERNATIVES ARE AVAILABLE

When a vaccine class is generating a huge number of adverse events in 8 months that are more than the events from all 70 vaccines over the past 30 years, it is reasonable to assume that there might be a significant safety problem with the vaccine.

In such a case, rather than focusing on the reduction of relative and absolute risk provided by the vaccine, it is instead more important to focus on whether there is a significant reduction in all-cause morbidity.

For the three vaccines, using data from the original clinical trials, it has been shown that in all cases, **the all-cause morbidity is significantly elevated by all the vaccines**. The elevation ranges from 1.5X to 4.2X. That is a **large move in the wrong direction.** It is **highly statistically significant** for all three vaccines. This of course is consistent with what we find in VAERS.

With respect to efficacy, nobody argues that the vaccines have saved people from dying from COVID. But the problem is that this benefit comes at a steep cost: an increase in death from other causes that completely negates the benefit of the reduction in COVID-related deaths.

But could an all-cause mortality benefit compensate for the higher all-cause morbidity? Our best data on that is the Pfizer 6-month study. A 50% reduction in COVID deaths was more than offset by a four times higher rate of cardiac arrest. As a result, the all cause mortality rate was higher in the treatment group than in the placebo group. This was true in **both** the pre-unblinding and post-unblinding phases. **The numbers were small but the point is that there is no demonstrable all-cause mortality benefit. Zero. If anything it was the other way around.**

As evidenced by the high number of reported deaths to the VAERS system, it is the all-cause morbidity statistic that is the new elephant in the room. If you can't show a lower all-cause morbidity, there is no reason to vaccinate.

We also have troubling anecdotes like the Sunnycrest nursing home in Ontario, Canada with 136 beds where all the residents were given the booster and 4 of them are dead and 7 hospitalized. **This is a 3% death rate from the vaccine that we'd guess is pretty common everywhere but nobody will talk**. We only found out about this through an insider. The media never covers this because they don't want to panic the public reporting on an anecdote that would dissuade people from taking the safe and effective vaccine.

Or the Hawaii nursing homes with 32 vaccine deaths vs. 16 COVID deaths. If it wasn't for one whistleblower, Abrien Aguirre, we'd never have known this because **all the nursing homes keep all this information secret so the public never knows about it**. Each nursing home thinks they are simply an unfortunate anecdote, where the reality is that their numbers are normal for this vaccine. If you try to call the homes directly, they won't talk. **So nobody ever finds out.**

What makes those two anecdotes interesting is that the reporters understand how the vaccines kill. **Most other nursing homes don't make the connection and will tell you that no one has died from the vaccine**. Since the vaccine can kill you over a 3 month period, they simply assume that the patient died from natural causes (like a massive heart attack or just "died") and it just "happened" that a lot of deaths coincidentally happened around vaccination time, but nobody is doing the statistical calculation. And since most nursing homes are small, a 3% death rate looks like "natural causes."

The Hawaii data, if confirmed, shows that the vaccines caused twice as many deaths as could have possibly been prevented even with a perfect vaccine.

Was he lying? What was his motivation? Aguirre basically put all his income on the line. For what? His reward: Aguirre was fired for telling the truth. This is exactly why people at nursing homes will not say anything. There is only punishment if you tell the truth. This is why the Sunnycrest whistleblower isn't identifying himself/herself.

The nursing homes aren't talking about the correct data. Why wouldn't they correct the data if it is wrong.

For the three vaccines, using data from the original clinical trials, it has been shown in the peer-reviewed literature that in all cases, the all-cause morbidity is significantly elevated. The elevation ranges from 1.5X to 4.2X. That is a large move in the wrong direction. It is highly statistically significant for all three vaccines. This of course is consistent with what we find in VAERS.

NOBODY WANTS TO TALK ON THE RECORD FOR FEAR OF LOSING THEIR JOB

One of my vaccine injured friends said the head anaesthesiologist at one of the world's top medical schools said "he wasn't willing to put it in writing" that it was caused by the vaccine because it would affect his reputation. However, his medical assistant was willing to put it in writing and sacrifice her career. My friend was told his symptoms would get worse over time. He's 39 years old and his life was ruined by the vaccine and nobody wants to end their career to speak out.

One of the top neurologists in my area (over 20,000 patients) won't talk publicly.

I talked to a medical examiner who didn't even feel comfortable sharing her name with me, but revealed autopsies are useless.

Basically everyone who could talk won't. They can't speak out publicly or they will lose their license.

They could speak to a reporter and talk without their names being disclosed, but no mainstream media would run the story, so there is no point. Reporters at top newspapers cannot get their stories run. *60 Minutes* won't touch the story either.

MEDICAL EXAMINER SAYS AUTOPSIES ARE USELESS, VAERS IS THE GOLD STANDARD FOR CAUSALITY

We were only able to find one medical examiner who would talk to us. Even then, she wouldn't reveal her last name or state.

Here are the key points:

- She is the only ME in her state looking at vaccine-related deaths. The other ME's all assume the vaccines are safe so never will implicate the vaccine.
- The ME's in general don't have the skills, they don't have the proper tests to determine causality for deaths caused by this vaccine (they don't exist in the post-mortem setting), they don't have the time, they don't have the medical records, and they get the body too late. They can see large blood clots of course
- THEY CAN'T EVEN ORDER A D-DIMER because they are told "well that's not generally done" so unless they fight for it, they simply give up.
- They even get a huge push back when asking for the medical records.
- Often, they don't even know the vax status or when the patient was vaccinated.
- She had to personally make a call to the family to determine whether a patient got vaccinated.
- THIS IS WHY the ME's cannot make the connection in the autopsy setting.
- She trusts VAERS way more than autopsy....says **NOBODY** is going to find this post-mortem
- She never had time to report any of her deaths in VAERS.... the ME's are overloaded with some cases from 6 months ago still not completed.
- She was operating today on 3 hours sleep. They are understaffed and overworked. It's exhausting.
- For vax deaths, she said autopsies are NOT the gold standard. It is VAERS.

CALCULATION OF REDUCED LIFESPAN

It is difficult to make a tradeoff between the elevated morbidity that reduces lifespan and the number of COVID deaths saved.

The COVID vaccines introduce both morbidity and mortality risks.

What ACIP has done is compare morbidity due to the vaccine vs. the same morbidity from COVID. That can be problematic if some some morbidities are improved and some are made worse. We'd have to look at all morbidities, something that ACIP hasn't done since they haven't seen the safety signals.

We believe that if we just look at the increased mortality due to the 1) direct deaths caused by the vaccine and 2) the reduction in total lifespan from all serious adverse events elevated by the vaccine, it would be clear that there is no mortality benefit.

We can see that from the Pfizer Phase 3 6 month study where more people in the treatment group died both pre- and post-unblinding. The Hawaii nursing home data is consistent: there was a 2:1 vaccine caused death:max possible vaccine saved death ratio which also supports stopping the vaccine.

Therefore, it seems likely to us that not only is there no morbidity benefit from the vaccines, but there is no all-cause mortality benefit from the vaccines either.

This makes the vaccines very hard to justify.

If we are wrong, we'd like to see the analysis.

WE ESTIMATE THAT APPROXIMATELY 574 KIDS HAVE BEEN KILLED BY THE VACCINE SO FAR; THAT'S MORE THAN HAVE DIED FROM COVID. WE ARE MAKING A HUGE MISTAKE. WE ARE KILLING OUR KIDS, NOT SAVING THEM.

The ACIP committee recently analyzed the cause of death of the 14 kids (aged 12 to 17) whose fatalities were recorded in the VAERS system. Had they had the table in the attached document, they would have realized that in every case (where there was sufficient symptom detail), the main cause of death was consistent with a symptom that was strongly elevated by the COVID19 vaccines. This should have led to a different outcome Mortality Among Teenagers Aged 12-19 Years: United States, 1999-2006 than simply listing the causes of death of the kids with no further discussion. No concern over the lack of autopsies was noted in the meeting notes. It is very likely that none of the kids had an autopsy done. There was no mention of this in the report.

We believe the lack of autopsies is a huge oversight for a vaccine that is generating so many legitimate adverse events. We believe it is imperative for the ACIP committee to immediately demand that autopsies be done. How many more kids must die before we look to find the real cause of death?

These children are dead now and their lives can never be recovered. But we can learn from their death if the ACIP committee members would simply read the 14 VAERS reports on each child and compare the cause of death with the symptoms listed in the table in the attached paper.

Five kids dying from cardiac arrest is not normal. Kids between 12 and 17 are twice as likely to die from cancer (6%) as from heart disease (3%). In this case, 38% died from heart disease and 0% died from cancer. That's statistically very unlikely. It points to the undeniable fact that these kids did not die of natural causes. Therefore, the hypothesis that the vaccines are safe seems highly unlikely. How does the ACIP panel explain this?

One of the children died with an intracranial hemorrhage. How could that have not raised a huge red flag. Kids that age never die from an intracranial hemorrhage.

We did a search in VAERS searching every record, over 70 vaccines over the last 30 years. There were only two deaths of kids aged 12-17 with "HAEMORRHAGE INTRACRANIAL" in the history of VAERS and both were associated with the recently approved Pfizer vaccine. There

weren't any deaths caused by an intracranial hemorrhage in the entire history of VAERS in that age range until the COVID vaccines arrived on the scene. One event could be written off as a fluke--- very bad luck. But two events are a complete train wreck. How this didn't raise any red flags in the ACIP committee is a mystery to us.

As this note is being written the BBC News just reported that BBC presenter Lisa Shaw died of a brain haemorrhage. The coroner determined the cause was the COVID vaccine. All of the causal factors in her death were consistent with the elevated symptoms we found in VAERS. Note that the Astra-Zeneca vaccine has a nearly identical mechanism of action as the mRNA vaccines.

Each of the 14 children who died in the CDC study represents 41*14=574 real deaths (as noted in the attached paper). Thus, more American kids have already been killed by the COVID vaccines than have been killed in the entire history of COVID to date (361). That's tragic.

Two of the kids died from a pulmonary embolism, a symptom that is very strongly caused by the vaccines. Over 5 years in VAERS, you'll find just one PE death in that age range. So to get one PE death in a year, that's bad luck. To get two, you have to at least say that it's more likely than not that it wasn't just random. Yet the CDC report dismissed it without comment.

AN ACCURATE MYOCARDITIS COST-BENEFIT ANALYSIS IS MISSING

The CDC myocarditis cost-benefit analysis omitted the determination of the VAERS under-reporting factor for "mild" events.

While we think myocarditis is a serious event, the CDC characterizes these events as "mild" and thus would be less likely to be reported than something "severe" like death.

Therefore, we'd estimate that the VAERS under-reporting of such an event might be somewhere around a factor of 100.

My question to the panel is whether **a 100 times greater rate than the rate reported in the report would make a difference in the recommendation of the ACIP panel?** We would be very surprised if this doesn't change the recommendation.

Also, as a sanity check on our results, please refer to Table 1 in Attachment3 which is Joshua Guetzkow's analysis showing a 91-fold increase over baseline myocarditis rates.

Also, it would be good to estimate the effect of this heart damage **(and all other conditions elevated by the vaccines)** on expected lifespan so it is clear that the shortened lifespan is worth the savings in the amount of deaths. This way, we can do a pure mortality tradeoff.

For a lot of AEs, the quality adjusted life years (QALYs) is not significant. For young people, myocarditis represents an enormous QALY calculation. This will include some deaths, but most of a lifetime of a large range of reduction of life value.

For public health officials to discard the data without acknowledging something like a QALY comparison (and the deaths) is inappropriate.

TRUSTING THE PHASE 3 TRIAL RESULTS AS THE "GOLD STANDARD" IS NOT A GOOD IDEA

When there is a disagreement between real-world results and the Phase 3 clinical trial, we think it is better to trust reality. Here are some of our reasons:

1. The paralysis of Maddie de Garay was not reported in the Pfizer 12-15 year old clinical trial, and the FDA failed to investigate this case even though they knew about it. This is serious misconduct happening and nobody is holding the FDA accountable.
2. Adverse events were difficult to impossible to report (and Facebook conveniently removed the evidence of people complaining about that)
3. At least one death that happened didn't show up. Who knows how many more?
4. The cohorts were not representative of the population as a whole (they were much healthier, e.g., rate of heart attacks was 10X lower than the overall population rate)
5. Five times as many people were disqualified from the treatment arm (311) compared to the control arm (61) for protocol violations even though the trial was supposed to be double blind.
6. Read this article on the Pfizer consent form. The consent form allows for participants who need emergency care and go straight to their doctor or hospital to be ejected from the study. But that's hardly the only problem.
7. Pfizer paid one of the largest criminal fines ever imposed on a drug company for the arthritis drug Bextra.
8. The company can't seem to find any safety signals even though it is obvious in VAERS.
9. **No autopsies to determine cause of death done in the treatment group**. This was a **very serious** oversight in our opinion.
10. The death rates make no sense. We know of a 132 bed nursing home that had 2 deaths within hours of getting the vaccine. And a larger nursing home in Hawaii with over 500 beds had 32 deaths after vaccination. The numbers don't match each other, but they are nowhere close to what was reported in the clinical trials which again suggests the cohorts were not representative of the population or that the company didn't find the deaths or both.

THE LACK OF AUTOPSIES IS INEXPLICABLE

Autopsies are the gold standard for determining causality.

How can the CDC say confidently that there have only been a few deaths? May we see the 249 autopsies? If not, why not?

In Germany, soon after the vaccines rolled out and deaths after vaccination started happening, the Federal Association of German Pathologists called upon the German authorities to require autopsies to validate the cause. Their requests were ignored presumably because nobody wants to know the answer.

In America, few people are asking for autopsies. And when they do, they are being denied

If we had the autopsies available, we wouldn't have to debate whether we are right or wrong about the numbers of deaths -- we'd have the data.

The Norwegian Medicines Agency linked 13 deaths to vaccine side effects. At the time that article was published, there were only 13 assessments completed. So in 100% of the cases, the deaths were deemed to be caused by the vaccine by the official government agency.

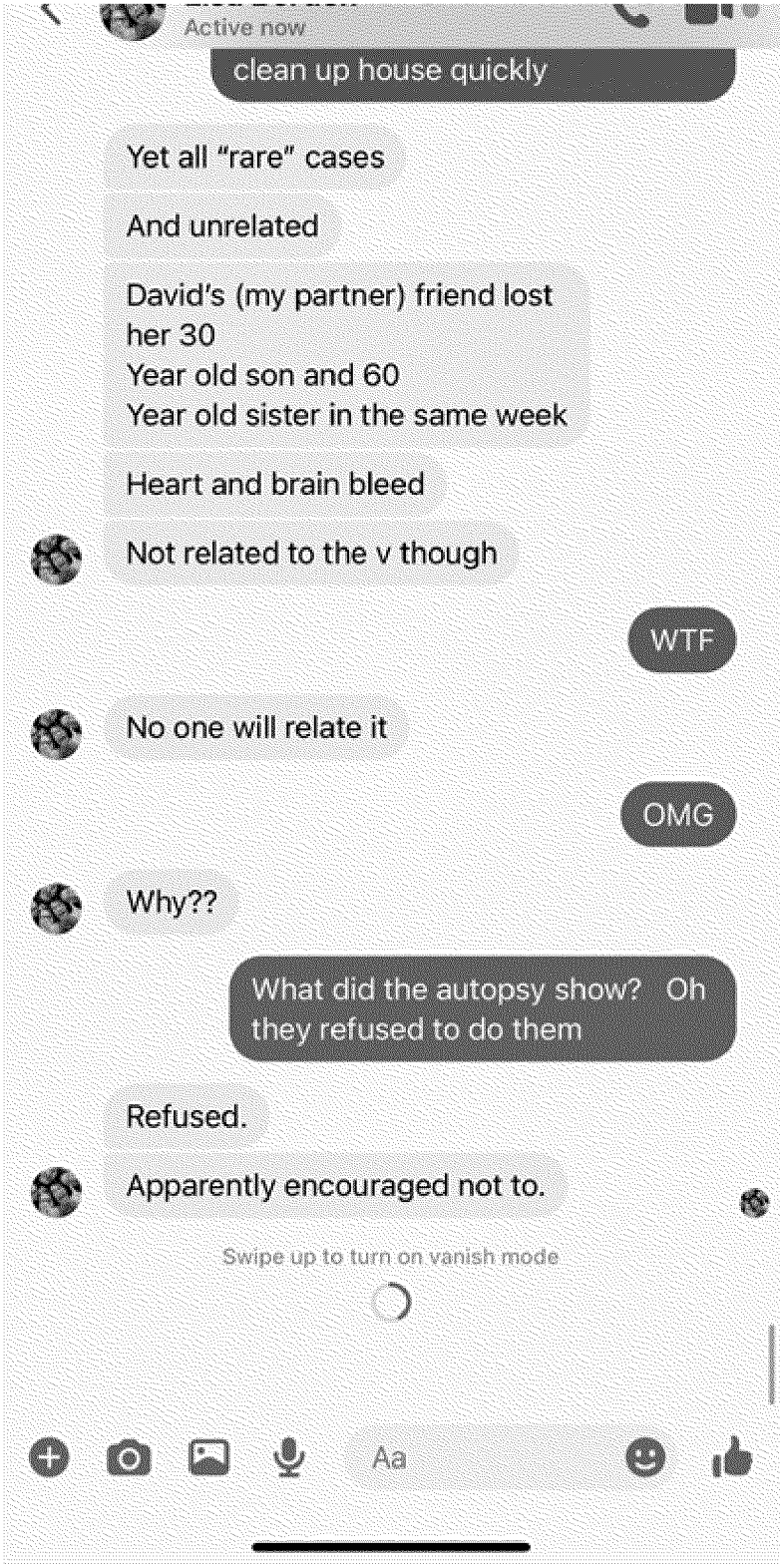
In Germany, they actually did autopsies of 40 people who died within 2 weeks after vaccination. They determined that at least 30% to 40% really did die from the vaccine. From Media Blackout: Renowned German Pathologist's Vaccine Autopsy Data is Shocking... and Being Censored:

> Dr. Peter Schirmacher is not just an average pathologist. The German doctor is world-renowned in his field, honored by The Pathologist as one of the 100 most influential in the world. He is the acting chairman of the German Society of Pathology, director of the Institute of Pathology at Heidelberg University Hospital, and president of the German Association for the Study of the Liver. Bottom line, this professor and doctor understands pathology like very few on the planet.

It is puzzling to us that nobody on the ACIP committee is calling for mandatory autopsies. Only 249 have been done on the 11,000 people who have died. It would be nice to know what they said.

Does ACIP think we should not have autopsies? I think it is important to clarify the committee's opinion on whether we should have the data on why people are dying after the vaccine or whether ACIP would rather have coroners look the other way.

Right now, it seems to be difficult to have an autopsy done, so if you want to gather the data, I think it is important to say something rather than remain silent on this issue.



IT IS BECOMING CLEAR THAT THE VACCINES ARE RAPIDLY BECOMING LESS EFFECTIVE

As far as effectiveness, we believe the recent paper from a team of Japanese researchers, "The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines" shows that the vaccines we received will soon become completely useless to protect us and, to make matters worse, are already enhancing the ability of current variants to infect us through **vaccine enhanced infection and/or replication** (rather than "classical ADE" which so far appears not to be happening).

From the abstract:

> Although Pfizer-BioNTech BNT162b2-immune sera neutralized the Delta variant, when four common mutations were introduced into the receptor binding domain (RBD) of the Delta variant (Delta 4+), some BNT162b2-immune sera lost neutralizing activity and **enhanced the infectivity.**

In short, even if the vaccine were perfectly safe and killed no one, vaccinating with a non-sterilizing vaccine in the middle of a pandemic is going to have a net negative benefit, exactly as Geert Vanden Bossche has been trying to tell the world since shortly after the vaccination program began. He called it a very serious mistake. Nobody in power listened.

The latest UK government data (Briefing #20), shows you are 57% more likely to die if you get delta and you are vaccinated than if you are unvaccinated. The computation for age<50 and fully vaxed vs. unvaxed is 13/48*147612/25536=1.57 which is consistent with the Japanese paper.

Therefore, not only are the vaccines not safe, but they are quickly becoming useless and may shortly be a liability as far as effectiveness is concerned.

EARLY TREATMENTS HAVE ALWAYS BEEN THE SAFER, MORE EFFECTIVE OPTION

Meanwhile, early treatments have been virtually ignored by mainstream academia and the NIH. Lack of suitable guidance from the NIH has caused the entire world to avoid early treatments. These treatments are both extremely safe and very effective. They work against all variants as well. For example, the protocols used by George Fareed and Bryan Tyson against COVID continue to work well against COVID and with over 6,000 patients treated in an area with one of the highest CFRs in the country, it is very rare for a patient to be hospitalized for COVID in their clinic; it only happens if the patient presents late. They have more than a 99% relative risk reduction against all COVID variants if the patients get treated early. The NIH has expressed no interest in trying to replicate this success despite the tremendous lifesaving potential and negligible risk. They are more interested in waiting for a new, unproven drug from Merck for treatment.

EARLY TREATMENTS HAVE BEEN CENSORED. NOBODY IN MEDICINE SEEMS TO MIND.

One of the earliest pioneers of early treatment, George Fareed, is banned for life from YouTube for trying to spread life-saving treatment protocols that work..

The Nobel Prize winning inventor of ivermectin, Dr. Satoshi Omura, had his video on ivermectin for COVID blocked on YouTube.

Ivermectin has a peer-reviewed systematic review and meta-analysis, the highest level of evidence in evidence based medicine.

We find it troubling that so few in the medical community are speaking out about such abuses.

These individuals are giving life-saving advice and have been censored and there are dozens of examples of many others that have been censored, banned for life, and/or demonetized.

It would be interesting to hear the ACIP members speak out on this subject, either endorsing the censorship or condemning it. Remaining silent on such an important issue will not help advance science and save lives. Normally, ACIP shouldn't have to do this, but everyone else is remaining silent.

THE UK SAID THE VACCINE IS NOT RECOMMENDED FOR THOSE < 18 YEARS OLD

The UK panel said the data doesn't justify vaccination of those under 18

Jul 19: UK opts not to vaccinate most under 18 against COVID-19

Then they changed their minds just 2 weeks later:

Aug 4: UK to roll out COVID-19 vaccines to 16 and 17-year-olds

Did the science really change that quickly? What new things were learned? Or is science being driven by politics which would be a new low point. If there was new science, it would be useful for everyone to know what it was.

16% NEVER CAME BACK FOR A SECOND SHOT. WHY?

62% of Americans are vaccinated vs. 52% who are fully vaccinated. So that's 16% (52/62=.84) that never came back for a second shot

Why is there such a large gap when in order to do anything (like keep your job, go to school, etc) you need to be fully vaccinated?

We understand why people don't get vaccinated at all (they are well informed). But what's the reason for the 16% gap?

We know from user surveys that 3% of people who took the vaccine required treatment by a doctor. And 5% are still suffering from side effects. So that explains half of the gap. Basically 8% of people who got the vaccine had a large enough bad first experience, they aren't going back for a second shot. This leaves 8% unexplained, but likely due to a bad first reaction.

We think that 12M injured Americans is a lot of people especially in light of the lack of an all cause mortality benefit and a clear lack of all-cause morbidity benefit. That's a lot of people who have been injured for no proven net benefit (yes, COVID lives were saved, but it was an overall cost of lives). But that's just our opinion.

SUMMARY

Analysis of multiple researchers using different sources confirms that the current COVID vaccines are very dangerous and are significantly increasing all-cause morbidity. The vaccines can trigger a wide range of serious neurological and cardiovascular symptoms, re-activate latent viruses, trigger flare-ups in people with cancer, and more. Multiple studies show 60% of patients have elevated D-dimers that persist for 3 months after vaccination. These vaccines should be immediately halted. If they cannot be halted, then it is imperative that we inform the American public of the risks. Children, pregnant women, and previously infected people should be instructed to avoid vaccination. All vaccine mandates should end immediately until there is scientific proof of an all-cause morbidity benefit.

Early treatment has always been a superior strategy for treating COVID: it is safer, more effective, and has a number of other important benefits.

Virtually none of the people diagnosed with COVID in the hospital today were treated early. That is the message we should be sending to America.

A FINAL NOTE OF ACIP COMMITTEE WAS 14-0 IN FAVOR OF APPROVAL

They said they are there to protect the health of the public.

As far as we can tell, no member of the ACIP committee read this note or any of the other public comments submitted prior to the vote. So this comment didn't matter. The public comments portal is just to placate the public.

There was no mention of early treatment as an alternative to vaccination.

This suggests to us that the committee is not interested in hearing from qualified people who disagree.

The data they presented was just one side of the story.

I loved how the slides showing bad data were left on the screen for like 2 seconds. And when the rate of severe adverse events was 10% vs. 2% for placebo, they just didn't discuss that at all!

My favorite was Dr. Lee's presentation (VaST). Look at slide 18. It showed that the vaccines reduce your risk for pulmonary embolisms. Which is very interesting because our VAERS analysis showed the PE rates were off the charts.

First of all two of the 14 kids (12-17 year old) died from PE. That can't happen. How do they explain that? But our chart showed PE rates were elevated by 473 times. It was the most extreme event we saw in VAERS that was elevated. So this is a stunning divergence of reality vs. data presented to ACIP. This is an objective example of how the data that they used to make the recommendation diverges from VAERS and nobody was interested in resolving the inconsistency.

From OpenVAERS, we got 5164 events so 1411 events per million with 41X underreporting. The normal rate of PE is 0.39 per million. So this is an elevation of **3,617X from normal** if we compare with the baseline incidence rate. And it is likely more than that since 41X is likely a lower-bound on the reporting rate factor.

But our opinions don't matter.

Science is supposed to matter though. The science says only one hypothesis fits the facts: the vax is safe or it isn't.

Here's a table pulmonary embolism to help you decide:

	Safe	Not safe
Mechanism of action	x	✔
VAERS data is elevated by 473	x	✔
VAERS data is 3,617 above normal	x	✔
2 of the 14 kids died from PE	x	✔

The point is that if you look for the hypothesis that is consistent with what is measured and observed, there is only one hypothesis that fits the data. That's how science is supposed to work.

Today, science is about dropping critical thinking on the floor, censoring or ignoring qualified experts who disagree, and finding ways to support the mainstream political narrative.

If ivermectin has a systematic review and meta-analysis published in a peer-reviewed journal, the NIH simply ignores the recommendation. If NAC has caused no harm over 60 years, the FDA pulls it from the shelves and makes it prescription only while at the same time taking a vaccine which has killed over 200,000 people and making it available without a prescription and without warnings of just how deadly and/or disabling it is.

It's very sad how quickly the wheels have come off the science bus.

OUR TEAM OF EXPERTS

1. **Dr. Robert Malone**, widely recognized as the inventor of the mRNA vaccine. He immediately recognized the dangers of the current vaccines when the biodistribution data was revealed after a FOIA request. He was one of the first people to go on record warning the world about vaccine enhanced infection and replication.
2. **Dr. Geert Vanden Bossche**, one of the few virologists in the world to warn the world about vaccinating with a non-sterilizing vaccine against a virus capable of mutation in the middle of a pandemic.
3. **Dr. Byram Bridle,** a highly respected viral immunologist at University of Guelph, did the FOIA request that exposed the biodistribution data showing the vaccines do not stay at the injection site like people thought, but instead cause the production of a toxin in all parts of the body including the brain.
4. **Dr. Peter McCullough**, Professor of Medicine, is the author of over 1,000 peer reviewed publications, He serves as editor of two journals and sits on the editorial boards of multiple specialty journals.
5. **Dr. Ryan Cole,** one of the few pathologists who has been unafraid to speak out.
6. **Dr. Bret Weinstein** host of the DarkHorse podcast, expert in evolutionary biology.
7. **Dr. Chris Martenson,** pathologist and host of Peak Prosperity on YouTube. Chris's videos on YouTube are the most insightful videos about the virus and the vaccines.
8. **Dr. Pierre Kory** is our ivermectin expert, and one of our experts on early treatment.
9. **Dr. Paul Alexander** has expertise in the teaching of epidemiology (clinical epidemiology), evidence-based medicine, and research methodology. He is a former professor at McMaster University in evidence-based medicine; former COVID pandemic advisor to WHO-PAHO in Washington, D.C. (2020); and a former senior advisor on COVID pandemic policy at the U.S. government's Department of Health and Human Services (HHS) in Washington, D.C.
10. **Dr. Ira Bernstein**, a physician in Canada. Bernstein replicated Hoffe's D-dimer test which is extremely frightening.
11. **Dr. Jessica Rose** is an expert on the VAERS system. Her YouTube video on VAERS have never been challenged. She has a published paper on VAERS with several more on the way.
12. **Dr. Meryl Nass,** is a physician and VAERS expert.
13. **Dr. Sin Hang Lee,** an expert on DNA sequencing.
14. **Mathew Crawford**, is a mathematician and statistician who writes frequently about the pandemic including two articles on a serious CDC math error that no other person had noticed (Part I and Part II)
15. **Dr. Charles Hoffe**, is a physician in Canada.
16. **Marc Girardot**, is a member of PANDA. https://www.pandata.org/team/. PANDA is a politically and economically independent organization, focused on science-based explanations and tests them against international data. Marc has published extensively on the pandemic.

17. **Dr. George Fareed,** a physician in southern California who developed an extremely effective protocol for treating COVID-19 infections with a 99.76% risk reduction which is far more effective and safer than any vaccine
18. **Tyson Gabriel** is our mask expert. He produced this 1 hour instructional video. Nobody wants to challenge him to a debate on mask wearing.
19. **Stephanie Seneff**, senior research scientist at MIT. Although her field is computer science, she has an amazing breadth of knowledge in biology.

Attachments

Estimating the number of COVID vaccine deaths in America
This document uses VAERS to estimate the total number of excess deaths caused by the vaccines. This estimate is validated using multiple other methods.

There is also a table of elevated adverse events showing the pulmonary embolism is elevated by 473 times above baseline (typical VAERS year).

Adverse Events Reported Following COVID-19 Vaccinations
This research by Professor Josh Guetzkow is an independent confirmation of two of the factors we found in our analysis:

1. VAERS isn't being "over reported" this year as the FDA and CDC have falsely claimed due to greater "awareness" and propensity to report
2. VAERS isn't be over-reported this year due to the number of vaccinations

From: Steve Kirsch [stk@skirsch.com]
Sent: 9/2/2021 5:43:02 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
CC: Su, John (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4241352c8141e8a2760a441cf9182b-HHS-ezu2-cd]; (b) (6) Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Scott, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91620658ce0243e38241d198be1a5461-ScottJ]; Walderhaug, Mark O [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14515448efee47098c38798d5c409b02-MWALDERH]; (b) (6)
Subject: RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP
Attachments: ACIP comment 8-30-21.pdf

Lorrie,

Updated PDF including your comments, as promised. Waiting to hear back from you on my request to meet. Please either point out specific errors, or supply your own excess death analysis of the VAERS data and we will provide a critique.

-steve

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Thursday, September 2, 2021 1:27 PM
To: Steve Kirsch <stk@skirsch.com>
Cc: Su, John (CDC) <ezu2@cdc.gov>; (b) (6) Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6) (b) (6)
Subject: RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

Dear Mr. Kirsch,

While your email was not directly addressed to FDA, we would like to note that we do not agree with the analysis put forth in your comment, as we believe the data from VAERS that you reference were not properly interpreted. This is due to the limitations of VAERS itself, as well as limitations regarding certain private patient information that is not available to individuals outside of the FDA and CDC, as we noted in our correspondence to you dated July 27, 2021.

FDA and CDC have multiple systems in place to monitor the safety of COVID-19 vaccines, including VAERS. We continue to find that the COVID-19 vaccines have a favorable benefit-risk profile, supporting their use under Emergency Use Authorization. Additionally, FDA's approval last week of Comirnaty (COVID-19 Vaccine, mRNA) followed a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

Sincerely,

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

-----Original Message-----
From: Steve Kirsch <stk@skirsch.com>
Sent: Wednesday, September 1, 2021 2:35 PM
To: Su, John (CDC) <ezu2@cdc.gov>; (b) (6)
Cc: Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6)
(b) (6)
Subject: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello,

Attached is an updated public comment I submitted at the ACIP meeting. Since you are both mentioned by name in the comment, I would like to give you an opportunity to respond before I publish this on TrialSiteNews.

To the CBER team members on the Cc: line, you should take a very close look at this. If you can find an error please let me know. If I don't hear from you, I will assume you have no objections to the methods and the conclusions.

I worked with a team of 20 scientists in putting this together... VAERS experts, statisticians, physicians, one Medical Examiner, multiple pathologists, and the inventor of the mRNA vaccine.

Thanks!

-steve

Comment to ACIP meeting of August 30, 2021 submitted by

Steve Kirsch

Executive Director of the COVID-19 Early Treatment Fund
stk@treatearly.org

September 1, 2021

NOTE:

1. This document is an updated version of the original August 29, 2021 US Government filing.
2. If you are viewing a PDF version of this document, the most up-to-date version is here.

ABOUT ME

I am the founder of the COVID-19 Early Treatment Fund (www.treatearly.org). Our work in funding early treatments for COVID was featured on *60 Minutes*.

I am not anti-vax. I have been vaccinated and my entire family has been fully vaccinated.

I am against unsafe drugs, **especially ones that disable or kill my friends**.

Starting on May 9, 2021, I began to hear stories from my friends that were very troubling. For example, one friend had three relatives who were formerly healthy all die within days after getting the vaccine. Another friend had a heart attack 2 minutes after the injection and is now disabled, apparently for life. He's 39 and has been told by his neurologist that the pain will get worse and worse every year. On a scale of 1 to 10, he's a 10 every minute he's awake. His life is ruined, likely forever, according to his doctors. That's after just one shot.

I assembled a team of 20 doctors and scientists listed at the end of this comment to investigate the available evidence. The more we learned, the more concerned we got. When we tried to voice our concerns publicly, we were intimidated, censored, or ignored.

Nobody has responded with any evidence that addresses what we found and shows that we got it wrong.

Even more troubling is that nobody from the CDC or FDA would even respond to our repeated requests by email and phone to look at our analysis. **They didn't even want to see it.**

OUR FINDINGS

Using the VAERS database and other official government data sources from the US and around the world (covering 35% of the world's population), we found that the current vaccines are significantly more dangerous than has been previously believed.

Our most important findings include:

1. The "real world" fatality data from VAERS does not match the fatality data from the Phase 3 trials. They aren't even close. Using multiple independent methods from independent researchers, we show that it is likely that **over 150,000 Americans** have already been killed (see Attachment 2). Even with a $1M reward to academics to spot an error in our analysis, there were no takers. It is urgent to resolve this discrepancy as soon as possible as we strongly believe that the real world data is right and the vaccines kill more people than they save. Even Pfizer's own 6 month study failed to show any evidence of a net mortality benefit either before or after unblinding (at the end, 20 people who got the vaccine died vs. 14 people who got the placebo). And all three vaccines showed they significantly increase morbidity (highly statistically significant for all vaccines).
2. **The vaccines should be stopped immediately** based on the 150,000 Americans killed alone. Arguing about myocarditis cases and morbidity trade offs like they do at the ACIP meeting is like rearranging deck chairs on the Titanic. We have never had a vaccine in recent history that has killed 150,000 Americans. The H1N1 vaccine was stopped in 1976 after killing around 32 people. Today, we ignore all these deaths, writing them all off to "bad luck."
3. None of the COVID vaccines reduce all-cause morbidity. It's the opposite: they all significantly increase all-cause morbidity by as much as 4.2 times baseline ($p<=0.00001$). The CDC must know this since this information is hiding in plain sight in the published literature. What is the point of offering an optional medical intervention which significantly increases all-cause morbidity when safer alternatives such as early treatment are available?
4. There is an error in the adverse event detection formula used by the CDC that appears to have prevented the CDC from seeing the safety signals that were obvious to our VAERS experts.
5. Early treatment and prophylaxis protocols are a superior option to the current vaccines on every single meaningful metric:
    a. Higher relative risk reduction (over 99%)
    b. Simple prophylaxis protocols be used to prevent infection with up to 100% success without the use of any drugs whatsoever
    c. Greater safety (minor temporary side effects, known safety profile)
    d. They lower both all-cause mortality and all-cause morbidity
    e. They work equally well on all variants
    f. They do not promote escape variants
    g. They do not cause vaccine enhanced infectivity/replication
    h. They do not cause prion diseases

i. They prevent long-haul COVID syndrome nearly 100% of the time
j. They enable people to acquire recovered immunity which is both 13 times stronger and more durable than vaccine-induced immunity

6. Because of all of these advantages, **all early treatment methods are being deliberately sabotaged by the FDA and NIH** so that people will believe that the vaccines are the only option. Even when drugs are proven in high quality large Phase 3 trials (fluvoxamine), or when there are multiple systematic reviews showing ivermectin is an effective early treatment for COVID (Lawrie ivermectin systematic review showing 62% reduced mortality and Zein ivermectin systematic review showing 61% reduced mortality), the NIH and medical community ignores these treatments and rates them as NEUTRAL which doctors all take as a sign to avoid. Most pharmacies will not fill ivermectin prescriptions anymore (**they did this AFTER both ivermectin systematic reviews were published which is a new low for evidence-based medicine**). Some pharmacies will report physicians to the medical boards who prescribe ivermectin. You can get ivermectin on Amazon, but the wait is months. Amazon conveniently puts a notice on the web page that The FDA advises against the use of ivermectin to treat or prevent COVID-19 but does not inform consumers of the peer-reviewed systematic review and meta-analysis. The ACTIV-6 trial deliberately underdoses ivermectin so it will fail to have an effect so they can "prove" to the world they were right. This is a waste of taxpayer money because everyone will concede that the trial they are running will fail. Watch this CNN video where Dr. Lena Wen conveniently references the systematic review that she claims "proves" ivermectin does nothing (it limited the studies it looked at and found that ivermectin reduced mortality by 60%, not 0%) and she claims that one of the safest drugs ever invented is risky, and she conveniently ignores the higher quality systematic review that shows that ivermectin works (that one gets no mention). The FDA made NAC available by prescription after it was proven to work for COVID even though there have never been any deaths from NAC in 60 years and it is incorporated into 1,100 different products all of which had to be reformulated. What was the reason for that? They pull a drug that kills no one, and approve a vaccine that kills 2 people for every 1 it saves and make it available without a prescription.
7. **Nobody of any stature in the medical world will agree to publicly debate** our team on any of the issues raised in this document, even with huge financial incentives to do so. People at the NIH, FDA, and CDC refuse to comment or respond to any of the issues raised in this document. Dr. Lena Wen, Eric Topol, Monica Gandhi, etc. will never debate us because they will be discredited. You never see fair and balanced coverage. CNN only has qualified experts on one side of the issue; they never hear from anyone competent who will provide a balanced view for the public. This CNN video is typical: all three talking heads are bashing early treatment.
8. **The censorship and intimidation** done by doctors, the White House, mainstream media, and social media companies makes it so everyone is afraid to speak the truth is unprecedented. Censorship is used on all social media platforms to keep this information out of public view. Reporters who attempt to write stories find that they will not be published. Fact checkers will not reply to corrections on their fact checks. Top academic scientists who seek to challenge the narrative with peer-reviewed papers find that the

papers never make it into the journal. When we pointed out Phase 3 clinical trial fraud (Maddie de Garay), the FDA promised to investigate and did nothing. This is not how science is supposed to work but no one in the mainstream academic community (except for Peter Doshi of the BMJ and even he has to be very careful) is speaking out about this.

9. In Congress, **Senator Ron Johnson** has been the only member to speak out about what has happened. Everyone else in Congress is afraid of being labelled "anti-science" if they oppose the vaccines. Nobody in Congress (except for Johnson's staff) will talk to me after one meeting because they can't answer any of my questions like "How many people have to die before you will call for a halt to the vaccination program?" or "Why aren't you asking the NIH for Fauci's unredacted emails?" or "How do you explain how Dr. Peter Schirmacher one of the world's top pathologists finds 30% to 40% death rate after vaccination while the CDC hasn't found any deaths?" These are the questions that the press should be asking, but aren't. Investigative journalism is dead. The media is simply amplifying the false narrative of the White House and ignoring the science.
10. Experts like Dr. Geert Vanden Bossche, Dr. Robert Malone, Dr. Peter McCullough, and others have been right about these issues since they started speaking out, but they are being ignored or censored by the mainstream media.
11. It is insulting to us for the ACIP committee to ask for comments before the meeting and then vote on approving the vaccine before reading any of the comments. The ACIP committee is sending a very clear message to the public that any comments made will be ignored. The public comment process is for show. This is doubly insulting to me personally as I tried to directly contact ACIP members and they all said file it as a public comment. Did that. It never gets read.

We recommend the committee take the following actions:

1. Require autopsies for all deaths within 4 weeks of any COVID19 vaccination so that data is available to compute an estimate of the true all-cause mortality.
2. Make available the analysis of the 11,000 deaths investigation in VAERS for public inspection. It's important for the public to understand why the CDC couldn't attribute a single death to the vaccine whereas one of the world's top pathologists ascribed at least 30% of all deaths to the vaccine.
3. Explain publicly why there is a death peak on the second day after vaccination if the vaccinations are perfectly safe and not causing deaths.
4. Explain publicly why the severe adverse side effects are dose dependent
5. Publish the proper elevated event table (see Attachment 2. Page 17)
6. Publish your analysis of the VAERS data including the propensity to report factor and the under reporting factor for fatalities or serious events. Please show us the correct analysis showing that there are no excess deaths this year as has been claimed.
7. Meet with our team as soon as possible to assess the validity of the points above.
8. Fix the adverse event signal detection system so it can at least recognize all the serious adverse events identified in Attachment 2, page 17.

9. Review the VAERS multiplier used in the myocarditis analysis. It appears to be 1. That makes absolutely no sense to us. How was that justified?
10. Recommend that vaccine mandates should not be issued without evidence of a statistically significant all-cause morbidity decrease (which there is not in this case).
11. Define a COVID vaccine stopping condition after which that vaccine should be halted until the stopping issues are addressed. In 1976, the stopping threshold was 32 deaths.
12. Ask the CDC to engage with us in a public discussion on vaccination issues so the public can hear first hand from qualified experts on both sides. This is a more effective way to combat vaccine hesitancy than censorship.

If the meetings with our team result in the validation of our assertions, then the following actions should be considered:

1. Recommend that at least three classes of people should not be vaccinated and should use early treatment if infected:
    a. Previously infected
    b. Women who are pregnant or might soon become pregnant
    c. Anyone under age 50
2. Inform the public of the complete list of elevated risks and their rates for the COVID vaccines.

THE MECHANISM OF ACTION OF THE COVID VACCINES IS DIFFERENT FROM THAT OF TRADITIONAL VACCINES

Dr. Robert Malone has described the vaccine as causing a cytotoxic spike protein to be produced throughout the body for up to 48 hours, with the potential to cause blood clots, inflammation, and permanent scarring. In addition, the spike protein (particularly the S1 segment) could break free of the cell and freely circulate, causing damage which could lead to a very wide range of pulmonary, cardiovascular, and neurological events.

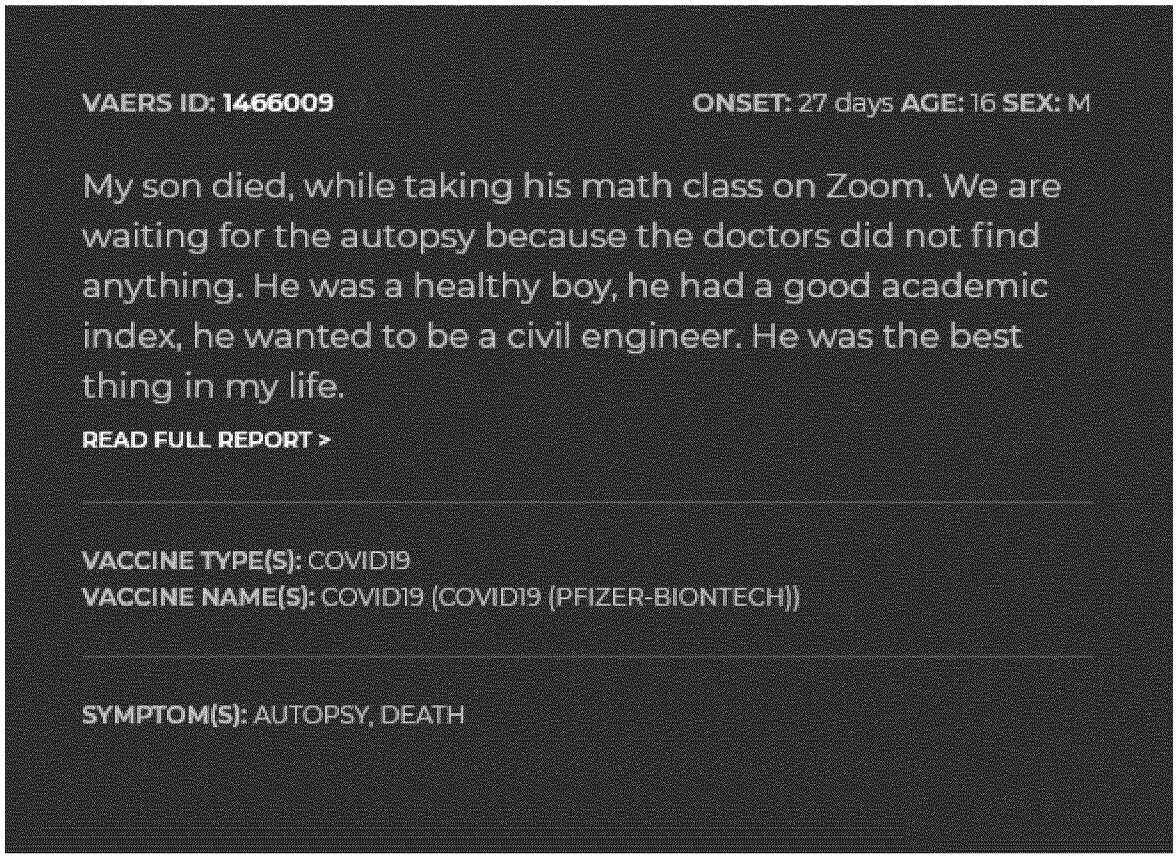
The gene-based vaccines (i.e., the 3 vaccines used in the US today) work in a completely different way than classical vaccines. With the latter, a fixed dose of killed or weakened pathogen or a toxin from the pathogen is injected and this sets a precise upper limit on how much foreign material is administered. In the former, while a fixed dose is also given, the upper limit of how much antigen is expressed depends on a series of steps each with substantial variability. This unavoidably greatly widens the range of amounts and concentrations of toxic spike protein in the body. Compounding this is the variability in anatomical distribution of the product with some body parts more prone to injury than others.

This built-in variability means that gene-based vaccines will likely always be much less safe than a classical vaccine. While the majority of people have no serious adverse events whatsoever, a significant number of people, perhaps in the millions, can be profoundly affected with one or more of a wide range of serious symptoms. Females are nearly 2.5 times as likely to be affected as males.

In particular, the VAERS data shows these symptoms include brain hemorrhages, strokes, heart attacks, multiple organ failure, pulmonary embolisms, and even sudden unexpected death.

A person can be perfectly normal and then just drop dead unexpectedly as the ACIP team already knows through their recent examination of the VAERS records of children 12-17 who died. For example, a 16 year old California student died unexpectedly in the middle of a Zoom math class. He had no prior health problems and appeared completely normal 20 minutes before his death.

If he didn't die from the vaccine, what did he die from?



There is a partial list of the elevated symptoms identified by VAERS analysis in Attachment 2, page 17.

Nearly every cardiovascular and neurological event occurred at a rate that was 10X or more than would be expected to be reported in a typical year by all of the vaccines in that year.

IT IS VITALLY IMPORTANT THAT ALL PHYSICIANS BE EDUCATED ON BOTH THE MECHANISM OF ACTION OF THE VACCINE AND THE RANGE OF SYMPTOMS THAT ARE BEING CAUSED ASAP BECAUSE IT IS COMPROMISING PATIENT CARE

Today, most doctors believe the vaccines are completely safe. There is virtually no knowledge of vaccine symptoms. This causes physicians to treat these symptoms as if they are caused by something other than the vaccine which results in treatments that are ineffective since they are not treating the underlying cause.

Maddie de Garay is a perfect example of this. She will pay the price of preventable misdiagnosis for the rest of her life because physicians were never informed that the vaccines could be causal for her symptoms; the doctors treated Maddie as if symptoms were all in her head.

Angela Wulbrecht who has been a nurse for 23 years in Northern California is another example. She was misdiagnosed by the world's best experts because the CDC never disclosed to anyone that the vaccines are super dangerous and how the vaccines can disable or kill people. She only found relief when she consulted Dr. Bruce Patterson who understood that the vaccines are deadly. She was able to get relief from her symptoms only when she was given drugs that targeted the vaccine damage.

Both of these people are public figures and are willing to speak out if you want to talk to them.

THE PROPER SAFETY TESTS WERE NEVER DONE

The FDA made the mistake of regulating the three COVID vaccines as a vaccine exclusively. As a result, the dose, duration, and amount of spike protein produced by these vaccines were never measured in advance of approval by the FDA.

Today, despite the evidence of unforeseen and unprecedented harm, these three critical parameters are still completely unknown.

Why haven't these tests been done in non-human primates with the actual vaccine?

THE D-DIMER AND CRP BIOMARKERS ARE A SMOKING GUN THAT THESE VACCINES ARE NOT SAFE

Even more concerning is that there has been no attempt to measure biomarkers that could clearly show that these vaccines are causing unexpected harm.

For example, measuring C-Reactive Protein and D-dimer of people before and after vaccination is a very simple experiment to show that the vaccines are causing problems.

Multiple researchers (contact us for the details) have done such a study in hundreds of patients and found that both biomarkers are elevated above normal levels for around three months in over 60% of patients.

This is very serious. It is a smoking gun that indicates that something is very wrong with these vaccines. For example, a 73 year-old female on her second dose had a D-dimer of 1186 ng/mL

(normally it is less than 250 ng/mL) two weeks after the shot. **It remained above normal for three months.**

AN OVER-RELIANCE ON DELEGATED TRUST HAS MAGNIFIED SMALL ERRORS INTO LARGER ERRORS

We live in a world of delegated trust. But if the root of that trust makes a mistake, it creates a ripple effect where the consequences are magnified exponentially.

Our first example of amplified errors due to delegated trust is the safety signal detection of the VAERS database that John Su at the CDC has been monitoring.

The ACIP committee trusts the CDC staff to monitor VAERS. If there is a bug in the monitoring algorithm used by the CDC, the CDC will miss the critical safety signals and the ACIP committee will not be alerted. ACIP members do not have the time or expertise to analyze the VAERS data themselves, as it is not a simple task, requiring many months of dedicated effort using specialized tools. If such a critical safety signal is missed by the CDC, there are immeasurable consequences and harm to the public.

When we looked at the VAERS database, we found dozens of very serious safety signals that the CDC failed to detect.

The attached analysis (see Attachment 2, page 17) shows that every neurological and cardiovascular event that we investigated was strongly elevated as compared to previous vaccines, most by at least 10X and some by as much as 473 times higher than what is normally expected in a typical year across all vaccines. This is impossible to explain if the COVID vaccines are perfectly safe.

We just received a similar analysis from Professor Josh Guetzkow which can be viewed at Attachment 3. In Table 1, for example, death is happening at a rate 91X higher than normal. That sort of increase cannot possibly be explained by “stimulated reporting” or “more people got vaccinations.”

This is independent confirmation that the explanation from the CDC and FDA does not match reality. The ACIP committee is also clueless about this and apparently lacks basic critical thinking skills.

All the evidence has been in plain sight since January 2021, not just in VAERS, but to those practicing doctors, neurologists, and pathologists who were seeing a huge spike in adverse events and deaths and were willing to consider the possibility that the vaccines were not as safe as had been claimed by the CDC and FDA.

In addition, all of the neurological and cardiovascular symptoms with elevated event counts were consistent with the mechanism of action described at the start of this comment. Each and

every symptom we looked at satisfies all the traditional Bradford-Hill causality criteria using both absolute rate elevation compared to baseline rates as well as Dose 1 vs. Dose 2 response disparities.

A BUG IN THE SAFETY SIGNAL ALGORITHM ALLOWS SAFETY SIGNALS TO ESCAPE DETECTION

Why was the CDC oblivious to these same signals? The answer: a bug in the algorithm used by the CDC. This bug only manifests itself when the vaccine being monitored produces a wider than normal range of side effects. This has not been the case with earlier vaccines which is why it wasn't detected earlier.

The bug in the safety signal algorithm is documented in this post: https://roundingtheearth.substack.com/p/defining-away-vaccine-safety-signals-572 (this is Part III, which contains links to Parts I and II). We would be happy to meet with CDC staff to go over this in detail.

WHY ARE YOU IGNORING PEOPLE WHO ARE TRYING TO HELP YOU SPOT SAFETY SIGNALS?

Repeated attempts to inform any ACIP committee member of this anomaly were unsuccessful. Considering that the ACIP committee is tasked with the critical monitoring of safety in the world's single most important drug, we are puzzled by the lack of interest in receiving safety information from qualified researchers. We were directed to submit comments to a non-existent docket number.

Failing to get anyone on the ACIP committee to respond, we next attempted to communicate the signal error to the CBER group at the FDA. Not one person responded, including Dr. Steven A. Anderson and his staff, despite multiple emails and phone calls. Again, we are puzzled by the lack of interest in receiving safety information from qualified researchers. Dr. Anderson had said in a video call that he was the main person responsible for the safety monitoring.

Emails to both John Su and Anne M. Hause were also not responded to.

Perhaps the FDA and CDC should simply let people know that "**if you find an urgent safety problem, don't bother to contact us because we aren't interested in hearing what you have to say.**"

If this were more well known, it would have saved our time and yours.

MYTH BUSTED: "VAERS CANNOT BE USED TO SHOW CAUSALITY"

For the current COVID vaccines, our team is extremely confident that we can meet all the Bradford-Hill criteria for causality using VAERS analysis alone. Will our statisticians and VAERS experts be permitted to meet with any ACIP members to discuss the data?

For example, it is well established that a clear dose dependency relationship can be used to satisfy one of the Bradford-Hill criteria. Because two of the vaccines are multi-dose vaccines, a Dose 1/Dose 2 ratio analysis shows a very clear signal. Sadly, this type of analysis is currently being completely ignored by the CDC.

THE FDA HAS ASSUMED THAT VAERS WAS JUST OVER-REPORTED THIS YEAR

Our second example of amplified errors due to delegated trust is the calculation of the VAERS event counts.

A detailed analysis of the VAERS data (Attachment 2 and Attachment 3) both show that the FDA has made a very serious error in assuming (without any evidence whatsoever as far as we've seen) that the propensity to report to VAERS is much higher this year and that these are simply all background events that can safely be ignored. The two analyses found the same thing and were done by different people, in different countries, who never met. The results were the same.

If the propensity to report is drastically increased, then it should be easy to prove. Randomly survey 100 neurologists and ask them the number of reportable events vs. reports last year vs. this year.

One neurologist told us she had events for 2,000 patients and got so frustrated with the time commitment after making 2 VAERS reports she stopped doing it. Note that she is NOT required by law to report it, only the person who did the vaccination is. So she reported just 1 in 1,000 events.

A physician in Canada said he's only made only 1 vaccine report in the last 29 years. This year he's filed 25 so far.

Other anecdotes we've heard many times from patients is when doctor A talks to doctor B and it goes something like this: Q: "Did you report it to VAERS?" A: "Of course not!"

Most consumers don't know anything about VAERS.

The actual reason VAERS is over-reported this year is because there are so many events to report, a possibility that the FDA never considered.

We are waiting to see the evidence from people claiming that it is overreported. So far, all the evidence and anecdotes we do have shows it isn't.

THE CDC CLAIMS "ANYONE CAN REPORT TO VAERS"

Many people assume that the large number of VAERS reports are due to anti-vaxxers gaming the system. But none of them can provide any evidence whatsoever that that is true. It is a claim that fits the narrative that is done without looking at the data at all. There is no such analysis.

In fact, when you do the analysis of the data, you find that 86% of the reports are consistent with vaccine injury and the other 14% lack enough information in the reports to tell. See the Mclachlan study.

So the evidence shows the opposite. If you make the claim the reports are all fraudulent, you need to show the analysis to back up the claim.

Interestingly, the people who make such claims on no evidence are the same people who demand peer-reviewed research to believe OUR arguments.

It is a federal offense to file a false VAERS report and all reports are screened by HHS (including requesting the medical records) before being published.

We are aware of 2 false VAERS reports in over 1.4M records. So it is true that not everything in VAERS is true, but the number of false reports is small and both of the reporters were referred to the FDA for prosecution.

YOU CAN LEARN A LOT BY TALKING TO A NEUROLOGIST

Some of the things we learned by talking to a neurologist with over 15 years of experience and a 20,000 patient practice are worth keeping in mind:

1. They can't reveal their identity publicly or they would lose their license
2. They can't speak out against the vaccine to their patients or risk loss of license
3. Patient load went up 20X during the vaccine rollout. Never saw anything like it in her career.
4. Over 2,000 patients had serious side effects from the vaccine
5. They only reported 2 to VAERS: it was too frustrating to use; it would crash every 2 minutes and you'd have to start over from scratch.
6. Only the doctor doing the injection must report to VAERS, so they don't have to, so they stopped doing it since it was so cumbersome.
7. Has always known about VAERS, but never need to use it before since never had to report an adverse event!!! This year would have reported all 2,000 patients if VAERS was easier to use. Instead, made just 2 reports (1 of 1,000)
8. Neurologists are now booked up for 3-4 months is typical. At Stanford is 6 months.
9. Most neurologists are clueless on how to treat vax events. Most neurologists don't associate the vax as the cause of the problem. Treatments are useless. When patient goes on Patterson treatment protocol, they can recover back to "normal" in 8 weeks. However, they get no medical training at all on this (because doing so would be an

admission that the vaccines aren't safe) so most people who are vaccine injured remain disabled.
10. At UC Davis, 40% of staff is unvaxed. They have to wait in line twice a week and come in 2.5 hours early to get in line for COVID testing. They endure that because they've seen first hand how bad the vax reactions can be.
11. Long-term impact of the vaccination program: Increase in multiple neurological conditions.
12. For the vaccine injured, the standard blood tests (including all extended testing such as CRP, D-dimer, etc) can all show completely normal. Angela Wulbrecht was given every test under the sun and they were all normal. It was only when she took Patterson's cytokine panel and S-protein tests that showed she was clearly very sick.

FDA FALSE STATEMENT: "DEATHS CAUSED BY THE VACCINE ARE EXTREMELY RARE"

In a letter dated August 23, 2021, Janet Woodcock writes to Senator Johnson, "Reports of death after COVID-19 vaccination that are found to be related, or even possibly related, to vaccination with COVID-19 vaccines have been extremely rare."

Where are the 249 autopsies on which that statement was made? Has the committee reviewed all 249 autopsy reports?

We were able to prove causality using the Bradford-Hill criteria from just the VAERS data alone. We didn't need the autopsies.

It was shocking to us that the CDC and FDA couldn't find these signals despite access to 249 autopsy reports.

There is something seriously wrong here. You cannot have a few excess deaths from the vaccine when both the VAERS database itself and the data from other countries shows that there have to be 150,000 deaths. They both cannot be right. We think the CDC is mistaken because the death data we used to compute the 150,000 deaths comes from 35% of the world's population. This error needs to be corrected as soon as possible.

SYMPTOM CODE FOR A VACCINE DEATH

What is the SYMPTOM code for a vaccine death? We looked at all the VAERS records with autopsies and we couldn't find a single record with a coding for a COVID VACCINE DEATH.

OUR ANALYSIS SHOWS THAT IT IS HIGHLY LIKELY THAT OVER 150,000 PREVIOUSLY HEALTHY AMERICANS HAVE BEEN KILLED BY THE COVID VACCINES IN 2021

The analysis in Attachment 2 shows that 150,000 previously healthy vaccinated Americans have had their lives cut short prematurely due to the vaccines. We confirmed this number using independent methods from independent researchers. We used both US data and data from other countries. Our analysis used data from over 35% of the world's population.

Our results are also consistent with reports from doctors we know who report that they have lost more patients to the vaccine than to COVID. For example, one doctor with 700 patients lost 2 patients to the vaccine and no patients to COVID. These doctors are special because they are "vaccine aware" and understand the mechanisms of action. In another case, one nursing home with 132 beds lost two patients within hours after vaccination.

Unfortunately, most doctors are blind to the association between the COVID vaccines and deaths and if asked, always report 0 vaccine deaths because they believe the narrative that the vaccines are "safe and effective." Any deaths would be anecdotes and ascribed to some other cause. For example, when the fetus of a recently vaccinated pregnant woman had a massive brain hemorrhage, the doctor considered the event caused by a "genetic defect." The vaccine is never even considered as a possible cause.

As far as we know, not a single doctor in the US has determined that any deaths were caused by the COVID vaccines. There isn't even a column in the CDC weekly report for deaths from the COVID vaccine. Apparently, it is impossible to die from the COVID vaccines if you live in the US.

However, a methodology based on excess death analysis (as detailed in Attachment 2) and autopsy results in other countries of people who died after getting the vaccine tells a completely different story: a story of a very deadly vaccine that has likely killed over 150,000 Americans so far.

It has been enormously frustrating to us that the CDC and FDA look the other way and have ignored all our attempts to share our analysis. That is not a good safety practice to ignore qualified people who disagree with you, especially when 150,000 lives are at stake. This is not serving the public interest. Safety must be a top priority at these agencies but when there are deaths from the vaccine, people are simply looking the other way and don't want to hear it. This is why all our attempts to contact people were ignored.

If the CDC or FDA engages with us and finds an error in our analysis and can show evidence that no lives have been lost to the vaccine, then this would do wonders for reducing vaccine hesitancy. Conversely, if the CDC or FDA confirms we are correct, we can immediately stop future loss of life by aborting the vaccination campaign.

Whichever way it ends up, the clarity that happens when both sides engage in an open public discussion of the methods and evidence used will benefit all parties and the public.

THERE IS NO EVIDENCE ANYWHERE OF AN ALL-CAUSE MORBIDITY BENEFIT. WITHOUT THAT, DEPLOYING THESE VACCINES MAKES NO SENSE, ESPECIALLY SINCE SUPERIOR ALTERNATIVES ARE AVAILABLE

When a vaccine class is generating a huge number of adverse events in 8 months that are more than the events from all 70 vaccines over the past 30 years, it is reasonable to assume that there might be a significant safety problem with the vaccine.

In such a case, rather than focusing on the reduction of relative and absolute risk provided by the vaccine, it is instead more important to focus on whether there is a significant reduction in all-cause morbidity.

For the three vaccines, using data from the original clinical trials, it has been shown that in all cases, **the all-cause morbidity is significantly elevated by all the vaccines**. The elevation ranges from 1.5X to 4.2X. That is a **large move in the wrong direction.** It is **highly statistically significant** for all three vaccines. This of course is consistent with what we find in VAERS.

With respect to efficacy, nobody argues that the vaccines have saved people from dying from COVID. But the problem is that this benefit comes at a steep cost: an increase in death from other causes that completely negates the benefit of the reduction in COVID-related deaths.

But could an all-cause mortality benefit compensate for the higher all-cause morbidity? Our best data on that is the Pfizer 6-month study. A 50% reduction in COVID deaths was more than offset by a four times higher rate of cardiac arrest. As a result, the all cause mortality rate was higher in the treatment group than in the placebo group. This was true in **both** the pre-unblinding and post-unblinding phases. **The numbers were small but the point is that there is no demonstrable all-cause mortality benefit. Zero. If anything it was the other way around.**

As evidenced by the high number of severe adverse events reported to the VAERS system, it is the all-cause morbidity statistic that is the new elephant in the room. If you can't show a lower all-cause morbidity, there is no reason to vaccinate.

For the three vaccines, using data from the original clinical trials, it has been shown in the peer-reviewed literature that in all cases, the all-cause morbidity is significantly elevated. The elevation ranges from 1.5X to 4.2X. That is a large move in the wrong direction. It is highly statistically significant for all three vaccines. This of course is consistent with what we find in VAERS.

THE VACCINES KILL MORE PEOPLE THAN THEY SAVE (3 INDEPENDENT SOURCES)

We also have troubling anecdotes like the nursing home with 136 beds where all the residents were given the booster just before September 1 and now 4 of them are dead and 7 hospitalized as a result. We are keeping the nursing home secret for now to protect our whistleblower.

This is a 3% death rate from the vaccine. We only found out about this through an insider. The media never covers this because they don't want to panic the public reporting on an anecdote that would dissuade people from taking the safe and effective vaccine.

Let's compare this to the expected COVID deaths (without a vaccine). Using 156 deaths per million in US for 65+, we'd expect to see **1 COVID death per year** among that population of 136 (assuming all the beds were filled). But the rates might be higher for nursing homes, but the rates of COVID are lower today due to all the vaccinations so that's probably a wash.

So if the vaccines remain 100% effective for an entire year, over a 1 year period **we are killing 4 elderly per COVID case saved**. This is not a good tradeoff.

But it's even worse: 7 people got hospitalized. Some of those may die shortly or have their lives cut short.

Thanks to a courageous whistleblower Abrien Aguirre we can confirm the death toll from the nursing home. Aguirre said that they had 32 vaccine deaths vs. 16 virus deaths. In other words, the vaccine has killed **twice as many people as the virus** in the very setting that the vaccine is supposed to be the most beneficial.

So in both cases, the vaccine is killing more people than COVID (4:1 and 2:1).

This is why **all the nursing homes keep all this information secret so the public never knows about it**. Each nursing home thinks they are simply an unfortunate anecdote, where the reality is that their numbers are normal for this vaccine. If you try to call the homes directly, they won't talk. Nobody returns your calls. **So nobody ever finds out.**

What makes those two anecdotes interesting is that the whistleblowers understand how the vaccines kill. **Most other nursing homes don't make the connection and will tell you that no one has died from the vaccine (they'd just say they died from natural causes)**.

Since the vaccine can also kill you over a 3 month period, they simply assume that the patient died from natural causes (like a massive heart attack or just "died") and it just "happened" that a lot of deaths coincidentally happened around vaccination time, but nobody is doing the statistical calculation.

And since most nursing homes are small, a 3% death rate looks like "natural causes."

Was he lying? What was his motivation? Aguirre basically put all his income on the line. For what? His reward: Aguirre was fired for telling the truth. This is exactly why people at nursing homes will not say anything. Here is the follow-up video.

There is only punishment if you tell the truth. This is why the nursing home whistleblower isn't identifying himself/herself.

Neither nursing homes would talk about the correct data. Why wouldn't they correct the data if it is wrong? **Why are they hiding in the shadows?**

But you don't have to believe these anecdotes. Another story just came out based on UK data:

The Covid-19 Vaccines have killed more people in 8 months than Covid-19 has killed in 18 months

by Daily Expose

And another commenter to ACIP had similar numbers using yet another approach.

So if you have different data that shows the opposite, we'd love to see it! So we have three independent sources now showing the vaccines are deadlier than the virus.

NOBODY WANTS TO TALK ON THE RECORD FOR FEAR OF LOSING THEIR JOB

One of my vaccine injured friends said the head anaesthesiologist at one of the world's top medical schools said "he wasn't willing to put it in writing" that it was caused by the vaccine because it would affect his reputation. However, his medical assistant was willing to put it in writing and sacrifice her career. My friend was told his symptoms would get worse over time. He's 39 years old and his life was ruined by the vaccine and nobody wants to end their career to speak out.

One of the top neurologists in my area (over 20,000 patients) won't talk publicly.

I talked to a medical examiner who didn't even feel comfortable sharing her name with me, but revealed autopsies are useless.

Basically everyone who could talk won't. They can't speak out publicly or they will lose their license.

They could speak to a reporter and talk without their names being disclosed, but no mainstream media would run the story, so there is no point. Reporters at top newspapers cannot get their stories run. *60 Minutes* won't touch the story either.

MEDICAL EXAMINER SAYS AUTOPSIES ARE USELESS, VAERS IS THE GOLD STANDARD FOR CAUSALITY

We were only able to find one medical examiner who would talk to us. Even then, she wouldn't reveal her last name or state.

Here are the key points:

- She is the only ME in her state looking at vaccine-related deaths. The other ME's all assume the vaccines are safe so never will implicate the vaccine.
- The ME's in general don't have the skills, they don't have the proper tests to determine causality for deaths caused by this vaccine (they don't exist in the post-mortem setting), they don't have the time, they don't have the medical records, and they get the body too late. They can see large blood clots of course
- THEY CAN'T EVEN ORDER A D-DIMER because they are told "well that's not generally done" so unless they fight for it, they simply give up.
- They even get a huge push back when asking for the medical records.
- Often, they don't even know the vax status or when the patient was vaccinated.
- She had to personally make a call to the family to determine whether a patient got vaccinated.
- THIS IS WHY the ME's cannot make the connection in the autopsy setting.
- She trusts VAERS way more than autopsy....says **NOBODY** is going to find this post-mortem
- She never had time to report any of her deaths in VAERS.... the ME's are overloaded with some cases from 6 months ago still not completed.
- She was operating today on 3 hours sleep. They are understaffed and overworked. It's exhausting.
- For vax deaths, she said autopsies are NOT the gold standard. It is VAERS.

CALCULATION OF REDUCED LIFESPAN

It is difficult to make a tradeoff between the elevated morbidity that reduces lifespan and the number of COVID deaths saved.

The COVID vaccines introduce both morbidity and mortality risks.

What ACIP has done is compare morbidity due to the vaccine vs. the same morbidity from COVID. That can be problematic if some some morbidities are improved and some are made worse. We'd have to look at all morbidities, something that ACIP hasn't done since they haven't seen the safety signals.

We believe that if we just look at the increased mortality due to the 1) direct deaths caused by the vaccine and 2) the reduction in total lifespan from all serious adverse events elevated by the vaccine, it would be clear that there is no mortality benefit.

We can see that from the Pfizer Phase 3 6 month study where more people in the treatment group died both pre- and post-unblinding. The Hawaii nursing home data is consistent: there was a 2:1 vaccine caused death:max possible vaccine saved death ratio which also supports stopping the vaccine.

Therefore, it seems likely to us that not only is there no morbidity benefit from the vaccines, but there is no all-cause mortality benefit from the vaccines either.

This makes the vaccines very hard to justify.

If we are wrong, we'd like to see the analysis.

WE ESTIMATE THAT APPROXIMATELY 574 KIDS HAVE BEEN KILLED BY THE VACCINE SO FAR; THAT'S MORE THAN HAVE DIED FROM COVID. WE ARE MAKING A HUGE MISTAKE. WE ARE KILLING OUR KIDS, NOT SAVING THEM.

The ACIP committee recently analyzed the cause of death of the 14 kids (aged 12 to 17) whose fatalities were recorded in the VAERS system. Had they had the table in the attached document, they would have realized that in every case (where there was sufficient symptom detail), the main cause of death was consistent with a symptom that was strongly elevated by the COVID19 vaccines. This should have led to a different outcome Mortality Among Teenagers Aged 12-19 Years: United States, 1999-2006 than simply listing the causes of death of the kids with no further discussion. No concern over the lack of autopsies was noted in the meeting notes. It is very likely that none of the kids had an autopsy done. There was no mention of this in the report.

We believe the lack of autopsies is a huge oversight for a vaccine that is generating so many legitimate adverse events. We believe it is imperative for the ACIP committee to immediately demand that autopsies be done. How many more kids must die before we look to find the real cause of death?

These children are dead now and their lives can never be recovered. But we can learn from their death if the ACIP committee members would simply read the 14 VAERS reports on each child and compare the cause of death with the symptoms listed in the table in the attached paper.

Five kids dying from cardiac arrest is not normal. Kids between 12 and 17 are twice as likely to die from cancer (6%) as from heart disease (3%). In this case, 38% died from heart disease and 0% died from cancer. That's statistically very unlikely. It points to the undeniable fact that these kids did not die of natural causes. Therefore, the hypothesis that the vaccines are safe seems highly unlikely. How does the ACIP panel explain this?

One of the children died with an intracranial hemorrhage. How could that have not raised a huge red flag. Kids that age never die from an intracranial hemorrhage.

We did a search in VAERS searching every record, over 70 vaccines over the last 30 years. There were only two deaths of kids aged 12-17 with "HAEMORRHAGE INTRACRANIAL" in the history of VAERS and both were associated with the recently approved Pfizer vaccine. There weren't any deaths caused by an intracranial hemorrhage in the entire history of VAERS in that age range until the COVID vaccines arrived on the scene. One event could be written off as a fluke--- very bad luck. But two events are a complete train wreck. How this didn't raise any red flags in the ACIP committee is a mystery to us.

As this note is being written the BBC News just reported that BBC presenter Lisa Shaw died of a brain haemorrhage. The coroner determined the cause was the COVID vaccine. All of the causal factors in her death were consistent with the elevated symptoms we found in VAERS. Note that the Astra-Zeneca vaccine has a nearly identical mechanism of action as the mRNA vaccines.

Each of the 14 children who died in the CDC study represents 41*14=574 real deaths (as noted in the attached paper). Thus, more American kids have already been killed by the COVID vaccines than have been killed in the entire history of COVID to date (361). That's tragic.

Two of the kids died from a pulmonary embolism, a symptom that is very strongly caused by the vaccines. Over 5 years in VAERS, you'll find just one PE death in that age range. So to get one PE death in a year, that's bad luck. To get two, you have to at least say that it's more likely than not that it wasn't just random. Yet the CDC report dismissed it without comment.

AN ACCURATE MYOCARDITIS COST-BENEFIT ANALYSIS IS MISSING

The CDC myocarditis cost-benefit analysis omitted the determination of the VAERS under-reporting factor for "mild" events.

While we think myocarditis is a serious event, the CDC characterizes these events as "mild" and thus would be less likely to be reported than something "severe" like death.

Therefore, we'd estimate that the VAERS under-reporting of such an event might be somewhere around a factor of 100.

My question to the panel is whether **a 100 times greater rate than the rate reported in the report would make a difference in the recommendation of the ACIP panel?** We would be very surprised if this doesn't change the recommendation.

Also, as a sanity check on our results, please refer to Table 1 in Attachment3 which is Joshua Guetzkow's analysis showing a 91-fold increase over baseline myocarditis rates.

Also, it would be good to estimate the effect of this heart damage **(and all other conditions elevated by the vaccines)** on expected lifespan so it is clear that the shortened lifespan is worth the savings in the amount of deaths. This way, we can do a pure mortality tradeoff.

For a lot of AEs, the quality adjusted life years (QALYs) is not significant. For young people, myocarditis represents an enormous QALY calculation. This will include some deaths, but most of a lifetime of a large range of reduction of life value.

For public health officials to discard the data without acknowledging something like a QALY comparison (and the deaths) is inappropriate.

TRUSTING THE PHASE 3 TRIAL RESULTS AS THE "GOLD STANDARD" IS NOT A GOOD IDEA

When there is a disagreement between real-world results and the Phase 3 clinical trial, we think it is better to trust reality. Here are some of our reasons:

1. The paralysis of Maddie de Garay was not reported in the Pfizer 12-15 year old clinical trial, and the FDA failed to investigate this case even though they knew about it. This is serious misconduct happening and nobody is holding the FDA accountable.
2. Adverse events were difficult to impossible to report (and Facebook conveniently removed the evidence of people complaining about that)
3. At least one death that happened didn't show up. Who knows how many more?
4. The cohorts were not representative of the population as a whole (they were much healthier, e.g., rate of heart attacks was 10X lower than the overall population rate)
5. Five times as many people were disqualified from the treatment arm (311) compared to the control arm (61) for protocol violations even though the trial was supposed to be double blind.
6. Read this article on the Pfizer consent form. The consent form allows for participants who need emergency care and go straight to their doctor or hospital to be ejected from the study. But that's hardly the only problem.
7. Pfizer paid one of the largest criminal fines ever imposed on a drug company for the arthritis drug Bextra.
8. The company can't seem to find any safety signals even though it is obvious in VAERS.
9. **No autopsies were done to determine the cause of death were done in the treatment group**. This was a **very serious** oversight in our opinion. Nobody on the FDA or ACIP panel seemed to think this was a problem.
10. The death rates make no sense. We know of a 132 bed nursing home that had 2 deaths within hours of getting the vaccine. And a larger nursing home in Hawaii with over 500 beds had 32 deaths after vaccination. The numbers don't match each other, but they are nowhere close to what was reported in the clinical trials which again suggests the cohorts were not representative of the population or that the company didn't find the deaths or both.

THE LACK OF AUTOPSIES IS INEXPLICABLE

Autopsies are the gold standard for determining causality. But for these vaccines, it's very tricky; you have to have the right skills and the right tests to make a proper diagnosis. Most medical examiners lack both.

How can the CDC say confidently that there have only been a few deaths? May we see the 249 autopsies? If not, why not?

In Germany, soon after the vaccines rolled out and deaths after vaccination started happening, the Federal Association of German Pathologists called upon the German authorities to require autopsies to validate the cause. Their requests were ignored presumably because nobody wants to know the answer.

In America, few people are asking for autopsies. And when they do, they are being denied

If we had the autopsies available, we wouldn't have to debate whether we are right or wrong about the numbers of deaths -- we'd have the data.

The Norwegian Medicines Agency linked 13 deaths to vaccine side effects. At the time that article was published, there were only 13 assessments completed. So in 100% of the cases, the deaths were deemed to be caused by the vaccine by the official government agency.

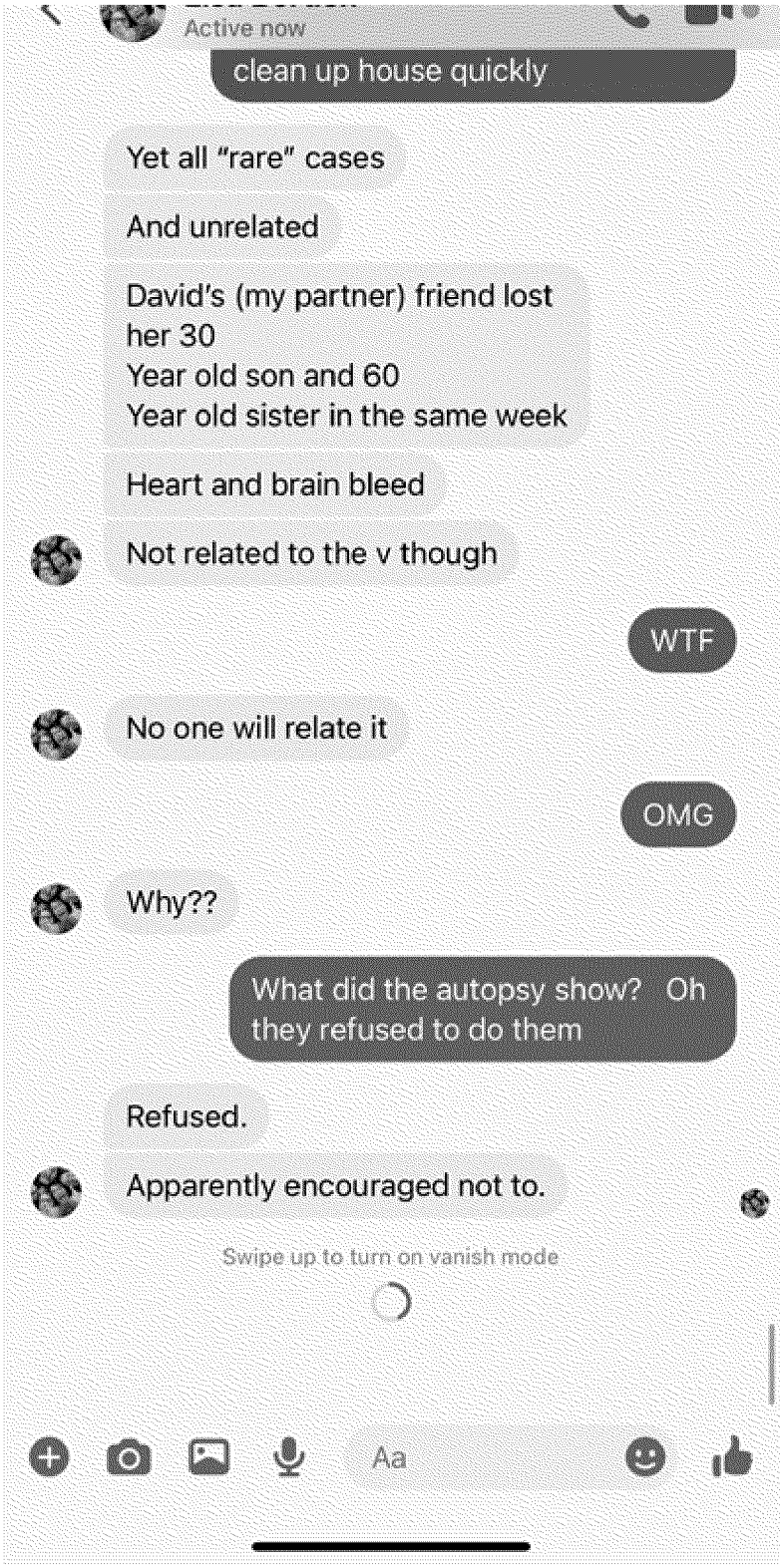
In Germany, they actually did autopsies of 40 people who died within 2 weeks after vaccination. They determined that at least 30% to 40% really did die from the vaccine. From Media Blackout: Renowned German Pathologist's Vaccine Autopsy Data is Shocking... and Being Censored:

> Dr. Peter Schirmacher is not just an average pathologist. The German doctor is world-renowned in his field, honored by The Pathologist as one of the 100 most influential in the world. He is the acting chairman of the German Society of Pathology, director of the Institute of Pathology at Heidelberg University Hospital, and president of the German Association for the Study of the Liver. Bottom line, this professor and doctor understands pathology like very few on the planet.

It is puzzling to us that nobody on the ACIP committee is calling for mandatory autopsies. Only 249 have been done on the 11,000 people who have died. It would be nice to know what they said.

Does ACIP think we should not have autopsies? I think it is important to clarify the committee's opinion on whether we should have the data on why people are dying after the vaccine or whether ACIP would rather have coroners look the other way.

Right now, it seems to be difficult to have an autopsy done, so if you want to gather the data, I think it is important to say something rather than remain silent on this issue.



IT IS BECOMING CLEAR THAT THE VACCINES ARE RAPIDLY BECOMING LESS EFFECTIVE

As far as effectiveness, we believe the recent paper from a team of Japanese researchers, "The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines" shows that the vaccines we received will soon become completely useless to protect us and, to make matters worse, are already enhancing the ability of current variants to infect us through **vaccine enhanced infection and/or replication** (rather than "classical ADE" which so far appears not to be happening).

From the abstract:

> Although Pfizer-BioNTech BNT162b2-immune sera neutralized the Delta variant, when four common mutations were introduced into the receptor binding domain (RBD) of the Delta variant (Delta 4+), some BNT162b2-immune sera lost neutralizing activity and **enhanced the infectivity.**

In short, even if the vaccine were perfectly safe and killed no one, vaccinating with a non-sterilizing vaccine in the middle of a pandemic is going to have a net negative benefit, exactly as Geert Vanden Bossche has been trying to tell the world since shortly after the vaccination program began. He called it a very serious mistake. Nobody in power listened.

The latest UK government data (Briefing #20), shows you are 57% more likely to die if you get delta and you are vaccinated than if you are unvaccinated. The computation for age<50 and fully vaxed vs. unvaxed is 13/48*147612/25536=1.57 which is consistent with the Japanese paper.

Therefore, not only are the vaccines not safe, but they are quickly becoming useless and may shortly be a liability as far as effectiveness is concerned.

EARLY TREATMENTS HAVE ALWAYS BEEN THE SAFER, MORE EFFECTIVE OPTION

Meanwhile, early treatments have been virtually ignored by mainstream academia and the NIH. Lack of suitable guidance from the NIH has caused the entire world to avoid early treatments. These treatments are both extremely safe and very effective. They work against all variants as well. For example, the protocols used by George Fareed and Bryan Tyson against COVID continue to work well against COVID and with over 6,000 patients treated in an area with one of the highest CFRs in the country, it is very rare for a patient to be hospitalized for COVID in their clinic; it only happens if the patient presents late. They have more than a 99% relative risk reduction against all COVID variants if the patients get treated early. The NIH has expressed no interest in trying to replicate this success despite the tremendous lifesaving potential and negligible risk. They are more interested in waiting for a new, unproven drug from Merck for treatment.

EARLY TREATMENTS HAVE BEEN CENSORED. NOBODY IN MEDICINE SEEMS TO MIND.

One of the earliest pioneers of early treatment, George Fareed, is banned for life from YouTube for trying to spread life-saving treatment protocols that work..

The Nobel Prize winning inventor of ivermectin, Dr. Satoshi Omura, had his video on ivermectin for COVID blocked on YouTube.

Ivermectin has several systematic reviews and meta-analyses showing that it works; the highest level of evidence in evidence-based medicine. But since this competes with the vaccine, everyone is instructed to ignore evidence-based medicine and replace it with the lowest level of evidence: expert opinion (e.g., from an agency).

In short, no matter what level of evidence you pass, it is not enough if it goes against the political false narrative.

We find it troubling that so few in the medical community are speaking out about such abuses.

These individuals are giving life-saving advice and have been censored and there are dozens of examples of many others that have been censored, banned for life, and/or demonetized.

It would be interesting to hear the ACIP members speak out on this subject, either endorsing the censorship or condemning it. Remaining silent on such an important issue will not help advance science and save lives. Normally, ACIP shouldn't have to do this, but everyone else is remaining silent.

THE UK SAID THE VACCINE IS NOT RECOMMENDED FOR THOSE < 18 YEARS OLD

The UK panel said the data doesn't justify vaccination of those under 18

Jul 19: UK opts not to vaccinate most under 18 against COVID-19

Then they changed their minds just 2 weeks later:

Aug 4: UK to roll out COVID-19 vaccines to 16 and 17-year-olds

Did the science really change that quickly? What new things were learned? Or is science being driven by politics which would be a new low point. If there was new science, it would be useful for everyone to know what it was.

16% NEVER CAME BACK FOR A SECOND SHOT. WHY?

62% of Americans are vaccinated vs. 52% who are fully vaccinated. So that's 16% (52/62=.84) that never came back for a second shot

Why is there such a large gap when in order to do anything (like keep your job, go to school, etc) you need to be fully vaccinated?

We understand why people don't get vaccinated at all (they are well informed). But what's the reason for the 16% gap?

We know from user surveys that 3% of people who took the vaccine required treatment by a doctor. And 5% are still suffering from side effects. So that explains half of the gap. Basically 8% of people who got the vaccine had a large enough bad first experience, they aren't going back for a second shot. This leaves 8% unexplained, but likely due to a bad first reaction.

We think that 12M injured Americans is a lot of people especially in light of the lack of an all cause mortality benefit and a clear lack of all-cause morbidity benefit. That's a lot of people who have been injured for no proven net benefit (yes, COVID lives were saved, but it was an overall cost of lives). But that's just our opinion.

SUMMARY

Analysis of multiple researchers using different sources confirms that the current COVID vaccines are very dangerous and are significantly increasing all-cause morbidity. The vaccines can trigger a wide range of serious neurological and cardiovascular symptoms, re-activate latent viruses, trigger flare-ups in people with cancer, and more. Multiple studies show 60% of patients have elevated D-dimers that persist for 3 months after vaccination.

These vaccines should be immediately halted. If they cannot be halted, then it is imperative that we inform the American public of the risks. Children, pregnant women, and previously infected people should be instructed to avoid vaccination. All vaccine mandates should end immediately until there is scientific proof of an all-cause morbidity and mortality benefit.

The censorship and intimidation of experts with dissenting opinions must end. You cannot speak the truth anymore on any social media platform without being blocked, banned, and/or demonetized. Pharmacies are allowed to not fill prescriptions on drugs and dosages that are proven to work in dozens of clinical trials: they can make these decisions without scientific evidence in support of their positions. They are not held accountable for their decisions.

Early treatment has always been a superior strategy for treating COVID: it is safer, more effective, and has a number of other important benefits. But it is being deliberately suppressed despite passing normal scientific milestones including large, well done Phase 3 trials and systematic reviews. Trials of ivermectin are being done by NIH that deliberately underdose the drug in order to prove to the world that it doesn't work.

Virtually none of the people diagnosed with COVID in the hospital today were treated early with a “proven in clinical practice” early treatment protocol. That is the message we should be sending to America.

VOTE OF THE ACIP COMMITTEE WAS 14-0 IN FAVOR OF APPROVAL

They said they are there to protect the health of the public.

As far as we can tell, no member of the ACIP committee read this note or any of the other public comments submitted prior to the vote. So this comment didn't matter. The public comments portal is just to placate the public.

There was no mention of early treatment as an alternative to vaccination.

This suggests to us that the committee is not interested in hearing from qualified people who disagree.

The data they presented was just one side of the story.

I loved how the slides showing bad data were left on the screen for like 2 seconds. And when the rate of severe adverse events was 10% vs. 2% for placebo, they just didn't discuss that at all!

My favorite was Dr. Grace Lee's presentation (VaST). Look at slide 18 which is from Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting (published in NEJM). It showed that the vaccines **reduce your risk** for pulmonary embolisms (PE) and intracranial hemorrhage (IH) compared to baseline pretreatment (the dotted line). Which is very interesting because our VAERS analysis (and the mechanism of action of the vaccine) showed the PE rates were off the charts. Anyone with a basic understanding of the mechanism of action of the vaccine and basic medicine would say there is no way PE can be reduced. However, nobody on the committee flagged this.

But PE risk is very very important. But our chart showed PE rates were elevated by 473 times. It was the most extreme event we saw in VAERS that was elevated.

To validate our results, the CDC itself found that two of the 14 kids (12-17 year old) died from PE and two from intracranial hemorrhage. What? According to the figure Dr. Lee presented, those two SAEs are both reduced by the vax. Yet based on our analysis, PE is 473X and IH is 42X more likely than baseline.

So this is a stunning divergence of reality vs. data presented to ACIP. And the death data is consistent with our VAERS analysis of SAE rates, and is not consistent with the clinical trial findings and the NEJM paper.

This is an objective example of how the data that they used to make the recommendation diverges from VAERS and nobody was interested in resolving the inconsistency. We got it right, but our data was never shown since it isn't published.

From OpenVAERS search, we got 5164 PE events so 1411 events per million with 41X underreporting. The normal rate of PE is 0.39 per million. So this is an elevation of **3,617X from normal** if we compare with the baseline incidence rate.

The science says only one hypothesis fits the facts: the vax is safe or it isn't.

Here's a table pulmonary embolism to help you decide which hypothesis is a better fit to the facts:

	Safe hypothesis	Not safe hypothesis
Mechanism of action	x	✔
VAERS data is elevated by 473	x	✔
VAERS data is 3,617 above normal	x	✔
Studies of >100 people show elevated D-dimer in over 60% for 3 months	x	✔
2 of the 14 kids died from PE	x	✔
2 of the 14 kids died from IH	x	✔

The point is that if you look for the hypothesis that is consistent with what is measured and observed, there is only one hypothesis that fits the data. That's how science is supposed to work.

Today, science is about dropping critical thinking on the floor, censoring or ignoring qualified experts who disagree, and finding ways to support the mainstream political narrative. It is fitting the data to match the politics.

If ivermectin has a systematic review and meta-analysis published in a peer-reviewed journal, the NIH simply ignores the recommendation and pharmacies refuse to fill prescriptions. If NAC has caused no harm over 60 years, the FDA pulls it from the shelves and makes it prescription only while at the same time taking a vaccine which has killed over 200,000 people and making it available without a prescription and without warnings of just how deadly and/or disabling it is.

It's very sad how quickly the wheels have come off the science bus.

OUR TEAM OF EXPERTS

1. **Dr. Robert Malone**, widely recognized as the inventor of the mRNA vaccine. He immediately recognized the dangers of the current vaccines when the biodistribution data was revealed after a FOIA request. He was one of the first people to go on record warning the world about vaccine enhanced infection and replication.
2. **Dr. Geert Vanden Bossche**, one of the few virologists in the world to warn the world about vaccinating with a non-sterilizing vaccine against a virus capable of mutation in the middle of a pandemic.
3. **Dr. Byram Bridle,** a highly respected viral immunologist at University of Guelph, did the FOIA request that exposed the biodistribution data showing the vaccines do not stay at the injection site like people thought, but instead cause the production of a toxin in all parts of the body including the brain.
4. **Dr. Peter McCullough**, Professor of Medicine, is the author of over 1,000 peer reviewed publications, He serves as editor of two journals and sits on the editorial boards of multiple specialty journals.
5. **Dr. Ryan Cole,** one of the few pathologists who has been unafraid to speak out.
6. **Dr. Bret Weinstein** host of the DarkHorse podcast, expert in evolutionary biology.
7. **Dr. Chris Martenson,** pathologist and host of Peak Prosperity on YouTube. Chris's videos on YouTube are the most insightful videos about the virus and the vaccines.
8. **Dr. Pierre Kory** is our ivermectin expert, and one of our experts on early treatment.
9. **Dr. Paul Alexander** has expertise in the teaching of epidemiology (clinical epidemiology), evidence-based medicine, and research methodology. He is a former professor at McMaster University in evidence-based medicine; former COVID pandemic advisor to WHO-PAHO in Washington, D.C. (2020); and a former senior advisor on COVID pandemic policy at the U.S. government's Department of Health and Human Services (HHS) in Washington, D.C.
10. **Dr. Ira Bernstein**, a physician in Canada. Bernstein replicated Hoffe's D-dimer test which is extremely frightening.
11. **Dr. Jessica Rose** is an expert on the VAERS system. Her YouTube video on VAERS have never been challenged. She has a published paper on VAERS with several more on the way.
12. **Dr. Meryl Nass,** is a physician and VAERS expert.
13. **Dr. Sin Hang Lee,** an expert on DNA sequencing.
14. **Mathew Crawford**, is a mathematician and statistician who writes frequently about the pandemic including two articles on a serious CDC math error that no other person had noticed (Part I and Part II)
15. **Dr. Charles Hoffe**, is a physician in Canada.
16. **Marc Girardot**, is a member of PANDA. https://www.pandata.org/team/. PANDA is a politically and economically independent organization, focused on science-based explanations and tests them against international data. Marc has published extensively on the pandemic.

17. **Dr. George Fareed,** a physician in southern California who developed an extremely effective protocol for treating COVID-19 infections with a 99.76% risk reduction which is far more effective and safer than any vaccine
18. **Tyson Gabriel** is our mask expert. He produced this 1 hour instructional video. Nobody wants to challenge him to a debate on mask wearing.
19. **Stephanie Seneff**, senior research scientist at MIT. Although her field is computer science, she has an amazing breadth of knowledge in biology.
20. **Aditi Bhargava,** Professor, ObGyn and CRS, UCSF.

FDA response

Dear Mr. Kirsch,

While your email was not directly addressed to FDA, we would like to note that we do not agree with the analysis put forth in your comment, as we believe the data from VAERS that you reference were not properly interpreted. This is due to the limitations of VAERS itself, as well as limitations regarding certain private patient information that is not available to individuals outside of the FDA and CDC, as we noted in our correspondence to you dated July 27, 2021.

FDA and CDC have multiple systems in place to monitor the safety of COVID-19 vaccines, including VAERS. We continue to find that the COVID-19 vaccines have a favorable benefit-risk profile, supporting their use under Emergency Use Authorization. Additionally, FDA's approval last week of Comirnaty (COVID-19 Vaccine, mRNA) followed a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

Sincerely,

Lorrie H. McNeill

Director
Office of Communication, Outreach and Development

My response to the FDA

Lorrie,

Thanks. As promised, I will include your response in my comment so people can see your point of view.

It appears you did not read the material carefully. As we pointed out, the VAERS estimate we did was CONFIRMED with several other methods from independent researchers who used data outside the US and found the same numbers. Even with a $1M bug bounty, nobody found an error.

Since you didn't like our analysis, perhaps you can show us YOUR analysis of the excess deaths in VAERS so we will show you the flaws in that analysis. We'd love to see your calculation of the "correct" propensity to report, the under-reporting factor used, and the subtraction of the background deaths.

Just today, I was talking with a physician, and he said he's made one adverse event report in the last 29 years. This year alone, he's made 25. I asked him why and he said, "well I've only ever seen one thing in the past 29 years that I've need to report."

I talked to a top neurologist who gave up on VAERS after filing 2 reports. She had 2,000 patients she wanted to report on. So that's an under-reporting rate of 1,000X, and all of these 2,000 were serious.

And 2 days ago, I heard about a nursing home with 136 beds. They all got boosters. 4 died, 7 hospitalized. So we ***could*** be killing 4 people to save 1 person a year from COVID.

The point is this: ALL the evidence ***we*** have access to disagrees with the evidence ***you*** have access to.

One of us is right, one of us is wrong.

Can we meet with anyone at FDA so we can resolve the conflict?

This is important to resolve for the public. Peter Doshi and Daniel O'Connor will be happy to cover this so we can inform the public as well of the result of our discussions.

-steve

Attachments

Estimating the number of COVID vaccine deaths in America
This document uses VAERS to estimate the total number of excess deaths caused by the vaccines. This estimate is validated using multiple other methods.

There is also a table of elevated adverse events showing the pulmonary embolism is elevated by 473 times above baseline (typical VAERS year).

Adverse Events Reported Following COVID-19 Vaccinations
This research by Professor Josh Guetzkow is an independent confirmation of two of the factors we found in our analysis:

1. VAERS isn't being "over reported" this year as the FDA and CDC have falsely claimed due to greater "awareness" and propensity to report
2. VAERS isn't be over-reported this year due to the number of vaccinations

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 9/2/2021 6:16:18 PM
To: Anderson, Steven [Steven.Anderson@fda.hhs.gov]; Richard Forshee (Richard.Forshee@fda.hhs.gov) [Richard.Forshee@fda.hhs.gov]
CC: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]
Subject: FW: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP
Attachments: ACIP comment 8-30-21.pdf; RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

Dear Steve and Rich,

See the incoming from Mr. Kirsch. I am wondering if we make one last attempt at responding to him and then end further correspondence. He has a number of fixed false beliefs. Just let me know your thoughts – I don't feel strongly, and also realize what a time sink this is.

Best Regards,
Peter

From: Steve Kirsch <stk@skirsch.com>
Sent: Thursday, September 2, 2021 5:43 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Cc: Su, John (CDC) <ezu2@cdc.gov>; (b) (6) Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6) (b) (6)
Subject: RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Lorrie,

Updated PDF including your comments, as promised. Waiting to hear back from you on my request to meet. Please either point out specific errors, or supply your own excess death analysis of the VAERS data and we will provide a critique.

-steve

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Thursday, September 2, 2021 1:27 PM
To: Steve Kirsch <stk@skirsch.com>
Cc: Su, John (CDC) <ezu2@cdc.gov>; (b) (6) Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6) (b) (6)
Subject: RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

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Sincerely,

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

-----Original Message-----
From: Steve Kirsch <stk@skirsch.com>
Sent: Wednesday, September 1, 2021 2:35 PM
To: Su, John (CDC) <ezu2@cdc.gov>; (b) (6)
Cc: Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6)
(b) (6)
Subject: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello,

Attached is an updated public comment I submitted at the ACIP meeting. Since you are both mentioned by name in the comment, I would like to give you an opportunity to respond before I publish this on TrialSiteNews.

To the CBER team members on the Cc: line, you should take a very close look at this. If you can find an error please let me know. If I don't hear from you, I will assume you have no objections to the methods and the conclusions.

I worked with a team of 20 scientists in putting this together... VAERS experts, statisticians, physicians, one Medical Examiner, multiple pathologists, and the inventor of the mRNA vaccine.

Thanks!

-steve

Comment to ACIP meeting of August 30, 2021 submitted by

Steve Kirsch

Executive Director of the COVID-19 Early Treatment Fund
stk@treatearly.org

September 1, 2021

NOTE:

1. This document is an updated version of the original August 29, 2021 US Government filing.
2. If you are viewing a PDF version of this document, the most up-to-date version is here.

ABOUT ME

I am the founder of the COVID-19 Early Treatment Fund (www.treatearly.org). Our work in funding early treatments for COVID was featured on *60 Minutes*.

I am not anti-vax. I have been vaccinated and my entire family has been fully vaccinated.

I am against unsafe drugs, **especially ones that disable or kill my friends**.

Starting on May 9, 2021, I began to hear stories from my friends that were very troubling. For example, one friend had three relatives who were formerly healthy all die within days after getting the vaccine. Another friend had a heart attack 2 minutes after the injection and is now disabled, apparently for life. He's 39 and has been told by his neurologist that the pain will get worse and worse every year. On a scale of 1 to 10, he's a 10 every minute he's awake. His life is ruined, likely forever, according to his doctors. That's after just one shot.

I assembled a team of 20 doctors and scientists listed at the end of this comment to investigate the available evidence. The more we learned, the more concerned we got. When we tried to voice our concerns publicly, we were intimidated, censored, or ignored.

Nobody has responded with any evidence that addresses what we found and shows that we got it wrong.

Even more troubling is that nobody from the CDC or FDA would even respond to our repeated requests by email and phone to look at our analysis. **They didn't even want to see it.**

OUR FINDINGS

Using the VAERS database and other official government data sources from the US and around the world (covering 35% of the world's population), we found that the current vaccines are significantly more dangerous than has been previously believed.

Our most important findings include:

1. The "real world" fatality data from VAERS does not match the fatality data from the Phase 3 trials. They aren't even close. Using multiple independent methods from independent researchers, we show that it is likely that **over 150,000 Americans** have already been killed (see Attachment 2). Even with a $1M reward to academics to spot an error in our analysis, there were no takers. It is urgent to resolve this discrepancy as soon as possible as we strongly believe that the real world data is right and the vaccines kill more people than they save. Even Pfizer's own 6 month study failed to show any evidence of a net mortality benefit either before or after unblinding (at the end, 20 people who got the vaccine died vs. 14 people who got the placebo). And all three vaccines showed they significantly increase morbidity (highly statistically significant for all vaccines).
2. **The vaccines should be stopped immediately** based on the 150,000 Americans killed alone. Arguing about myocarditis cases and morbidity trade offs like they do at the ACIP meeting is like rearranging deck chairs on the Titanic. We have never had a vaccine in recent history that has killed 150,000 Americans. The H1N1 vaccine was stopped in 1976 after killing around 32 people. Today, we ignore all these deaths, writing them all off to "bad luck."
3. None of the COVID vaccines reduce all-cause morbidity. It's the opposite: they all significantly increase all-cause morbidity by as much as 4.2 times baseline ($p<=0.00001$). The CDC must know this since this information is hiding in plain sight in the published literature. What is the point of offering an optional medical intervention which significantly increases all-cause morbidity when safer alternatives such as early treatment are available?
4. There is an error in the adverse event detection formula used by the CDC that appears to have prevented the CDC from seeing the safety signals that were obvious to our VAERS experts.
5. Early treatment and prophylaxis protocols are a superior option to the current vaccines on every single meaningful metric:
    a. Higher relative risk reduction (over 99%)
    b. Simple prophylaxis protocols be used to prevent infection with up to 100% success without the use of any drugs whatsoever
    c. Greater safety (minor temporary side effects, known safety profile)
    d. They lower both all-cause mortality and all-cause morbidity
    e. They work equally well on all variants
    f. They do not promote escape variants
    g. They do not cause vaccine enhanced infectivity/replication
    h. They do not cause prion diseases

i. They prevent long-haul COVID syndrome nearly 100% of the time
j. They enable people to acquire recovered immunity which is both 13 times stronger and more durable than vaccine-induced immunity

6. Because of all of these advantages, **all early treatment methods are being deliberately sabotaged by the FDA and NIH** so that people will believe that the vaccines are the only option. Even when drugs are proven in high quality large Phase 3 trials (fluvoxamine), or when there are multiple systematic reviews showing ivermectin is an effective early treatment for COVID (Lawrie ivermectin systematic review showing 62% reduced mortality and Zein ivermectin systematic review showing 61% reduced mortality), the NIH and medical community ignores these treatments and rates them as NEUTRAL which doctors all take as a sign to avoid. Most pharmacies will not fill ivermectin prescriptions anymore (**they did this AFTER both ivermectin systematic reviews were published which is a new low for evidence-based medicine**). Some pharmacies will report physicians to the medical boards who prescribe ivermectin. You can get ivermectin on Amazon, but the wait is months. Amazon conveniently puts a notice on the web page that The FDA advises against the use of ivermectin to treat or prevent COVID-19 but does not inform consumers of the peer-reviewed systematic review and meta-analysis. The ACTIV-6 trial deliberately underdoses ivermectin so it will fail to have an effect so they can "prove" to the world they were right. This is a waste of taxpayer money because everyone will concede that the trial they are running will fail. Watch this CNN video where Dr. Lena Wen conveniently references the systematic review that she claims "proves" ivermectin does nothing (it limited the studies it looked at and found that ivermectin reduced mortality by 60%, not 0%) and she claims that one of the safest drugs ever invented is risky, and she conveniently ignores the higher quality systematic review that shows that ivermectin works (that one gets no mention). The FDA made NAC available by prescription after it was proven to work for COVID even though there have never been any deaths from NAC in 60 years and it is incorporated into 1,100 different products all of which had to be reformulated. What was the reason for that? They pull a drug that kills no one, and approve a vaccine that kills 2 people for every 1 it saves and make it available without a prescription.
7. **Nobody of any stature in the medical world will agree to publicly debate** our team on any of the issues raised in this document, even with huge financial incentives to do so. People at the NIH, FDA, and CDC refuse to comment or respond to any of the issues raised in this document. Dr. Lena Wen, Eric Topol, Monica Gandhi, etc. will never debate us because they will be discredited. You never see fair and balanced coverage. CNN only has qualified experts on one side of the issue; they never hear from anyone competent who will provide a balanced view for the public. This CNN video is typical: all three talking heads are bashing early treatment.
8. **The censorship and intimidation** done by doctors, the White House, mainstream media, and social media companies makes it so everyone is afraid to speak the truth is unprecedented. Censorship is used on all social media platforms to keep this information out of public view. Reporters who attempt to write stories find that they will not be published. Fact checkers will not reply to corrections on their fact checks. Top academic scientists who seek to challenge the narrative with peer-reviewed papers find that the

papers never make it into the journal. When we pointed out Phase 3 clinical trial fraud (Maddie de Garay), the FDA promised to investigate and did nothing. This is not how science is supposed to work but no one in the mainstream academic community (except for Peter Doshi of the BMJ and even he has to be very careful) is speaking out about this.

9. In Congress, **Senator Ron Johnson** has been the only member to speak out about what has happened. Everyone else in Congress is afraid of being labelled "anti-science" if they oppose the vaccines. Nobody in Congress (except for Johnson's staff) will talk to me after one meeting because they can't answer any of my questions like "How many people have to die before you will call for a halt to the vaccination program?" or "Why aren't you asking the NIH for Fauci's unredacted emails?" or "How do you explain how Dr. Peter Schirmacher one of the world's top pathologists finds 30% to 40% death rate after vaccination while the CDC hasn't found any deaths?" These are the questions that the press should be asking, but aren't. Investigative journalism is dead. The media is simply amplifying the false narrative of the White House and ignoring the science.
10. Experts like Dr. Geert Vanden Bossche, Dr. Robert Malone, Dr. Peter McCullough, and others have been right about these issues since they started speaking out, but they are being ignored or censored by the mainstream media.
11. It is insulting to us for the ACIP committee to ask for comments before the meeting and then vote on approving the vaccine before reading any of the comments. The ACIP committee is sending a very clear message to the public that any comments made will be ignored. The public comment process is for show. This is doubly insulting to me personally as I tried to directly contact ACIP members and they all said file it as a public comment. Did that. It never gets read.

We recommend the committee take the following actions:

1. Require autopsies for all deaths within 4 weeks of any COVID19 vaccination so that data is available to compute an estimate of the true all-cause mortality.
2. Make available the analysis of the 11,000 deaths investigation in VAERS for public inspection. It's important for the public to understand why the CDC couldn't attribute a single death to the vaccine whereas one of the world's top pathologists ascribed at least 30% of all deaths to the vaccine.
3. Explain publicly why there is a death peak on the second day after vaccination if the vaccinations are perfectly safe and not causing deaths.
4. Explain publicly why the severe adverse side effects are dose dependent
5. Publish the proper elevated event table (see Attachment 2. Page 17)
6. Publish your analysis of the VAERS data including the propensity to report factor and the under reporting factor for fatalities or serious events. Please show us the correct analysis showing that there are no excess deaths this year as has been claimed.
7. Meet with our team as soon as possible to assess the validity of the points above.
8. Fix the adverse event signal detection system so it can at least recognize all the serious adverse events identified in Attachment 2, page 17.

9. Review the VAERS multiplier used in the myocarditis analysis. It appears to be 1. That makes absolutely no sense to us. How was that justified?
10. Recommend that vaccine mandates should not be issued without evidence of a statistically significant all-cause morbidity decrease (which there is not in this case).
11. Define a COVID vaccine stopping condition after which that vaccine should be halted until the stopping issues are addressed. In 1976, the stopping threshold was 32 deaths.
12. Ask the CDC to engage with us in a public discussion on vaccination issues so the public can hear first hand from qualified experts on both sides. This is a more effective way to combat vaccine hesitancy than censorship.

If the meetings with our team result in the validation of our assertions, then the following actions should be considered:

1. Recommend that at least three classes of people should not be vaccinated and should use early treatment if infected:
    a. Previously infected
    b. Women who are pregnant or might soon become pregnant
    c. Anyone under age 50
2. Inform the public of the complete list of elevated risks and their rates for the COVID vaccines.

THE MECHANISM OF ACTION OF THE COVID VACCINES IS DIFFERENT FROM THAT OF TRADITIONAL VACCINES

Dr. Robert Malone has described the vaccine as causing a cytotoxic spike protein to be produced throughout the body for up to 48 hours, with the potential to cause blood clots, inflammation, and permanent scarring. In addition, the spike protein (particularly the S1 segment) could break free of the cell and freely circulate, causing damage which could lead to a very wide range of pulmonary, cardiovascular, and neurological events.

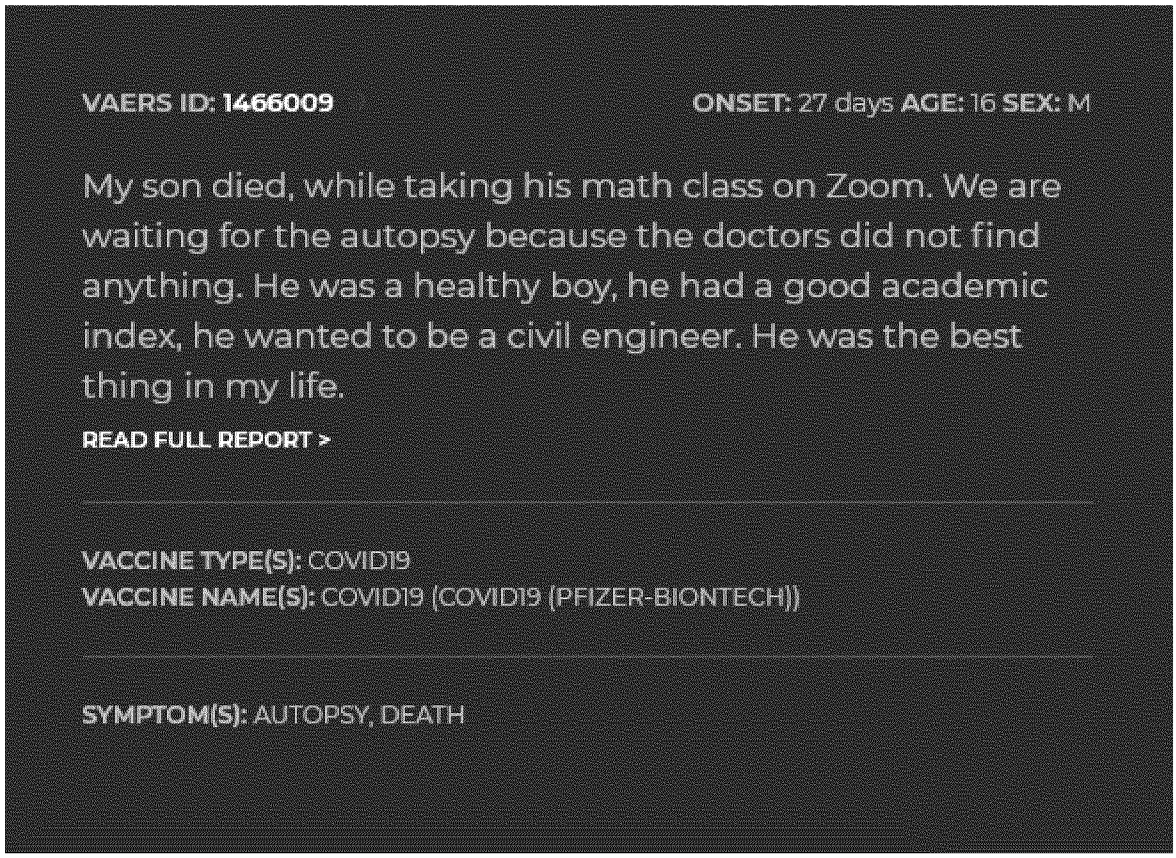
The gene-based vaccines (i.e., the 3 vaccines used in the US today) work in a completely different way than classical vaccines. With the latter, a fixed dose of killed or weakened pathogen or a toxin from the pathogen is injected and this sets a precise upper limit on how much foreign material is administered. In the former, while a fixed dose is also given, the upper limit of how much antigen is expressed depends on a series of steps each with substantial variability. This unavoidably greatly widens the range of amounts and concentrations of toxic spike protein in the body. Compounding this is the variability in anatomical distribution of the product with some body parts more prone to injury than others.

This built-in variability means that gene-based vaccines will likely always be much less safe than a classical vaccine. While the majority of people have no serious adverse events whatsoever, a significant number of people, perhaps in the millions, can be profoundly affected with one or more of a wide range of serious symptoms. Females are nearly 2.5 times as likely to be affected as males.

In particular, the VAERS data shows these symptoms include brain hemorrhages, strokes, heart attacks, multiple organ failure, pulmonary embolisms, and even sudden unexpected death.

A person can be perfectly normal and then just drop dead unexpectedly as the ACIP team already knows through their recent examination of the VAERS records of children 12-17 who died. For example, a 16 year old California student died unexpectedly in the middle of a Zoom math class. He had no prior health problems and appeared completely normal 20 minutes before his death.

If he didn't die from the vaccine, what did he die from?



There is a partial list of the elevated symptoms identified by VAERS analysis in Attachment 2, page 17.

Nearly every cardiovascular and neurological event occurred at a rate that was 10X or more than would be expected to be reported in a typical year by all of the vaccines in that year.

IT IS VITALLY IMPORTANT THAT ALL PHYSICIANS BE EDUCATED ON BOTH THE MECHANISM OF ACTION OF THE VACCINE AND THE RANGE OF SYMPTOMS THAT ARE BEING CAUSED ASAP BECAUSE IT IS COMPROMISING PATIENT CARE

Today, most doctors believe the vaccines are completely safe. There is virtually no knowledge of vaccine symptoms. This causes physicians to treat these symptoms as if they are caused by something other than the vaccine which results in treatments that are ineffective since they are not treating the underlying cause.

Maddie de Garay is a perfect example of this. She will pay the price of preventable misdiagnosis for the rest of her life because physicians were never informed that the vaccines could be causal for her symptoms; the doctors treated Maddie as if symptoms were all in her head.

Angela Wulbrecht who has been a nurse for 23 years in Northern California is another example. She was misdiagnosed by the world's best experts because the CDC never disclosed to anyone that the vaccines are super dangerous and how the vaccines can disable or kill people. She only found relief when she consulted Dr. Bruce Patterson who understood that the vaccines are deadly. She was able to get relief from her symptoms only when she was given drugs that targeted the vaccine damage.

Both of these people are public figures and are willing to speak out if you want to talk to them.

THE PROPER SAFETY TESTS WERE NEVER DONE

The FDA made the mistake of regulating the three COVID vaccines as a vaccine exclusively. As a result, the dose, duration, and amount of spike protein produced by these vaccines were never measured in advance of approval by the FDA.

Today, despite the evidence of unforeseen and unprecedented harm, these three critical parameters are still completely unknown.

Why haven't these tests been done in non-human primates with the actual vaccine?

THE D-DIMER AND CRP BIOMARKERS ARE A SMOKING GUN THAT THESE VACCINES ARE NOT SAFE

Even more concerning is that there has been no attempt to measure biomarkers that could clearly show that these vaccines are causing unexpected harm.

For example, measuring C-Reactive Protein and D-dimer of people before and after vaccination is a very simple experiment to show that the vaccines are causing problems.

Multiple researchers (contact us for the details) have done such a study in hundreds of patients and found that both biomarkers are elevated above normal levels for around three months in over 60% of patients.

This is very serious. It is a smoking gun that indicates that something is very wrong with these vaccines. For example, a 73 year-old female on her second dose had a D-dimer of 1186 ng/mL

(normally it is less than 250 ng/mL) two weeks after the shot. **It remained above normal for three months.**

AN OVER-RELIANCE ON DELEGATED TRUST HAS MAGNIFIED SMALL ERRORS INTO LARGER ERRORS

We live in a world of delegated trust. But if the root of that trust makes a mistake, it creates a ripple effect where the consequences are magnified exponentially.

Our first example of amplified errors due to delegated trust is the safety signal detection of the VAERS database that John Su at the CDC has been monitoring.

The ACIP committee trusts the CDC staff to monitor VAERS. If there is a bug in the monitoring algorithm used by the CDC, the CDC will miss the critical safety signals and the ACIP committee will not be alerted. ACIP members do not have the time or expertise to analyze the VAERS data themselves, as it is not a simple task, requiring many months of dedicated effort using specialized tools. If such a critical safety signal is missed by the CDC, there are immeasurable consequences and harm to the public.

When we looked at the VAERS database, we found dozens of very serious safety signals that the CDC failed to detect.

The attached analysis (see Attachment 2, page 17) shows that every neurological and cardiovascular event that we investigated was strongly elevated as compared to previous vaccines, most by at least 10X and some by as much as 473 times higher than what is normally expected in a typical year across all vaccines. This is impossible to explain if the COVID vaccines are perfectly safe.

We just received a similar analysis from Professor Josh Guetzkow which can be viewed at Attachment 3. In Table 1, for example, death is happening at a rate 91X higher than normal. That sort of increase cannot possibly be explained by “stimulated reporting” or “more people got vaccinations.”

This is independent confirmation that the explanation from the CDC and FDA does not match reality. The ACIP committee is also clueless about this and apparently lacks basic critical thinking skills.

All the evidence has been in plain sight since January 2021, not just in VAERS, but to those practicing doctors, neurologists, and pathologists who were seeing a huge spike in adverse events and deaths and were willing to consider the possibility that the vaccines were not as safe as had been claimed by the CDC and FDA.

In addition, all of the neurological and cardiovascular symptoms with elevated event counts were consistent with the mechanism of action described at the start of this comment. Each and

every symptom we looked at satisfies all the traditional Bradford-Hill causality criteria using both absolute rate elevation compared to baseline rates as well as Dose 1 vs. Dose 2 response disparities.

A BUG IN THE SAFETY SIGNAL ALGORITHM ALLOWS SAFETY SIGNALS TO ESCAPE DETECTION

Why was the CDC oblivious to these same signals? The answer: a bug in the algorithm used by the CDC. This bug only manifests itself when the vaccine being monitored produces a wider than normal range of side effects. This has not been the case with earlier vaccines which is why it wasn't detected earlier.

The bug in the safety signal algorithm is documented in this post: https://roundingtheearth.substack.com/p/defining-away-vaccine-safety-signals-572 (this is Part III, which contains links to Parts I and II). We would be happy to meet with CDC staff to go over this in detail.

WHY ARE YOU IGNORING PEOPLE WHO ARE TRYING TO HELP YOU SPOT SAFETY SIGNALS?

Repeated attempts to inform any ACIP committee member of this anomaly were unsuccessful. Considering that the ACIP committee is tasked with the critical monitoring of safety in the world's single most important drug, we are puzzled by the lack of interest in receiving safety information from qualified researchers. We were directed to submit comments to a non-existent docket number.

Failing to get anyone on the ACIP committee to respond, we next attempted to communicate the signal error to the CBER group at the FDA. Not one person responded, including Dr. Steven A. Anderson and his staff, despite multiple emails and phone calls. Again, we are puzzled by the lack of interest in receiving safety information from qualified researchers. Dr. Anderson had said in a video call that he was the main person responsible for the safety monitoring.

Emails to both John Su and Anne M. Hause were also not responded to.

Perhaps the FDA and CDC should simply let people know that "**if you find an urgent safety problem, don't bother to contact us because we aren't interested in hearing what you have to say.**"

If this were more well known, it would have saved our time and yours.

MYTH BUSTED: "VAERS CANNOT BE USED TO SHOW CAUSALITY"

For the current COVID vaccines, our team is extremely confident that we can meet all the Bradford-Hill criteria for causality using VAERS analysis alone. Will our statisticians and VAERS experts be permitted to meet with any ACIP members to discuss the data?

For example, it is well established that a clear dose dependency relationship can be used to satisfy one of the Bradford-Hill criteria. Because two of the vaccines are multi-dose vaccines, a Dose 1/Dose 2 ratio analysis shows a very clear signal. Sadly, this type of analysis is currently being completely ignored by the CDC.

THE FDA HAS ASSUMED THAT VAERS WAS JUST OVER-REPORTED THIS YEAR

Our second example of amplified errors due to delegated trust is the calculation of the VAERS event counts.

A detailed analysis of the VAERS data (Attachment 2 and Attachment 3) both show that the FDA has made a very serious error in assuming (without any evidence whatsoever as far as we've seen) that the propensity to report to VAERS is much higher this year and that these are simply all background events that can safely be ignored. The two analyses found the same thing and were done by different people, in different countries, who never met. The results were the same.

If the propensity to report is drastically increased, then it should be easy to prove. Randomly survey 100 neurologists and ask them the number of reportable events vs. reports last year vs. this year.

One neurologist told us she had events for 2,000 patients and got so frustrated with the time commitment after making 2 VAERS reports she stopped doing it. Note that she is NOT required by law to report it, only the person who did the vaccination is. So she reported just 1 in 1,000 events.

A physician in Canada said he's only made only 1 vaccine report in the last 29 years. This year he's filed 25 so far.

Other anecdotes we've heard many times from patients is when doctor A talks to doctor B and it goes something like this: Q: "Did you report it to VAERS?" A: "Of course not!"

Most consumers don't know anything about VAERS.

The actual reason VAERS is over-reported this year is because there are so many events to report, a possibility that the FDA never considered.

We are waiting to see the evidence from people claiming that it is overreported. So far, all the evidence and anecdotes we do have shows it isn't.

THE CDC CLAIMS "ANYONE CAN REPORT TO VAERS"

Many people assume that the large number of VAERS reports are due to anti-vaxxers gaming the system. But none of them can provide any evidence whatsoever that that is true. It is a claim that fits the narrative that is done without looking at the data at all. There is no such analysis.

In fact, when you do the analysis of the data, you find that 86% of the reports are consistent with vaccine injury and the other 14% lack enough information in the reports to tell. See the Mclachlan study.

So the evidence shows the opposite. If you make the claim the reports are all fraudulent, you need to show the analysis to back up the claim.

Interestingly, the people who make such claims on no evidence are the same people who demand peer-reviewed research to believe OUR arguments.

It is a federal offense to file a false VAERS report and all reports are screened by HHS (including requesting the medical records) before being published.

We are aware of 2 false VAERS reports in over 1.4M records. So it is true that not everything in VAERS is true, but the number of false reports is small and both of the reporters were referred to the FDA for prosecution.

YOU CAN LEARN A LOT BY TALKING TO A NEUROLOGIST

Some of the things we learned by talking to a neurologist with over 15 years of experience and a 20,000 patient practice are worth keeping in mind:

1. They can't reveal their identity publicly or they would lose their license
2. They can't speak out against the vaccine to their patients or risk loss of license
3. Patient load went up 20X during the vaccine rollout. Never saw anything like it in her career.
4. Over 2,000 patients had serious side effects from the vaccine
5. They only reported 2 to VAERS: it was too frustrating to use; it would crash every 2 minutes and you'd have to start over from scratch.
6. Only the doctor doing the injection must report to VAERS, so they don't have to, so they stopped doing it since it was so cumbersome.
7. Has always known about VAERS, but never need to use it before since never had to report an adverse event!!! This year would have reported all 2,000 patients if VAERS was easier to use. Instead, made just 2 reports (1 of 1,000)
8. Neurologists are now booked up for 3-4 months is typical. At Stanford is 6 months.
9. Most neurologists are clueless on how to treat vax events. Most neurologists don't associate the vax as the cause of the problem. Treatments are useless. When patient goes on Patterson treatment protocol, they can recover back to "normal" in 8 weeks. However, they get no medical training at all on this (because doing so would be an

admission that the vaccines aren't safe) so most people who are vaccine injured remain disabled.
10. At UC Davis, 40% of staff is unvaxed. They have to wait in line twice a week and come in 2.5 hours early to get in line for COVID testing. They endure that because they've seen first hand how bad the vax reactions can be.
11. Long-term impact of the vaccination program: Increase in multiple neurological conditions.
12. For the vaccine injured, the standard blood tests (including all extended testing such as CRP, D-dimer, etc) can all show completely normal. Angela Wulbrecht was given every test under the sun and they were all normal. It was only when she took Patterson's cytokine panel and S-protein tests that showed she was clearly very sick.

FDA FALSE STATEMENT: "DEATHS CAUSED BY THE VACCINE ARE EXTREMELY RARE"

In a letter dated August 23, 2021, Janet Woodcock writes to Senator Johnson, "Reports of death after COVID-19 vaccination that are found to be related, or even possibly related, to vaccination with COVID-19 vaccines have been extremely rare."

Where are the 249 autopsies on which that statement was made? Has the committee reviewed all 249 autopsy reports?

We were able to prove causality using the Bradford-Hill criteria from just the VAERS data alone. We didn't need the autopsies.

It was shocking to us that the CDC and FDA couldn't find these signals despite access to 249 autopsy reports.

There is something seriously wrong here. You cannot have a few excess deaths from the vaccine when both the VAERS database itself and the data from other countries shows that there have to be 150,000 deaths. They both cannot be right. We think the CDC is mistaken because the death data we used to compute the 150,000 deaths comes from 35% of the world's population. This error needs to be corrected as soon as possible.

SYMPTOM CODE FOR A VACCINE DEATH

What is the SYMPTOM code for a vaccine death? We looked at all the VAERS records with autopsies and we couldn't find a single record with a coding for a COVID VACCINE DEATH.

OUR ANALYSIS SHOWS THAT IT IS HIGHLY LIKELY THAT OVER 150,000 PREVIOUSLY HEALTHY AMERICANS HAVE BEEN KILLED BY THE COVID VACCINES IN 2021

The analysis in Attachment 2 shows that 150,000 previously healthy vaccinated Americans have had their lives cut short prematurely due to the vaccines. We confirmed this number using independent methods from independent researchers. We used both US data and data from other countries. Our analysis used data from over 35% of the world's population.

Our results are also consistent with reports from doctors we know who report that they have lost more patients to the vaccine than to COVID. For example, one doctor with 700 patients lost 2 patients to the vaccine and no patients to COVID. These doctors are special because they are "vaccine aware" and understand the mechanisms of action. In another case, one nursing home with 132 beds lost two patients within hours after vaccination.

Unfortunately, most doctors are blind to the association between the COVID vaccines and deaths and if asked, always report 0 vaccine deaths because they believe the narrative that the vaccines are "safe and effective." Any deaths would be anecdotes and ascribed to some other cause. For example, when the fetus of a recently vaccinated pregnant woman had a massive brain hemorrhage, the doctor considered the event caused by a "genetic defect." The vaccine is never even considered as a possible cause.

As far as we know, not a single doctor in the US has determined that any deaths were caused by the COVID vaccines. There isn't even a column in the CDC weekly report for deaths from the COVID vaccine. Apparently, it is impossible to die from the COVID vaccines if you live in the US.

However, a methodology based on excess death analysis (as detailed in Attachment 2) and autopsy results in other countries of people who died after getting the vaccine tells a completely different story: a story of a very deadly vaccine that has likely killed over 150,000 Americans so far.

It has been enormously frustrating to us that the CDC and FDA look the other way and have ignored all our attempts to share our analysis. That is not a good safety practice to ignore qualified people who disagree with you, especially when 150,000 lives are at stake. This is not serving the public interest. Safety must be a top priority at these agencies but when there are deaths from the vaccine, people are simply looking the other way and don't want to hear it. This is why all our attempts to contact people were ignored.

If the CDC or FDA engages with us and finds an error in our analysis and can show evidence that no lives have been lost to the vaccine, then this would do wonders for reducing vaccine hesitancy. Conversely, if the CDC or FDA confirms we are correct, we can immediately stop future loss of life by aborting the vaccination campaign.

Whichever way it ends up, the clarity that happens when both sides engage in an open public discussion of the methods and evidence used will benefit all parties and the public.

THERE IS NO EVIDENCE ANYWHERE OF AN ALL-CAUSE MORBIDITY BENEFIT. WITHOUT THAT, DEPLOYING THESE VACCINES MAKES NO SENSE, ESPECIALLY SINCE SUPERIOR ALTERNATIVES ARE AVAILABLE

When a vaccine class is generating a huge number of adverse events in 8 months that are more than the events from all 70 vaccines over the past 30 years, it is reasonable to assume that there might be a significant safety problem with the vaccine.

In such a case, rather than focusing on the reduction of relative and absolute risk provided by the vaccine, it is instead more important to focus on whether there is a significant reduction in all-cause morbidity.

For the three vaccines, using data from the original clinical trials, it has been shown that in all cases, **the all-cause morbidity is significantly elevated by all the vaccines**. The elevation ranges from 1.5X to 4.2X. That is a **large move in the wrong direction.** It is **highly statistically significant** for all three vaccines. This of course is consistent with what we find in VAERS.

With respect to efficacy, nobody argues that the vaccines have saved people from dying from COVID. But the problem is that this benefit comes at a steep cost: an increase in death from other causes that completely negates the benefit of the reduction in COVID-related deaths.

But could an all-cause mortality benefit compensate for the higher all-cause morbidity? Our best data on that is the Pfizer 6-month study. A 50% reduction in COVID deaths was more than offset by a four times higher rate of cardiac arrest. As a result, the all cause mortality rate was higher in the treatment group than in the placebo group. This was true in **both** the pre-unblinding and post-unblinding phases. **The numbers were small but the point is that there is no demonstrable all-cause mortality benefit. Zero. If anything it was the other way around.**

As evidenced by the high number of severe adverse events reported to the VAERS system, it is the all-cause morbidity statistic that is the new elephant in the room. If you can't show a lower all-cause morbidity, there is no reason to vaccinate.

For the three vaccines, using data from the original clinical trials, it has been shown in the peer-reviewed literature that in all cases, the all-cause morbidity is significantly elevated. The elevation ranges from 1.5X to 4.2X. That is a large move in the wrong direction. It is highly statistically significant for all three vaccines. This of course is consistent with what we find in VAERS.

THE VACCINES KILL MORE PEOPLE THAN THEY SAVE (3 INDEPENDENT SOURCES)

We also have troubling anecdotes like the nursing home with 136 beds where all the residents were given the booster just before September 1 and now 4 of them are dead and 7 hospitalized as a result. We are keeping the nursing home secret for now to protect our whistleblower.

This is a 3% death rate from the vaccine. We only found out about this through an insider. The media never covers this because they don't want to panic the public reporting on an anecdote that would dissuade people from taking the safe and effective vaccine.

Let's compare this to the expected COVID deaths (without a vaccine). Using 156 deaths per million in US for 65+, we'd expect to see **1 COVID death per year** among that population of 136 (assuming all the beds were filled). But the rates might be higher for nursing homes, but the rates of COVID are lower today due to all the vaccinations so that's probably a wash.

So if the vaccines remain 100% effective for an entire year, over a 1 year period **we are killing 4 elderly per COVID case saved**. This is not a good tradeoff.

But it's even worse: 7 people got hospitalized. Some of those may die shortly or have their lives cut short.

Thanks to a courageous whistleblower Abrien Aguirre we can confirm the death toll from the nursing home. Aguirre said that they had 32 vaccine deaths vs. 16 virus deaths. In other words, the vaccine has killed **twice as many people as the virus** in the very setting that the vaccine is supposed to be the most beneficial.

So in both cases, the vaccine is killing more people than COVID (4:1 and 2:1).

This is why **all the nursing homes keep all this information secret so the public never knows about it**. Each nursing home thinks they are simply an unfortunate anecdote, where the reality is that their numbers are normal for this vaccine. If you try to call the homes directly, they won't talk. Nobody returns your calls. **So nobody ever finds out.**

What makes those two anecdotes interesting is that the whistleblowers understand how the vaccines kill. **Most other nursing homes don't make the connection and will tell you that no one has died from the vaccine (they'd just say they died from natural causes)**.

Since the vaccine can also kill you over a 3 month period, they simply assume that the patient died from natural causes (like a massive heart attack or just "died") and it just "happened" that a lot of deaths coincidentally happened around vaccination time, but nobody is doing the statistical calculation.

And since most nursing homes are small, a 3% death rate looks like "natural causes."

Was he lying? What was his motivation? Aguirre basically put all his income on the line. For what? His reward: Aguirre was fired for telling the truth. This is exactly why people at nursing homes will not say anything. Here is the follow-up video.

There is only punishment if you tell the truth. This is why the nursing home whistleblower isn't identifying himself/herself.

Neither nursing homes would talk about the correct data. Why wouldn't they correct the data if it is wrong? **Why are they hiding in the shadows?**

But you don't have to believe these anecdotes. Another story just came out based on UK data:

The Covid-19 Vaccines have killed more people in 8 months than Covid-19 has killed in 18 months

by Daily Expose

And another commenter to ACIP had similar numbers using yet another approach.

So if you have different data that shows the opposite, we'd love to see it! So we have three independent sources now showing the vaccines are deadlier than the virus.

NOBODY WANTS TO TALK ON THE RECORD FOR FEAR OF LOSING THEIR JOB

One of my vaccine injured friends said the head anaesthesiologist at one of the world's top medical schools said "he wasn't willing to put it in writing" that it was caused by the vaccine because it would affect his reputation. However, his medical assistant was willing to put it in writing and sacrifice her career. My friend was told his symptoms would get worse over time. He's 39 years old and his life was ruined by the vaccine and nobody wants to end their career to speak out.

One of the top neurologists in my area (over 20,000 patients) won't talk publicly.

I talked to a medical examiner who didn't even feel comfortable sharing her name with me, but revealed autopsies are useless.

Basically everyone who could talk won't. They can't speak out publicly or they will lose their license.

They could speak to a reporter and talk without their names being disclosed, but no mainstream media would run the story, so there is no point. Reporters at top newspapers cannot get their stories run. *60 Minutes* won't touch the story either.

MEDICAL EXAMINER SAYS AUTOPSIES ARE USELESS, VAERS IS THE GOLD STANDARD FOR CAUSALITY

We were only able to find one medical examiner who would talk to us. Even then, she wouldn't reveal her last name or state.

Here are the key points:

- She is the only ME in her state looking at vaccine-related deaths. The other ME's all assume the vaccines are safe so never will implicate the vaccine.
- The ME's in general don't have the skills, they don't have the proper tests to determine causality for deaths caused by this vaccine (they don't exist in the post-mortem setting), they don't have the time, they don't have the medical records, and they get the body too late. They can see large blood clots of course
- THEY CAN'T EVEN ORDER A D-DIMER because they are told "well that's not generally done" so unless they fight for it, they simply give up.
- They even get a huge push back when asking for the medical records.
- Often, they don't even know the vax status or when the patient was vaccinated.
- She had to personally make a call to the family to determine whether a patient got vaccinated.
- THIS IS WHY the ME's cannot make the connection in the autopsy setting.
- She trusts VAERS way more than autopsy....says **NOBODY** is going to find this post-mortem
- She never had time to report any of her deaths in VAERS.... the ME's are overloaded with some cases from 6 months ago still not completed.
- She was operating today on 3 hours sleep. They are understaffed and overworked. It's exhausting.
- For vax deaths, she said autopsies are NOT the gold standard. It is VAERS.

CALCULATION OF REDUCED LIFESPAN

It is difficult to make a tradeoff between the elevated morbidity that reduces lifespan and the number of COVID deaths saved.

The COVID vaccines introduce both morbidity and mortality risks.

What ACIP has done is compare morbidity due to the vaccine vs. the same morbidity from COVID. That can be problematic if some some morbidities are improved and some are made worse. We'd have to look at all morbidities, something that ACIP hasn't done since they haven't seen the safety signals.

We believe that if we just look at the increased mortality due to the 1) direct deaths caused by the vaccine and 2) the reduction in total lifespan from all serious adverse events elevated by the vaccine, it would be clear that there is no mortality benefit.

We can see that from the Pfizer Phase 3 6 month study where more people in the treatment group died both pre- and post-unblinding. The Hawaii nursing home data is consistent: there was a 2:1 vaccine caused death:max possible vaccine saved death ratio which also supports stopping the vaccine.

Therefore, it seems likely to us that not only is there no morbidity benefit from the vaccines, but there is no all-cause mortality benefit from the vaccines either.

This makes the vaccines very hard to justify.

If we are wrong, we'd like to see the analysis.

WE ESTIMATE THAT APPROXIMATELY 574 KIDS HAVE BEEN KILLED BY THE VACCINE SO FAR; THAT'S MORE THAN HAVE DIED FROM COVID. WE ARE MAKING A HUGE MISTAKE. WE ARE KILLING OUR KIDS, NOT SAVING THEM.

The ACIP committee recently analyzed the cause of death of the 14 kids (aged 12 to 17) whose fatalities were recorded in the VAERS system. Had they had the table in the attached document, they would have realized that in every case (where there was sufficient symptom detail), the main cause of death was consistent with a symptom that was strongly elevated by the COVID19 vaccines. This should have led to a different outcome Mortality Among Teenagers Aged 12-19 Years: United States, 1999-2006 than simply listing the causes of death of the kids with no further discussion. No concern over the lack of autopsies was noted in the meeting notes. It is very likely that none of the kids had an autopsy done. There was no mention of this in the report.

We believe the lack of autopsies is a huge oversight for a vaccine that is generating so many legitimate adverse events. We believe it is imperative for the ACIP committee to immediately demand that autopsies be done. How many more kids must die before we look to find the real cause of death?

These children are dead now and their lives can never be recovered. But we can learn from their death if the ACIP committee members would simply read the 14 VAERS reports on each child and compare the cause of death with the symptoms listed in the table in the attached paper.

Five kids dying from cardiac arrest is not normal. Kids between 12 and 17 are twice as likely to die from cancer (6%) as from heart disease (3%). In this case, 38% died from heart disease and 0% died from cancer. That's statistically very unlikely. It points to the undeniable fact that these kids did not die of natural causes. Therefore, the hypothesis that the vaccines are safe seems highly unlikely. How does the ACIP panel explain this?

One of the children died with an intracranial hemorrhage. How could that have not raised a huge red flag. Kids that age never die from an intracranial hemorrhage.

We did a search in VAERS searching every record, over 70 vaccines over the last 30 years. There were only two deaths of kids aged 12-17 with "HAEMORRHAGE INTRACRANIAL" in the history of VAERS and both were associated with the recently approved Pfizer vaccine. There weren't any deaths caused by an intracranial hemorrhage in the entire history of VAERS in that age range until the COVID vaccines arrived on the scene. One event could be written off as a fluke--- very bad luck. But two events are a complete train wreck. How this didn't raise any red flags in the ACIP committee is a mystery to us.

As this note is being written the BBC News just reported that BBC presenter Lisa Shaw died of a brain haemorrhage. The coroner determined the cause was the COVID vaccine. All of the causal factors in her death were consistent with the elevated symptoms we found in VAERS. Note that the Astra-Zeneca vaccine has a nearly identical mechanism of action as the mRNA vaccines.

Each of the 14 children who died in the CDC study represents 41*14=574 real deaths (as noted in the attached paper). Thus, more American kids have already been killed by the COVID vaccines than have been killed in the entire history of COVID to date (361). That's tragic.

Two of the kids died from a pulmonary embolism, a symptom that is very strongly caused by the vaccines. Over 5 years in VAERS, you'll find just one PE death in that age range. So to get one PE death in a year, that's bad luck. To get two, you have to at least say that it's more likely than not that it wasn't just random. Yet the CDC report dismissed it without comment.

AN ACCURATE MYOCARDITIS COST-BENEFIT ANALYSIS IS MISSING

The CDC myocarditis cost-benefit analysis omitted the determination of the VAERS under-reporting factor for "mild" events.

While we think myocarditis is a serious event, the CDC characterizes these events as "mild" and thus would be less likely to be reported than something "severe" like death.

Therefore, we'd estimate that the VAERS under-reporting of such an event might be somewhere around a factor of 100.

My question to the panel is whether **a 100 times greater rate than the rate reported in the report would make a difference in the recommendation of the ACIP panel?** We would be very surprised if this doesn't change the recommendation.

Also, as a sanity check on our results, please refer to Table 1 in Attachment3 which is Joshua Guetzkow's analysis showing a 91-fold increase over baseline myocarditis rates.

Also, it would be good to estimate the effect of this heart damage **(and all other conditions elevated by the vaccines)** on expected lifespan so it is clear that the shortened lifespan is worth the savings in the amount of deaths. This way, we can do a pure mortality tradeoff.

For a lot of AEs, the quality adjusted life years (QALYs) is not significant. For young people, myocarditis represents an enormous QALY calculation. This will include some deaths, but most of a lifetime of a large range of reduction of life value.

For public health officials to discard the data without acknowledging something like a QALY comparison (and the deaths) is inappropriate.

TRUSTING THE PHASE 3 TRIAL RESULTS AS THE "GOLD STANDARD" IS NOT A GOOD IDEA

When there is a disagreement between real-world results and the Phase 3 clinical trial, we think it is better to trust reality. Here are some of our reasons:

1. The paralysis of Maddie de Garay was not reported in the Pfizer 12-15 year old clinical trial, and the FDA failed to investigate this case even though they knew about it. This is serious misconduct happening and nobody is holding the FDA accountable.
2. Adverse events were difficult to impossible to report (and Facebook conveniently removed the evidence of people complaining about that)
3. At least one death that happened didn't show up. Who knows how many more?
4. The cohorts were not representative of the population as a whole (they were much healthier, e.g., rate of heart attacks was 10X lower than the overall population rate)
5. Five times as many people were disqualified from the treatment arm (311) compared to the control arm (61) for protocol violations even though the trial was supposed to be double blind.
6. Read this article on the Pfizer consent form. The consent form allows for participants who need emergency care and go straight to their doctor or hospital to be ejected from the study. But that's hardly the only problem.
7. Pfizer paid one of the largest criminal fines ever imposed on a drug company for the arthritis drug Bextra.
8. The company can't seem to find any safety signals even though it is obvious in VAERS.
9. **No autopsies were done to determine the cause of death were done in the treatment group**. This was a **very serious** oversight in our opinion. Nobody on the FDA or ACIP panel seemed to think this was a problem.
10. The death rates make no sense. We know of a 132 bed nursing home that had 2 deaths within hours of getting the vaccine. And a larger nursing home in Hawaii with over 500 beds had 32 deaths after vaccination. The numbers don't match each other, but they are nowhere close to what was reported in the clinical trials which again suggests the cohorts were not representative of the population or that the company didn't find the deaths or both.

THE LACK OF AUTOPSIES IS INEXPLICABLE

Autopsies are the gold standard for determining causality. But for these vaccines, it's very tricky; you have to have the right skills and the right tests to make a proper diagnosis. Most medical examiners lack both.

How can the CDC say confidently that there have only been a few deaths? May we see the 249 autopsies? If not, why not?

In Germany, soon after the vaccines rolled out and deaths after vaccination started happening, the Federal Association of German Pathologists called upon the German authorities to require autopsies to validate the cause. Their requests were ignored presumably because nobody wants to know the answer.

In America, few people are asking for autopsies. And when they do, they are being denied

If we had the autopsies available, we wouldn't have to debate whether we are right or wrong about the numbers of deaths -- we'd have the data.

The Norwegian Medicines Agency linked 13 deaths to vaccine side effects. At the time that article was published, there were only 13 assessments completed. So in 100% of the cases, the deaths were deemed to be caused by the vaccine by the official government agency.

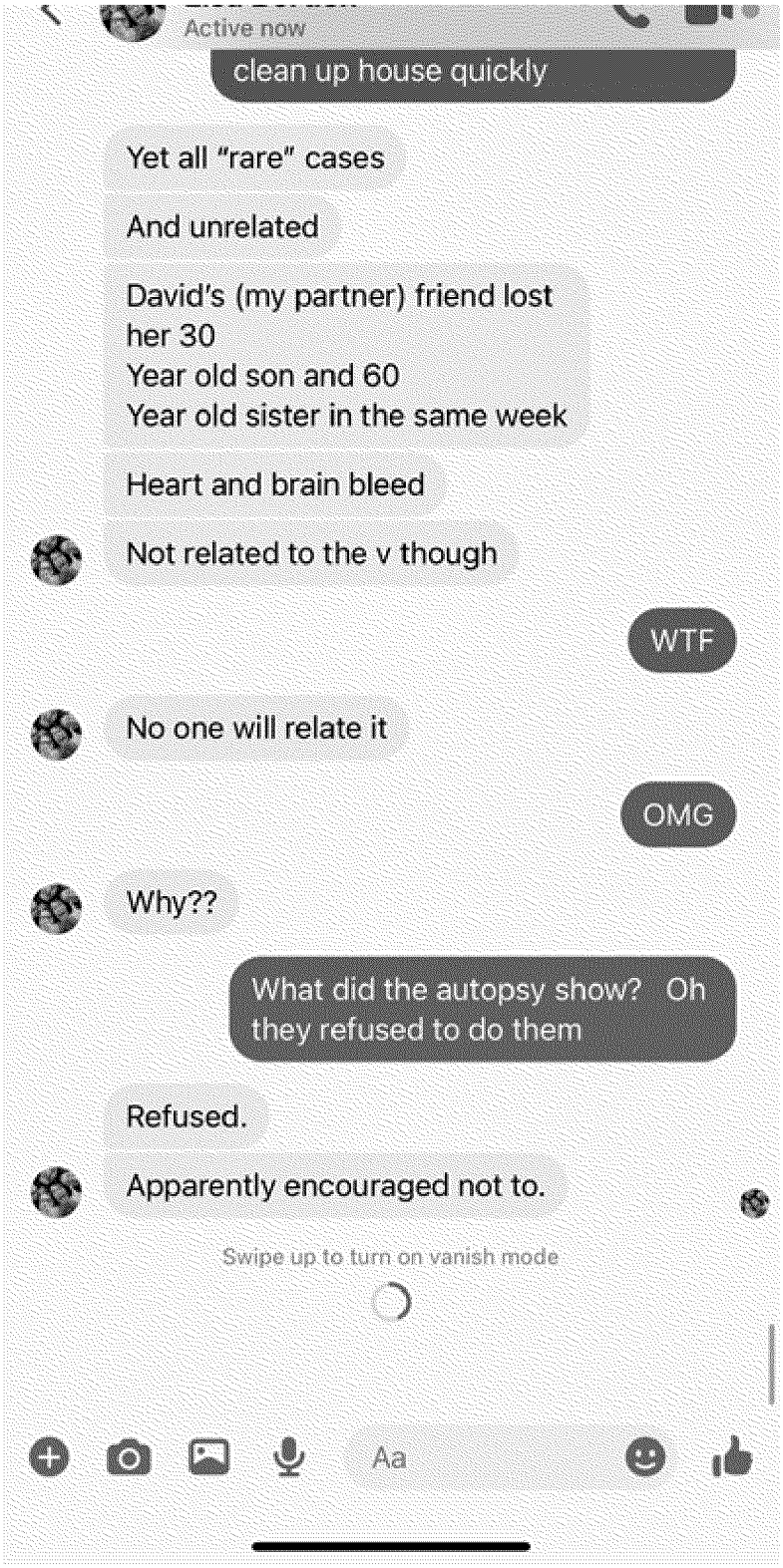
In Germany, they actually did autopsies of 40 people who died within 2 weeks after vaccination. They determined that at least 30% to 40% really did die from the vaccine. From Media Blackout: Renowned German Pathologist's Vaccine Autopsy Data is Shocking... and Being Censored:

> Dr. Peter Schirmacher is not just an average pathologist. The German doctor is world-renowned in his field, honored by The Pathologist as one of the 100 most influential in the world. He is the acting chairman of the German Society of Pathology, director of the Institute of Pathology at Heidelberg University Hospital, and president of the German Association for the Study of the Liver. Bottom line, this professor and doctor understands pathology like very few on the planet.

It is puzzling to us that nobody on the ACIP committee is calling for mandatory autopsies. Only 249 have been done on the 11,000 people who have died. It would be nice to know what they said.

Does ACIP think we should not have autopsies? I think it is important to clarify the committee's opinion on whether we should have the data on why people are dying after the vaccine or whether ACIP would rather have coroners look the other way.

Right now, it seems to be difficult to have an autopsy done, so if you want to gather the data, I think it is important to say something rather than remain silent on this issue.



IT IS BECOMING CLEAR THAT THE VACCINES ARE RAPIDLY BECOMING LESS EFFECTIVE

As far as effectiveness, we believe the recent paper from a team of Japanese researchers, "The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines" shows that the vaccines we received will soon become completely useless to protect us and, to make matters worse, are already enhancing the ability of current variants to infect us through **vaccine enhanced infection and/or replication** (rather than "classical ADE" which so far appears not to be happening).

From the abstract:

> Although Pfizer-BioNTech BNT162b2-immune sera neutralized the Delta variant, when four common mutations were introduced into the receptor binding domain (RBD) of the Delta variant (Delta 4+), some BNT162b2-immune sera lost neutralizing activity and **enhanced the infectivity.**

In short, even if the vaccine were perfectly safe and killed no one, vaccinating with a non-sterilizing vaccine in the middle of a pandemic is going to have a net negative benefit, exactly as Geert Vanden Bossche has been trying to tell the world since shortly after the vaccination program began. He called it a very serious mistake. Nobody in power listened.

The latest UK government data (Briefing #20), shows you are 57% more likely to die if you get delta and you are vaccinated than if you are unvaccinated. The computation for age<50 and fully vaxed vs. unvaxed is 13/48*147612/25536=1.57 which is consistent with the Japanese paper.

Therefore, not only are the vaccines not safe, but they are quickly becoming useless and may shortly be a liability as far as effectiveness is concerned.

EARLY TREATMENTS HAVE ALWAYS BEEN THE SAFER, MORE EFFECTIVE OPTION

Meanwhile, early treatments have been virtually ignored by mainstream academia and the NIH. Lack of suitable guidance from the NIH has caused the entire world to avoid early treatments. These treatments are both extremely safe and very effective. They work against all variants as well. For example, the protocols used by George Fareed and Bryan Tyson against COVID continue to work well against COVID and with over 6,000 patients treated in an area with one of the highest CFRs in the country, it is very rare for a patient to be hospitalized for COVID in their clinic; it only happens if the patient presents late. They have more than a 99% relative risk reduction against all COVID variants if the patients get treated early. The NIH has expressed no interest in trying to replicate this success despite the tremendous lifesaving potential and negligible risk. They are more interested in waiting for a new, unproven drug from Merck for treatment.

EARLY TREATMENTS HAVE BEEN CENSORED. NOBODY IN MEDICINE SEEMS TO MIND.

One of the earliest pioneers of early treatment, George Fareed, is banned for life from YouTube for trying to spread life-saving treatment protocols that work..

The Nobel Prize winning inventor of ivermectin, Dr. Satoshi Omura, had his video on ivermectin for COVID blocked on YouTube.

Ivermectin has several systematic reviews and meta-analyses showing that it works; the highest level of evidence in evidence-based medicine. But since this competes with the vaccine, everyone is instructed to ignore evidence-based medicine and replace it with the lowest level of evidence: expert opinion (e.g., from an agency).

In short, no matter what level of evidence you pass, it is not enough if it goes against the political false narrative.

We find it troubling that so few in the medical community are speaking out about such abuses.

These individuals are giving life-saving advice and have been censored and there are dozens of examples of many others that have been censored, banned for life, and/or demonetized.

It would be interesting to hear the ACIP members speak out on this subject, either endorsing the censorship or condemning it. Remaining silent on such an important issue will not help advance science and save lives. Normally, ACIP shouldn't have to do this, but everyone else is remaining silent.

THE UK SAID THE VACCINE IS NOT RECOMMENDED FOR THOSE < 18 YEARS OLD

The UK panel said the data doesn't justify vaccination of those under 18

Jul 19: UK opts not to vaccinate most under 18 against COVID-19

Then they changed their minds just 2 weeks later:

Aug 4: UK to roll out COVID-19 vaccines to 16 and 17-year-olds

Did the science really change that quickly? What new things were learned? Or is science being driven by politics which would be a new low point. If there was new science, it would be useful for everyone to know what it was.

16% NEVER CAME BACK FOR A SECOND SHOT. WHY?

62% of Americans are vaccinated vs. 52% who are fully vaccinated. So that's 16% (52/62=.84) that never came back for a second shot

Why is there such a large gap when in order to do anything (like keep your job, go to school, etc) you need to be fully vaccinated?

We understand why people don't get vaccinated at all (they are well informed). But what's the reason for the 16% gap?

We know from user surveys that 3% of people who took the vaccine required treatment by a doctor. And 5% are still suffering from side effects. So that explains half of the gap. Basically 8% of people who got the vaccine had a large enough bad first experience, they aren't going back for a second shot. This leaves 8% unexplained, but likely due to a bad first reaction.

We think that 12M injured Americans is a lot of people especially in light of the lack of an all cause mortality benefit and a clear lack of all-cause morbidity benefit. That's a lot of people who have been injured for no proven net benefit (yes, COVID lives were saved, but it was an overall cost of lives). But that's just our opinion.

SUMMARY

Analysis of multiple researchers using different sources confirms that the current COVID vaccines are very dangerous and are significantly increasing all-cause morbidity. The vaccines can trigger a wide range of serious neurological and cardiovascular symptoms, re-activate latent viruses, trigger flare-ups in people with cancer, and more. Multiple studies show 60% of patients have elevated D-dimers that persist for 3 months after vaccination.

These vaccines should be immediately halted. If they cannot be halted, then it is imperative that we inform the American public of the risks. Children, pregnant women, and previously infected people should be instructed to avoid vaccination. All vaccine mandates should end immediately until there is scientific proof of an all-cause morbidity and mortality benefit.

The censorship and intimidation of experts with dissenting opinions must end. You cannot speak the truth anymore on any social media platform without being blocked, banned, and/or demonetized. Pharmacies are allowed to not fill prescriptions on drugs and dosages that are proven to work in dozens of clinical trials: they can make these decisions without scientific evidence in support of their positions. They are not held accountable for their decisions.

Early treatment has always been a superior strategy for treating COVID: it is safer, more effective, and has a number of other important benefits. But it is being deliberately suppressed despite passing normal scientific milestones including large, well done Phase 3 trials and systematic reviews. Trials of ivermectin are being done by NIH that deliberately underdose the drug in order to prove to the world that it doesn't work.

Virtually none of the people diagnosed with COVID in the hospital today were treated early with a “proven in clinical practice” early treatment protocol. That is the message we should be sending to America.

VOTE OF THE ACIP COMMITTEE WAS 14-0 IN FAVOR OF APPROVAL

They said they are there to protect the health of the public.

As far as we can tell, no member of the ACIP committee read this note or any of the other public comments submitted prior to the vote. So this comment didn't matter. The public comments portal is just to placate the public.

There was no mention of early treatment as an alternative to vaccination.

This suggests to us that the committee is not interested in hearing from qualified people who disagree.

The data they presented was just one side of the story.

I loved how the slides showing bad data were left on the screen for like 2 seconds. And when the rate of severe adverse events was 10% vs. 2% for placebo, they just didn't discuss that at all!

My favorite was Dr. Grace Lee's presentation (VaST). Look at slide 18 which is from Safety of the BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Setting (published in NEJM). It showed that the vaccines **reduce your risk** for pulmonary embolisms (PE) and intracranial hemorrhage (IH) compared to baseline pretreatment (the dotted line). Which is very interesting because our VAERS analysis (and the mechanism of action of the vaccine) showed the PE rates were off the charts. Anyone with a basic understanding of the mechanism of action of the vaccine and basic medicine would say there is no way PE can be reduced. However, nobody on the committee flagged this.

But PE risk is very very important. But our chart showed PE rates were elevated by 473 times. It was the most extreme event we saw in VAERS that was elevated.

To validate our results, the CDC itself found that two of the 14 kids (12-17 year old) died from PE and two from intracranial hemorrhage. What? According to the figure Dr. Lee presented, those two SAEs are both reduced by the vax. Yet based on our analysis, PE is 473X and IH is 42X more likely than baseline.

So this is a stunning divergence of reality vs. data presented to ACIP. And the death data is consistent with our VAERS analysis of SAE rates, and is not consistent with the clinical trial findings and the NEJM paper.

This is an objective example of how the data that they used to make the recommendation diverges from VAERS and nobody was interested in resolving the inconsistency. We got it right, but our data was never shown since it isn't published.

From OpenVAERS search, we got 5164 PE events so 1411 events per million with 41X underreporting. The normal rate of PE is 0.39 per million. So this is an elevation of **3,617X from normal** if we compare with the baseline incidence rate.

The science says only one hypothesis fits the facts: the vax is safe or it isn't.

Here's a table pulmonary embolism to help you decide which hypothesis is a better fit to the facts:

	Safe hypothesis	Not safe hypothesis
Mechanism of action	x	✔
VAERS data is elevated by 473	x	✔
VAERS data is 3,617 above normal	x	✔
Studies of >100 people show elevated D-dimer in over 60% for 3 months	x	✔
2 of the 14 kids died from PE	x	✔
2 of the 14 kids died from IH	x	✔

The point is that if you look for the hypothesis that is consistent with what is measured and observed, there is only one hypothesis that fits the data. That's how science is supposed to work.

Today, science is about dropping critical thinking on the floor, censoring or ignoring qualified experts who disagree, and finding ways to support the mainstream political narrative. It is fitting the data to match the politics.

If ivermectin has a systematic review and meta-analysis published in a peer-reviewed journal, the NIH simply ignores the recommendation and pharmacies refuse to fill prescriptions. If NAC has caused no harm over 60 years, the FDA pulls it from the shelves and makes it prescription only while at the same time taking a vaccine which has killed over 200,000 people and making it available without a prescription and without warnings of just how deadly and/or disabling it is.

It's very sad how quickly the wheels have come off the science bus.

OUR TEAM OF EXPERTS

1. **Dr. Robert Malone**, widely recognized as the inventor of the mRNA vaccine. He immediately recognized the dangers of the current vaccines when the biodistribution data was revealed after a FOIA request. He was one of the first people to go on record warning the world about vaccine enhanced infection and replication.
2. **Dr. Geert Vanden Bossche**, one of the few virologists in the world to warn the world about vaccinating with a non-sterilizing vaccine against a virus capable of mutation in the middle of a pandemic.
3. **Dr. Byram Bridle,** a highly respected viral immunologist at University of Guelph, did the FOIA request that exposed the biodistribution data showing the vaccines do not stay at the injection site like people thought, but instead cause the production of a toxin in all parts of the body including the brain.
4. **Dr. Peter McCullough**, Professor of Medicine, is the author of over 1,000 peer reviewed publications, He serves as editor of two journals and sits on the editorial boards of multiple specialty journals.
5. **Dr. Ryan Cole,** one of the few pathologists who has been unafraid to speak out.
6. **Dr. Bret Weinstein** host of the DarkHorse podcast, expert in evolutionary biology.
7. **Dr. Chris Martenson,** pathologist and host of Peak Prosperity on YouTube. Chris's videos on YouTube are the most insightful videos about the virus and the vaccines.
8. **Dr. Pierre Kory** is our ivermectin expert, and one of our experts on early treatment.
9. **Dr. Paul Alexander** has expertise in the teaching of epidemiology (clinical epidemiology), evidence-based medicine, and research methodology. He is a former professor at McMaster University in evidence-based medicine; former COVID pandemic advisor to WHO-PAHO in Washington, D.C. (2020); and a former senior advisor on COVID pandemic policy at the U.S. government's Department of Health and Human Services (HHS) in Washington, D.C.
10. **Dr. Ira Bernstein**, a physician in Canada. Bernstein replicated Hoffe's D-dimer test which is extremely frightening.
11. **Dr. Jessica Rose** is an expert on the VAERS system. Her YouTube video on VAERS have never been challenged. She has a published paper on VAERS with several more on the way.
12. **Dr. Meryl Nass,** is a physician and VAERS expert.
13. **Dr. Sin Hang Lee,** an expert on DNA sequencing.
14. **Mathew Crawford**, is a mathematician and statistician who writes frequently about the pandemic including two articles on a serious CDC math error that no other person had noticed (Part I and Part II)
15. **Dr. Charles Hoffe**, is a physician in Canada.
16. **Marc Girardot**, is a member of PANDA. https://www.pandata.org/team/. PANDA is a politically and economically independent organization, focused on science-based explanations and tests them against international data. Marc has published extensively on the pandemic.

17. **Dr. George Fareed,** a physician in southern California who developed an extremely effective protocol for treating COVID-19 infections with a 99.76% risk reduction which is far more effective and safer than any vaccine
18. **Tyson Gabriel** is our mask expert. He produced this 1 hour instructional video. Nobody wants to challenge him to a debate on mask wearing.
19. **Stephanie Seneff**, senior research scientist at MIT. Although her field is computer science, she has an amazing breadth of knowledge in biology.
20. **Aditi Bhargava,** Professor, ObGyn and CRS, UCSF.

FDA response

Dear Mr. Kirsch,

While your email was not directly addressed to FDA, we would like to note that we do not agree with the analysis put forth in your comment, as we believe the data from VAERS that you reference were not properly interpreted. This is due to the limitations of VAERS itself, as well as limitations regarding certain private patient information that is not available to individuals outside of the FDA and CDC, as we noted in our correspondence to you dated July 27, 2021.

FDA and CDC have multiple systems in place to monitor the safety of COVID-19 vaccines, including VAERS. We continue to find that the COVID-19 vaccines have a favorable benefit-risk profile, supporting their use under Emergency Use Authorization. Additionally, FDA's approval last week of Comirnaty (COVID-19 Vaccine, mRNA) followed a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

Sincerely,

Lorrie H. McNeill

Director
Office of Communication, Outreach and Development

My response to the FDA

Lorrie,

Thanks. As promised, I will include your response in my comment so people can see your point of view.

It appears you did not read the material carefully. As we pointed out, the VAERS estimate we did was CONFIRMED with several other methods from independent researchers who used data outside the US and found the same numbers. Even with a $1M bug bounty, nobody found an error.

Since you didn't like our analysis, perhaps you can show us YOUR analysis of the excess deaths in VAERS so we will show you the flaws in that analysis. We'd love to see your calculation of the "correct" propensity to report, the under-reporting factor used, and the subtraction of the background deaths.

Just today, I was talking with a physician, and he said he's made one adverse event report in the last 29 years. This year alone, he's made 25. I asked him why and he said, "well I've only ever seen one thing in the past 29 years that I've need to report."

I talked to a top neurologist who gave up on VAERS after filing 2 reports. She had 2,000 patients she wanted to report on. So that's an under-reporting rate of 1,000X, and all of these 2,000 were serious.

And 2 days ago, I heard about a nursing home with 136 beds. They all got boosters. 4 died, 7 hospitalized. So we ***could*** be killing 4 people to save 1 person a year from COVID.

The point is this: ALL the evidence ***we*** have access to disagrees with the evidence ***you*** have access to.

One of us is right, one of us is wrong.

Can we meet with anyone at FDA so we can resolve the conflict?

This is important to resolve for the public. Peter Doshi and Daniel O'Connor will be happy to cover this so we can inform the public as well of the result of our discussions.

-steve

Attachments

Estimating the number of COVID vaccine deaths in America
This document uses VAERS to estimate the total number of excess deaths caused by the vaccines. This estimate is validated using multiple other methods.

There is also a table of elevated adverse events showing the pulmonary embolism is elevated by 473 times above baseline (typical VAERS year).

Adverse Events Reported Following COVID-19 Vaccinations
This research by Professor Josh Guetzkow is an independent confirmation of two of the factors we found in our analysis:

1. VAERS isn't being "over reported" this year as the FDA and CDC have falsely claimed due to greater "awareness" and propensity to report
2. VAERS isn't be over-reported this year due to the number of vaccinations

From: Steve Kirsch [stk@skirsch.com]
Sent: 9/2/2021 5:34:19 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
CC: Su, John (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4241352c8141e8a2760a441cf9182b-HHS-ezu2-cd]; (b) (6) Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Scott, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91620658ce0243e38241d198be1a5461-ScottJ]; Walderhaug, Mark O [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14515448efee47098c38798d5c409b02-MWALDERH]; (b) (6)
Subject: RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

Lorrie,

Thanks. As promised, I will include your response in my comment so people can see your point of view.

It appears you did not read the material carefully. As we pointed out, the VAERS estimate we did was CONFIRMED with several other methods from independent researchers who used data outside the US and found the same numbers. Even with $1M bug bounty, nobody found an error.

Since you didn't like our analysis, perhaps you can show us YOUR analysis of the excess deaths in VAERS so we will show you the flaws in that analysis. We'd love to see your calculation of the "correct" propensity to report, the under-reporting factor used, and the subtraction of the background deaths.

Just today, I was talking with a physician, and he said he's made one adverse event report in the last 29 years. This year alone, he's made 25. I asked him why and he said, "well I've only ever seen one thing in the past 29 years that I've need to report."

I talked to a top neurologist who gave up on VAERS after filing 2 reports. She had 2,000 patients she wanted to report on. So that's an under-reporting rate of 1,000X, and all of these 2,000 were serious.

And 2 days ago, I heard about a nursing home with 136 beds. They all got boosters. 4 died, 7 hospitalized. So we ***could*** be killing 4 people to save 1 person a year from COVID.

The point is this: ALL the evidence ***we*** have access to disagrees with the evidence ***you*** have access to.

One of us is right, one of us is wrong.

Can we meet with anyone at FDA so we can resolve the conflict?

This is important to resolve for the public. Peter Doshi and Daniel O'Connor will be happy to cover this so we can inform the public as well of the result of our discussions.

-steve

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Thursday, September 2, 2021 1:27 PM
To: Steve Kirsch <stk@skirsch.com>
Cc: Su, John (CDC) <ezu2@cdc.gov>; (b) (6) Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6) (b) (6)
Subject: RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

Dear Mr. Kirsch,

While your email was not directly addressed to FDA, we would like to note that we do not agree with the analysis put forth in your comment, as we believe the data from VAERS that you reference were not properly interpreted. This is due to the limitations of VAERS itself, as well as limitations regarding certain private patient information that is not available to individuals outside of the FDA and CDC, as we noted in our correspondence to you dated July 27, 2021.

FDA and CDC have multiple systems in place to monitor the safety of COVID-19 vaccines, including VAERS. We continue to find that the COVID-19 vaccines have a favorable benefit-risk profile, supporting their use under Emergency Use Authorization. Additionally, FDA's approval last week of Comirnaty (COVID-19 Vaccine, mRNA) followed a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

Sincerely,

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

-----Original Message-----
From: Steve Kirsch <stk@skirsch.com>
Sent: Wednesday, September 1, 2021 2:35 PM
To: Su, John (CDC) <ezu2@cdc.gov>; (b) (6)
Cc: Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6) (b) (6)
Subject: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello,

Attached is an updated public comment I submitted at the ACIP meeting. Since you are both mentioned by name in the comment, I would like to give you an opportunity to respond before I publish this on TrialSiteNews.

To the CBER team members on the Cc: line, you should take a very close look at this. If you can find an error please let me know. If I don't hear from you, I will assume you have no objections to the methods and the conclusions.

I worked with a team of 20 scientists in putting this together... VAERS experts, statisticians, physicians, one Medical Examiner, multiple pathologists, and the inventor of the mRNA vaccine.

Thanks!

-steve

Polasky, Alexandra

From: CBER VRBPAC
Sent: Thursday, September 23, 2021 7:56 AM
To: McNeill, Lorrie
Subject: FW: [EXTERNAL] Meeting 17th September Claims

Hi Lorrie,

Forwarding for response.

Thank you,

Monique Hill, MHA
Committee Management Specialist

Center for Biologics Evaluation and Research
Division of Scientific Advisors and Consultants
U.S. Food and Drug Administration
Tel: 301-796-4620
Bldg. 71, Room 1119
10903 New Hampshire Avenue
Silver Spring, MD 20993
monique.hill@fda.hhs.gov

From: (b) (6)
Sent: Wednesday, September 22, 2021 8:59 PM
To: CBER VRBPAC <VRBPAC@fda.hhs.gov>; FDA Office of Media Affairs <FDAOMA@FDA.HHS.GOV>
Subject: [EXTERNAL] Meeting 17th September Claims

Good morning

I watched the Vaccines and Related Biological Products Advisory Committee meeting on the 17th September via YouTube with great interest. Within that meeting it was clearly presented the risks that the vaccines pose and the damage that has been done already and I have highlighted some of the most alarming claims below, although there was more.

I would like to know what this group is doing to investigate these very serious claims to:

- Stop vaccination mandates particularly in relation to children
- Investigate the link to menstrual disorders as currently this is not acknowledged in any of the literature – and the effects on fertility
- Investigate the pCoVS as noted below that is predicted given the volume of people receiving the vaccines already.

What is the obligation of this group in regulating and taking action on this information? Can this group be held accountable by the law if they fail to take action?

I appreciate your response to this matter.

Highlights from the meeting:
Vaccines and Related Biological Products Advisory Committee – 9/17/2021 - YouTube
https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement

- Israel reached high levels of population-wide immunity 3 months before most countries and now experiences its highest levels of infection (delta variant) in spite of widespread 2nd dose vaccination with daily cases rising by more than 100 fold. Severe active cases increased >10-fold in a month with active severe fully vaccinated patients hospitalised.
- (4.09.52) Dr Jessica Rose a Viral Immunologist presented that:
  - there is over 1000% increase in adverse events in the Vaccine Adverse Events Reaction System (VAERS) for 2021 in comparison with all other vaccines over the past decade. It was noted that it was clear the risks outweighed any potential benefit particularly for children.
  - There are ~1500 immunological adverse events occurring per million fully injected people with 1/660 individuals reporting an immunological adverse event in context of COVID19 products.
- (4.20.36) Dr Steve Kirsh Executive Director of the COVID19 Early Treatment Fund noted: *"The vaccines kill more people than they save"*
  - There were 4 times as many heart attacks in the Pfizer 6 month trial group whilst the VAERS data has since shown that heart attacks happen 70 times more often with this vaccine compared with any other vaccines.
  - VAERS data shows that 1 in 317 boys (16-17) will get myocarditis from the vaccine, predicting that number will become 1 in 25 after the booster shot.
  - Excess Death:Life ratio is unacceptable at 5 excess deaths for every 1 life saved.
  - Maddie de Garay was a 12 year old participant in the Pfizer trial and was not recorded in the trial results. Her condition was reported as abdominal pain, however she is permanently disabled. This has been sited by Dr Kirst as trial fraud and is being investigated.
- (4.24.23) Dr David Wiseman PHD states "we see strong signals of death, serious adverse events, coagulaopathy and myocardial infarction" he went on to note that:
  - Menstrual disorders: "potential links between COVID19 vaccination and menstrual changes" and "Some women have reported experiencing irregular or missing menstrual periods, bleeding that is heavier than usual and other menstrual changes after receiving COVID19 vaccines.
  - VAERS data shows: 7037 separate menstrual disorder symptoms in 4783 unique reports. Other vaccines for all years show 897 symptoms in 798 unique events.
  - Pregnancy CDC Studies: "data insufficient to inform vaccine associated risks in pregnancy " (Comirnaty). He noted" There is an urgent need to monitor the safety of these vaccines during or around the time of pregnancy."
  - Post COVID Vaccine Syndrome (pCoVs) is noted as short and long term vaccine associated effects may become a major public health issue. It is defined as: A syndrome occurring after injection of antigen-inducing, gene therapy vaccines to SARS Cov-2 virus. The syndrome is currently understood to manifest variously as cardiac, vascular, haematological, musculoskeletal, intestinal, respiratory or neurologic symptoms of unknown long-term significance. In addition to effects of gestation, manifestations of the syndrome may be mediated by the spike protein antigen induced by the delivered nucleic acids, the nucleic acids themselves or vaccine adjuvants.
  - Long Term Safety Studies:
    - Comirnaty has not been evaluated for the potential to cause carcinogenicity, genotoxicity or impairment of male fertility.
    - "mRNA is considered a gene therapy product by the FDA" (Moderna 2020)
    - FDA Guidance: 5-15 year long term follow up for autoimmune diseases, cancers for gene therapy products.

(b) (6)

From: McNeill, Lorrie
To: Richards, Paul (paul.richards@fda.hhs.gov)
Cc: Bartell, Diane
Subject: FW: [EXTERNAL] Meeting 17th September Claims
Date: Friday, September 24, 2021 12:37:00 PM

Hi Paul –

I defer to you on responding. The inquirer doesn't understand the committee's role as advisory. The speakers highlighted are during the OPH portion, so we're not going to comment on those…

Thanks!

Lorrie

From: (b) (6)

Sent: Wednesday, September 22, 2021 8:59 PM

To: CBER VRBPAC <VRBPAC@fda.hhs.gov>; FDA Office of Media Affairs <FDAOMA@FDA.HHS.GOV>

Subject: [EXTERNAL] Meeting 17th September Claims

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https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-september-17-2021-meeting-announcement

- Israel reached high levels of population-wide immunity 3 months before most countries and now experiences its highest levels of infection (delta variant) in spite of widespread 2nd dose vaccination with daily cases rising by more than 100 fold. Severe active cases increased >10-fold in a month with active severe fully vaccinated patients hospitalised.
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    - “mRNA is considered a gene therapy product by the FDA” (Moderna 2020)
    - FDA Guidance: 5-15 year long term follow up for autoimmune diseases, cancers for gene therapy products.

(b) (6)

From: McNeill, Lorrie
To: (b) (6)
Cc: Atreya, Prabhakara; Hayes, Kathleen
Subject: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they"d investigate Maddie de Garay
Date: Monday, September 27, 2021 4:51:00 PM
Attachments: RE EXTERNAL Please respond to my public comment submitted at the ACIP meeting ASAP.msg

Dear Dr. Gans –
Dr. Atreya forwarded your email and asked if I could respond.
We have interacted with Mr. Kirsch on a number of occasions. We strongly disagree with the claims he's made with regard to VAERS, and have communicated that to him. I'm pasting below language we used to respond to Mr. Kirsch a couple of months ago when he initially contacted FDA/CBER; it's rather lengthy, but thought it best to share in its entirety for context.
He has continued to make claims about the data in VAERS, including that the vaccine has caused 200,000 deaths, and that there is massive underreporting to the system. The language below addressed these points. More recently, we responded to an email he directed to CDC (see attached). We pointed out the limitations of VAERS, including the fact that not all of the data are available to the public.
I'm not sure if this information is helpful to you, but wanted to share. Please know that we have tried to combat the misinformation he is spreading, including responding to numerous fact checkers from news outlets who have asked about his presentation at the September 17th VRBPAC meeting.
If I can be of further assistance, or if you have additional questions, please don't hesitate to contact me directly.
Best regards –
Lorrie

Lorrie H. McNeill
Director
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

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FDA response to Mr. Kirsch (July 2021)

FDA and the Centers for Disease Control and Prevention (CDC) place a high priority on vaccine safety - and are committed to the integrity and credibility of our vaccine safety monitoring and research efforts. FDA and CDC scientists continuously monitor the safety of all vaccines following approval or authorization using a multi-pronged approach including: 1) Spontaneous Reporting (or Passive Surveillance) through the Vaccine Adverse Event Reporting System (VAERS), combined with 2) Active Surveillance, using large population-based healthcare datasets.
VAERS (consisting of safety reports submitted by healthcare providers, patients, parents and other members of the public) serves as the nation's established "early warning" system for post licensure vaccine safety for both routine immunizations and COVID-19 vaccines by providing public health professionals with valuable information to assess possible safety concerns. This data is especially useful for rapidly detecting unusual or unexpected patterns of adverse event (AE) reporting that

might signal a possible safety problem with a vaccine. Anyone may submit a report to VAERS regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. Some of the limitations of VAERS include the lack of a control group - and reports may contain inaccurate or incomplete data. Thus, VAERS is not designed to assess causality, but rather for hypothesis testing. If VAERS monitoring identifies a potential safety signal, additional scientifically rigorous active surveillance studies or investigations can be conducted through BEST (Biologics Effectiveness and Safety) and the CMS (Center for Medicare and Medicaid) systems. The CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) Project can also be utilized for this purpose as well. Additional information about COVID-19 vaccine safety surveillance can be found here.

FDA has placed a strong focus on monitoring the safety of the COVID-19 vaccines. As part of this effort, the manufacturers of the COVID-19 vaccines submitted pharmacovigilance plans to FDA to monitor the safety of their vaccines. The pharmacovigilance plan for each vaccine includes a plan to complete long-term safety follow-up for participants enrolled in ongoing clinical trials. These plans also include other activities aimed at monitoring the safety of the vaccines to ensure that any safety concerns are identified and evaluated in a timely manner.

Additionally, the manufacturers and vaccine administrators are required to report to VAERS any adverse event that involved hospitalization, prolongation of existing hospitalization, life-threatening illness, permanent disability, congenital deformity, or death. These reports were required to be submitted irrespective of attribution to vaccination.

These mandatory requirements proved highly successful as in 2021, VAERS has received over 400,000 reports of adverse events compared to approximately 50,000 reports received in previous years. However, because these reports are required to be submitted regardless of the plausibility of the vaccine causing the event - not all of the reports involve an outcome caused by the vaccine. Also, vaccine recipients, parents and caregivers are encouraged to submit reports to VAERS.

As part of the review and analysis process medical records are requested for any serious report, and FDA medical officers continuously screen and analyze VAERS data for COVID-19 vaccines. These analyses include review of individual reports, aggregate analysis of VAERS data, and generating case series when indicated for possible safety concerns. In the course of these reviews, FDA has found that many reports do not represent side effects due to the vaccine. This may be because the diagnosis is not correct, medical records reveal the symptoms began prior to vaccination, or the patient has underlying medical conditions that explain the adverse event.

The robust reporting to VAERS related to the COVID-19 vaccines make an analysis of events using raw numbers in comparison to previous years unreliable. A more suitable analysis is to use the reporting rate for particular adverse event in VAERS and compare it to the background rate in the general population. While this calculation has limitations as well, it was used successfully to identify several safety signals related to COVID-19 vaccines, including Guillain Barre Syndrome (GBS), thrombosis with thrombocytopenia (TTS) following the Janssen COVID-19 vaccine, and myocarditis and anaphylaxis following the Pfizer-BioNTech and Moderna COVID-19 vaccines. Information on selected adverse events after COVID-19 vaccines are available here.

Reports of death after COVID-19 vaccination are rare. More than 339 million doses of COVID-19 vaccines were administered in the U.S. from December 14, 2020, through July 19, 2021. During this time, VAERS received 6,207 reports of death (0.0018%) among people who received a COVID-19 vaccine. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. It should be noted that early in the vaccine roll out the COVID-19 vaccines were primarily administered to large number of nursing home residents and older adults with co-morbidities that put them at high risk for more serious COVID-19

outcomes and death. These included conditions like diabetes, chronic lung diseases, hypertension, heart conditions, obesity, and liver disease. Persons with these conditions have a higher risk of mortality regardless of vaccination status. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. FDA and CDC have reviewed available clinical information, including death certificates, autopsy, and medical records, and have not established a causal link to COVID-19 vaccines with the exception of deaths due to TTS. An illustration of the effectiveness of this approach occurred in April, when FDA and CDC were able to initially identify six cases (including 3 deaths) of TTS out of 6.8 million individuals that had been vaccinated at that time.

There is no evidence that deaths are under reported in VAERS by 10-fold. Underreporting is a well-known limitation of all passive surveillance systems. This has been acknowledged multiple times by FDA and CDC at public meetings and on the VAERs website. It is why multiple systems in addition to VAERS are put in place to monitor vaccine safety. We are aware of two references that have been cited to support the contention that there is under-reporting of deaths in VAERS. However, neither reference addresses spontaneous adverse event reporting in the context of emergency use authorization (EUA). The first reference is a letter to the editor written by a retired pediatrician in 2010 (See - *BMJ 2010; 340 doi: https://doi.org/10.1136/bmj.c2994 (Published 09 June 2010*). It contrasts the reporting rate of Kawasaki disease in VAERS with its incidence in the pediatric population. Since a causal relationship between Kawasaki disease and vaccination has not been established, it is not surprising that there is a paucity of reports in VAERS. A likely scenario is that clinicians diagnosing or treating patients with Kawasaki disease did not feel it was related to the vaccine due to timing or other factors. The second reference is from a paper authored by CDC staff that evaluated the reporting sensitivity of VAERS for anaphylaxis and for Guillain-Barré syndrome (See - *Miller ER, McNeil MM, Moro PL, Duffy J, Su JR. The reporting sensitivity of the Vaccine Adverse Event Reporting System (VAERS) for anaphylaxis and for Guillain-Barré syndrome. Vaccine. 2020 Nov 3;38(47):7458-7463. doi: 10.1016/j.vaccine.2020.09.072. Epub 2020 Oct 7. PMID: 33039207*). This study found VAERS sensitivity for capturing anaphylaxis after seven different vaccines ranged from 13 to 76%, sensitivity for capturing GBS after three different vaccines ranged from 12 to 64%. Of note, the study found the highest percent of adverse events captured in VAERS were after the 2009 H1N1 inactivated pandemic influenza vaccine. During this time, 76% of cases of anaphylaxis and 64% of GBS were captured in VAERS. This suggests that the degree of under reporting in VAERS may be mitigated in the setting of a pandemic where there is a heavy emphasis on vaccine safety. The COVID-19 vaccine program is unique as under the EUA conditions of use there are mandatory reporting requirement for vaccine administrators and manufacturers which likely would lead to increasing capture of death reports. Although under reporting is a limitation in VAERS with regard to COVID-19 vaccine safety monitoring, there currently is not evidence to suggest it would underestimate the amount of COVID-19 associated related deaths to such a large degree.

In summary, FDA is continually monitoring the safety of COVID-19 vaccines using a number of different systems - including VAERS. Current data reveals the vaccines have a favorable risk benefit profile and supports use of these vaccines under EUA. FDA and CDC will continue to monitor reports of all adverse events and update the public as more information becomes available.

Additional resources that you may find helpful can be found below:

FDA and CDC are committed to transparency and have held a number of public meetings and released a wide range of materials discussing the safety of the COVID-19 vaccines. Examples of these

include:

- VRBPAC Presentations
- ACIP Presentations:
    - June 23, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/03-COVID-Shimabukuro-508.pdf
    - May 12, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf
    - April 23, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04-23/03-COVID-Shimabukuro-508.pdf
    - April 14, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04/03-COVID-Shimabukuro-508.pdf
    - February 28, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf
    - January 27, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf
    - December 1, 2020: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/COVID-04-Shimabukuro-508.pdf
- Morbidity and Mortality Weekly Reports (MMWR):
    - Gargano JW, Wallace M, Hadler SC, et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. MMWR Morb Mortal Wkly Rep. ePub: 6 July 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7027e2
    - Shay DK, Gee J, Su JR, et al. Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine — United States, March–April 2021. MMWR Morb Mortal Wkly Rep 2021;70:680–684. DOI: http://dx.doi.org/10.15585/mmwr.mm7018e2external icon
    - Hause AM, Gee J, Johnson T, et al. Anxiety-Related Adverse Event Clusters After Janssen COVID-19 Vaccination — Five U.S. Mass Vaccination Sites, April 2021. MMWR Morb Mortal Wkly Rep 2021;70:685–688. DOI: http://dx.doi.org/10.15585/mmwr.mm7018e3
    - MacNeil JR, Su JR, Broder KR, et al. Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021. MMWR Morb Mortal Wkly Rep 2021;70:651-656. DOI: http://dx.doi.org/10.15585/mmwr.mm7017e4
    - Gee J, Marquez P, Su J, et al. First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021. MMWR Morb Mortal Wkly Rep 2021;70:283–288. DOI: http://dx.doi.org/10.15585/mmwr.mm7008e3
    - Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021. MMWR Morb Mortal Wkly Rep 2021;70:125–129. DOI: http://dx.doi.org/10.15585/mmwr.mm7004e1
    - Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020. MMWR Morb Mortal Wkly Rep 2021;70:46–51. DOI: http://dx.doi.org/10.15585/mmwr.mm7002e1
- Other Peer-Reviewed Studies:
    - Shimabukuro T, Nair N. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine. JAMA. 2021;325(8):780–781. doi:10.1001/jama.2021.0600

    - Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021. JAMA. 2021;325(11):1101–1102. doi:10.1001/jama.2021.1967
- Healthcare Provider and Public Data and Informational Websites:
    - Selected Adverse Events Reported after COVID-19 Vaccination - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html
    - CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html
    - Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
    - CDC's VAERS WONDER Program - https://wonder.cdc.gov/vaers.html

From: Hayley Altman Gans (b) (6)
Sent: Sunday, September 26, 2021 6:16 PM
To: Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>
Subject: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Hi Kathleen
I am not sure who to reach out to, but I am getting numerous emails from Steve Kirsch, see example below. And I am wondering if others are since the communications are to VRBPAC and ACIP.
I am curious if the FDA or CDC has any communications people that may be able to respond to him.
I would also love to know the details regarding is claims, is there a way to understand what he is seeing in VAERS that appears to be at the foundation of his claims.
Thanks for any advise or if you prefer please put me in contact with someone who may be able to address this.
Best
Hayley

Sent from my iPhone

Begin forwarded message:

> **From:** Steve Kirsch <stk@skirsch.com>
> **Date:** September 26, 2021 at 9:38:59 AM PDT
> **To:** Stephanie de Garay <Shdegaray@outlook.com>
> **Cc:** "Daniel O'Connor (doconnor@trialsitenews.com)" <doconnor@trialsitenews.com>, Patrick deGaray <pdegaray@gmail.com>
> **Subject: RE: Janet Woodcock PROMISED me they'd investigate Maddie de Garay**
>
> Stephanie and Patrick,
> What happened to your daughter is not right. Clearly, it wasn't "bad luck" but as you point out from identical cases, caused by the vaccines. VAERS makes this crystal clear as well.
> Unfortunately, nobody cares about the fraud in the Pfizer trial. Nobody cares that the drug ruined your daughters life and the life of other kids. Or that other kids have died from the vaccine.

VAERS shows there have more deaths in kids from the vaccines than from COVID. John Su at CDC won't engage with me. He ignores all my emails and talking to him on the phone was like talking to a wall. T
he outside committees will not engage in a discussion.
NOTHING matters to them.
They are all rubber stamps of government policy. They won't pay attention to the data. They don't want to look at any peer-reviewed papers that confirm what I've been saying about the deaths.
They just don't give a shit if people die. Over 150,000 deaths using 8 different methods… doesn't matter. They can't dispute any of these methods. They pretend they don't exist.
A silicon valley billionaire who is one of the smartest people in the world spent 2 hours with me going over the data. He asked lots of questions. He could not find a hole in the analysis.
The committees? Well, they won't return a single email I sent.
I will keep trying to get their attention, but they were selected to be on the committee because they have 100% blind allegiance to the clinical trials which were gamed (but they aren't interested in hearing why) and everything that happens in the real world is ignored as anecdotal. So even though we can prove the trials were fraudulent, they aren't listening and will never listen. They are all miserable human beings.
-steve

From: Stephanie de Garay <Shdegaray@outlook.com>
Sent: Sunday, September 26, 2021 10:58 AM
To: Steve Kirsch <stk@skirsch.com>
Cc: Steve Kirsch <stk@alum.mit.edu>; Daniel O'Connor (doconnor@trialsitenews.com) <doconnor@trialsitenews.com>; Patrick deGaray <pdegaray@gmail.com>
Subject: Re: Janet Woodcock PROMISED me they'd investigate Maddie de Garay
There are two more teens with the exact same adverse reactions as Maddie. I have messaged with both parents, the sequence of events following the vaccine has been almost identical. None of us have been able to get the proper help for our daughters. All healthy, happy teenagers before they got the vaccine. This isn't right and it isn't fair. Please help our children so they can get back to who they were before the vaccine. And help prevent this from happening to more kids. That is all we want, nothing else.
https://www.facebook.com/100001699368259/posts/4517213821678552/?d=n
https://www.facebook.com/Littles-Fight-100182848984373/

Kind regards,
Stephanie de Garay
(Maddie's mom)
Sent from my iPhone

> On Sep 26, 2021, at 10:28 AM, Steve Kirsch <stk@skirsch.com> wrote:
>
> Dear VRBPAC and ACIP members:
> The FDA and CDC did nothing after Janet Woodcock told me she'd

investigate Maddie's paralysis that started <24 hours after her Pfizer injection.
Maddie was the 12 year old girl in the Pfizer phase 3 12-15 year old safety study with 1,100 kids in each arm.
She's paralyzed for life. She has to eat via a feeding tube. She cannot feel from the waist down. She can't hold her head up. It was reported in the trial as abdominal pain so the trial would be approved.
Janet promised to investigate and nothing happened.
I pointed this fraud out at the VRBPAC meeting when I spoke.
https://twitter.com/NeverSleever/status/1439489527094071297
Nobody cares there is clinical trial fraud in a pivotal safety study??????
Just for the record, so you all are going to do nothing, and pretend it didn't happen, RIGHT???
I wanted to give you all one last chance before I call out all of you for ignoring this. We can cripple 1 in 1,000 kids and this is OK???
-steve

From: McNeill, Lorrie
To: stk@skirsch.com
Cc: Su, John (CDC); (b) (6) Anderson, Steven; Marks, Peter; "Forshee, Richard (Richard.Forshee@fda.hhs.gov)"; Scott, John; Walderhaug, Mark O; (b) (6) (b) (6)
Subject: RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP
Date: Thursday, September 2, 2021 4:26:00 PM

Dear Mr. Kirsch,

While your email was not directly addressed to FDA, we would like to note that we do not agree with the analysis put forth in your comment, as we believe the data from VAERS that you reference were not properly interpreted. This is due to the limitations of VAERS itself, as well as limitations regarding certain private patient information that is not available to individuals outside of the FDA and CDC, as we noted in our correspondence to you dated July 27, 2021.

FDA and CDC have multiple systems in place to monitor the safety of COVID-19 vaccines, including VAERS. We continue to find that the COVID-19 vaccines have a favorable benefit-risk profile, supporting their use under Emergency Use Authorization. Additionally, FDA's approval last week of Comirnaty (COVID-19 Vaccine, mRNA) followed a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

Sincerely,

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

-----Original Message-----
From: Steve Kirsch <stk@skirsch.com>
Sent: Wednesday, September 1, 2021 2:35 PM
To: Su, John (CDC) <ezu2@cdc.gov>; (b) (6)
Cc: Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Walderhaug, Mark O <Mark.Walderhaug@fda.hhs.gov>; (b) (6) (b) (6)
Subject: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

Hello,

Attached is an updated public comment I submitted at the ACIP meeting. Since you are both mentioned by name in the comment, I would like to give you an opportunity to respond before I publish this on TrialSiteNews.

To the CBER team members on the Cc: line, you should take a very close look at this. If you can find an error please let me know. If I don't hear from you, I will assume you have no objections to the methods and the conclusions.

I worked with a team of 20 scientists in putting this together... VAERS experts, statisticians, physicians, one Medical Examiner, multiple pathologists, and the inventor of the mRNA vaccine.

Thanks!

-steve

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 9/27/2021 4:55:20 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Atreya, Prabhakara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f96e446284da421a91a4479bb6e553c1-AtreyaP]
CC: Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]
Subject: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay
Attachments: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Hi Peter –

Attached is my email to Dr. Gans. I copied Prabha and Kathleen.

Thanks!

Lorrie

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, September 27, 2021 10:16 AM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>
Cc: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Subject: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Dear Lorrie,

Thanks so much.

Best Regards,
Peter

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Monday, September 27, 2021 10:15 AM
To: Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Subject: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Hi all –

I will respond to Dr. Gans today.

Thanks –

Lorrie

From: Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>
Sent: Monday, September 27, 2021 9:52 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Dear Dr. Marks,

Thank you very much for your prompt response and quick advisement in the matter.

Best Regards,
Prabha

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, September 27, 2021 9:46 AM
To: Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>
Cc: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Dear Prabha,

My suggestion is that Lorrie send Dr. Gans a copy of the reply from OBE to Mr. Kirsch along with a cover note in response. Thanks.

Best Regards,
Peter

From: Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>
Sent: Monday, September 27, 2021 9:41 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: FW: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Good Morning Dr. Marks,

Please see below we received this request from Dr. Gans, one of the VRBPAC members about the multiple e-mails she keeps receiving from one of the OPH speakers, Mr. Kirsch, about some apparent VAERS data on children's deaths in Pfizer's ped. clinical trials.

Dr. Gans is requesting if she can speak with someone in CBER about the VAERS data that is part of the claims made by the OPH speaker? Also it would be great if she can receive a formal response from OCOD. If a formal CBER response is sent, I request to be copied, if possible.

She is also asking if CBER communications Dept. can respond to the OPH Speaker.

Thank you so much for your consideration.

Best Regards,
Prabha

From: Hayley Altman Gans (b) (6)
Sent: Sunday, September 26, 2021 6:16 PM
To: Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>
Subject: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

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Stephanie and Patrick,

What happened to your daughter is not right. Clearly, it wasn't "bad luck" but as you point out from identical cases, caused by the vaccines. VAERS makes this crystal clear as well.

Unfortunately, nobody cares about the fraud in the Pfizer trial. Nobody cares that the drug ruined your daughters life and the life of other kids. Or that other kids have died from the vaccine.

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Subject: Re: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

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https://www.facebook.com/100001699368259/posts/4517213821678552/?d=n

https://www.facebook.com/Littles-Fight-100182848984373/

Kind regards,

Stephanie de Garay
(Maddie's mom)

Sent from my iPhone

On Sep 26, 2021, at 10:28 AM, Steve Kirsch <stk@skirsch.com> wrote:

Dear VRBPAC and ACIP members:

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I pointed this fraud out at the VRBPAC meeting when I spoke.

https://twitter.com/NeverSleever/status/1439489527094071297

Nobody cares there is clinical trial fraud in a pivotal safety study??????

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From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 9/27/2021 4:51:56 PM
To: (b) (6)
CC: Atreya, Prabhakara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f96e446284da421a91a4479bb6e553c1-AtreyaP]; Hayes, Kathleen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb93ef79b3474f7099917a7d1ed56be9-Kathleen.Ha]
Subject: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay
Attachments: RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

Dear Dr. Gans –

Dr. Atreya forwarded your email and asked if I could respond.

We have interacted with Mr. Kirsch on a number of occasions. We strongly disagree with the claims he's made with regard to VAERS, and have communicated that to him. I'm pasting below language we used to respond to Mr. Kirsch a couple of months ago when he initially contacted FDA/CBER; it's rather lengthy, but thought it best to share in its entirety for context.

He has continued to make claims about the data in VAERS, including that the vaccine has caused 200,000 deaths, and that there is massive underreporting to the system. The language below addressed these points. More recently, we responded to an email he directed to CDC (see attached). We pointed out the limitations of VAERS, including the fact that not all of the data are available to the public.

I'm not sure if this information is helpful to you, but wanted to share. Please know that we have tried to combat the misinformation he is spreading, including responding to numerous fact checkers from news outlets who have asked about his presentation at the September 17th VRBPAC meeting.

If I can be of further assistance, or if you have additional questions, please don't hesitate to contact me directly.

Best regards –

Lorrie

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

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FDA response to Mr. Kirsch (July 2021)

FDA and the Centers for Disease Control and Prevention (CDC) place a high priority on vaccine safety - and are committed to the integrity and credibility of our vaccine safety monitoring and research efforts. FDA and CDC scientists continuously monitor the safety of all vaccines following approval or authorization using a multi-pronged approach including: 1) Spontaneous Reporting (or Passive Surveillance) through the Vaccine Adverse Event Reporting System (VAERS), combined with 2) Active Surveillance, using large population-based healthcare datasets.

VAERS (consisting of safety reports submitted by healthcare providers, patients, parents and other members of the public) serves as the nation's established "early warning" system for post licensure vaccine safety for both routine immunizations and COVID-19 vaccines by providing public health professionals with valuable information to assess possible safety concerns. This data is especially useful for rapidly detecting unusual or unexpected patterns of adverse event (AE) reporting that might signal a possible safety problem with a vaccine. Anyone may submit a report to VAERS regardless of the plausibility of the vaccine causing the event or the clinical seriousness of the event. Some of the limitations of VAERS include the lack of a control group - and reports may contain inaccurate or incomplete data. Thus, VAERS is not designed to assess causality, but rather for hypothesis testing. If VAERS monitoring identifies a potential safety signal, additional scientifically rigorous active surveillance studies or investigations can be conducted through BEST (Biologics Effectiveness and Safety) and the CMS (Center for Medicare and Medicaid) systems. The CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) Project can also be utilized for this purpose as well. Additional information about COVID-19 vaccine safety surveillance can be found here.

FDA has placed a strong focus on monitoring the safety of the COVID-19 vaccines. As part of this effort, the manufacturers of the COVID-19 vaccines submitted pharmacovigilance plans to FDA to monitor the safety of their vaccines. The pharmacovigilance plan for each vaccine includes a plan to complete long-term safety follow-up for participants enrolled in ongoing clinical trials. These plans also include other activities aimed at monitoring the safety of the vaccines to ensure that any safety concerns are identified and evaluated in a timely manner.

Additionally, the manufacturers and vaccine administrators are required to report to VAERS any adverse event that involved hospitalization, prolongation of existing hospitalization, life-threatening illness, permanent disability, congenital deformity, or death. These reports were required to be submitted irrespective of attribution to vaccination.

These mandatory requirements proved highly successful as in 2021, VAERS has received over 400,000 reports of adverse events compared to approximately 50,000 reports received in previous years. However, because these reports are required to be submitted regardless of the plausibility of the vaccine causing the event - not all of the reports involve an outcome caused by the vaccine.

Also, vaccine recipients, parents and caregivers are encouraged to submit reports to VAERS.

As part of the review and analysis process medical records are requested for any serious report, and FDA medical officers continuously screen and analyze VAERS data for COVID-19 vaccines. These analyses include review of individual reports, aggregate analysis of VAERS data, and generating case series when indicated for possible safety concerns. In the course of these reviews, FDA has found that many reports do not represent side effects due to the vaccine. This may be because the diagnosis is not correct, medical records reveal the symptoms began prior to vaccination, or the patient has underlying medical conditions that explain the adverse event.

The robust reporting to VAERS related to the COVID-19 vaccines make an analysis of events using raw numbers in comparison to previous years unreliable. A more suitable analysis is to use the reporting rate for particular adverse event in VAERS and compare it to the background rate in the general population. While this calculation has limitations as well, it was used successfully to identify several safety signals related to COVID-19 vaccines, including Guillain Barre Syndrome (GBS), thrombosis with thrombocytopenia (TTS) following the Janssen COVID-19 vaccine, and myocarditis and anaphylaxis following the Pfizer-BioNTech and Moderna COVID-19 vaccines. Information on selected adverse events after COVID-19 vaccines are available here.

Reports of death after COVID-19 vaccination are rare. More than 339 million doses of COVID-19 vaccines were administered in the U.S. from December 14, 2020, through July 19, 2021. During this time, VAERS received 6,207 reports

of death (0.0018%) among people who received a COVID-19 vaccine. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. It should be noted that early in the vaccine roll out the COVID-19 vaccines were primarily administered to large number of nursing home residents and older adults with co-morbidities that put them at high risk for more serious COVID-19 outcomes and death. These included conditions like diabetes, chronic lung diseases, hypertension, heart conditions, obesity, and liver disease. Persons with these conditions have a higher risk of mortality regardless of vaccination status. Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. FDA and CDC have reviewed available clinical information, including death certificates, autopsy, and medical records, and have not established a causal link to COVID-19 vaccines with the exception of deaths due to TTS. An illustration of the effectiveness of this approach occurred in April, when FDA and CDC were able to initially identify six cases (including 3 deaths) of TTS out of 6.8 million individuals that had been vaccinated at that time.

There is no evidence that deaths are under reported in VAERS by 10-fold. Underreporting is a well-known limitation of all passive surveillance systems. This has been acknowledged multiple times by FDA and CDC at public meetings and on the VAERs website. It is why multiple systems in addition to VAERS are put in place to monitor vaccine safety. We are aware of two references that have been cited to support the contention that there is under-reporting of deaths in VAERS. However, neither reference addresses spontaneous adverse event reporting in the context of emergency use authorization (EUA). The first reference is a letter to the editor written by a retired pediatrician in 2010 (See - *BMJ 2010; 340 doi: https://doi.org/10.1136/bmj.c2994 (Published 09 June 2010*). It contrasts the reporting rate of Kawasaki disease in VAERS with its incidence in the pediatric population. Since a causal relationship between Kawasaki disease and vaccination has not been established, it is not surprising that there is a paucity of reports in VAERS. A likely scenario is that clinicians diagnosing or treating patients with Kawasaki disease did not feel it was related to the vaccine due to timing or other factors. The second reference is from a paper authored by CDC staff that evaluated the reporting sensitivity of VAERS for anaphylaxis and for Guillain-Barré syndrome (See - *Miller ER, McNeil MM, Moro PL, Duffy J, Su JR. The reporting sensitivity of the Vaccine Adverse Event Reporting System (VAERS) for anaphylaxis and for Guillain-Barré syndrome. Vaccine. 2020 Nov 3;38(47):7458-7463. doi: 10.1016/j.vaccine.2020.09.072. Epub 2020 Oct 7. PMID: 33039207*). This study found VAERS sensitivity for capturing anaphylaxis after seven different vaccines ranged from 13 to 76%, sensitivity for capturing GBS after three different vaccines ranged from 12 to 64%. Of note, the study found the highest percent of adverse events captured in VAERS were after the 2009 H1N1 inactivated pandemic influenza vaccine. During this time, 76% of cases of anaphylaxis and 64% of GBS were captured in VAERS. This suggests that the degree of under reporting in VAERS may be mitigated in the setting of a pandemic where there is a heavy emphasis on vaccine safety. The COVID-19 vaccine program is unique as under the EUA conditions of use there are mandatory reporting requirement for vaccine administrators and manufacturers which likely would lead to increasing capture of death reports. Although under reporting is a limitation in VAERS with regard to COVID-19 vaccine safety monitoring, there currently is not evidence to suggest it would underestimate the amount of COVID-19 associated related deaths to such a large degree.

In summary, FDA is continually monitoring the safety of COVID-19 vaccines using a number of different systems - including VAERS. Current data reveals the vaccines have a favorable risk benefit profile and supports use of these vaccines under EUA. FDA and CDC will continue to monitor reports of all adverse events and update the public as more information becomes available.

Additional resources that you may find helpful can be found below:

FDA and CDC are committed to transparency and have held a number of public meetings and released a wide range of materials discussing the safety of the COVID-19 vaccines. Examples of these include:

- VRBPAC Presentations

- ACIP Presentations:
  - June 23, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/03-COVID-Shimabukuro-508.pdf

- May 12, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/07-COVID-Shimabukuro-508.pdf
- April 23, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04-23/03-COVID-Shimabukuro-508.pdf
- April 14, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-04/03-COVID-Shimabukuro-508.pdf
- February 28, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf
- January 27, 2021: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf
- December 1, 2020: https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-12/COVID-04-Shimabukuro-508.pdf

- Morbidity and Mortality Weekly Reports (MMWR):

- Gargano JW, Wallace M, Hadler SC, et al. Use of mRNA COVID-19 Vaccine After Reports of Myocarditis Among Vaccine Recipients: Update from the Advisory Committee on Immunization Practices — United States, June 2021. MMWR Morb Mortal Wkly Rep. ePub: 6 July 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7027e2
- Shay DK, Gee J, Su JR, et al. Safety Monitoring of the Janssen (Johnson & Johnson) COVID-19 Vaccine — United States, March–April 2021. MMWR Morb Mortal Wkly Rep 2021;70:680–684.
DOI: http://dx.doi.org/10.15585/mmwr.mm7018e2external icon
- Hause AM, Gee J, Johnson T, et al. Anxiety-Related Adverse Event Clusters After Janssen COVID-19 Vaccination — Five U.S. Mass Vaccination Sites, April 2021. MMWR Morb Mortal Wkly Rep 2021;70:685–688.
DOI: http://dx.doi.org/10.15585/mmwr.mm7018e3
- MacNeil JR, Su JR, Broder KR, et al. Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021. MMWR Morb Mortal Wkly Rep 2021;70:651-656. DOI: http://dx.doi.org/10.15585/mmwr.mm7017e4
- Gee J, Marquez P, Su J, et al. First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021. MMWR Morb Mortal Wkly Rep 2021;70:283–288.
DOI: http://dx.doi.org/10.15585/mmwr.mm7008e3
- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Moderna COVID-19 Vaccine — United States, December 21, 2020–January 10, 2021. MMWR Morb Mortal Wkly Rep 2021;70:125–129.
DOI: http://dx.doi.org/10.15585/mmwr.mm7004e1
- Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020. MMWR Morb Mortal Wkly Rep 2021;70:46–51.
DOI: http://dx.doi.org/10.15585/mmwr.mm7002e1

- Other Peer-Reviewed Studies:

- Shimabukuro T, Nair N. Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine. JAMA. 2021;325(8):780–781. doi:10.1001/jama.2021.0600
- Shimabukuro TT, Cole M, Su JR. Reports of Anaphylaxis After Receipt of mRNA COVID-19 Vaccines in the US—December 14, 2020-January 18, 2021. JAMA. 2021;325(11):1101–1102. doi:10.1001/jama.2021.1967

- Healthcare Provider and Public Data and Informational Websites:

- Selected Adverse Events Reported after COVID-19 Vaccination - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html
- CDC Recommends Use of Johnson & Johnson's Janssen COVID-19 Vaccine Resume - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html

- Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination - https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html
- CDC's VAERS WONDER Program - https://wonder.cdc.gov/vaers.html

---

From: Hayley Altman Gans (b) (6)
Sent: Sunday, September 26, 2021 6:16 PM
To: Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>
Subject: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Hi Kathleen

I am not sure who to reach out to, but I am getting numerous emails from Steve Kirsch, see example below. And I am wondering if others are since the communications are to VRBPAC and ACIP.

I am curious if the FDA or CDC has any communications people that may be able to respond to him.

I would also love to know the details regarding is claims, is there a way to understand what he is seeing in VAERS that appears to be at the foundation of his claims.

Thanks for any advise or if you prefer please put me in contact with someone who may be able to address this.

Best
Hayley

Sent from my iPhone

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From: Steve Kirsch <stk@skirsch.com>
Date: September 26, 2021 at 9:38:59 AM PDT
To: Stephanie de Garay <Shdegaray@outlook.com>
Cc: "Daniel O'Connor (doconnor@trialsitenews.com)" <doconnor@trialsitenews.com>, Patrick deGaray <pdegaray@gmail.com>
Subject: RE: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

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Kind regards,

Stephanie de Garay
(Maddie's mom)

Sent from my iPhone

On Sep 26, 2021, at 10:28 AM, Steve Kirsch <stk@skirsch.com> wrote:

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Maddie was the 12 year old girl in the Pfizer phase 3 12-15 year old safety study with 1,100 kids in each arm.

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I pointed this fraud out at the VRBPAC meeting when I spoke.

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Nobody cares there is clinical trial fraud in a pivotal safety study??????

Just for the record, so you all are going to do nothing, and pretend it didn't happen, RIGHT???

I wanted to give you all one last chance before I call out all of you for ignoring this. We can cripple 1 in 1,000 kids and this is OK???

-steve

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 9/2/2021 4:26:43 PM
To: stk@skirsch.com
CC: Su, John (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4241352c8141e8a2760a441cf9182b-HHS-ezu2-cd]; (b) (6) Anderson, Steven [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4c0c242feba45fa954f4f9b05eb3557-AndersonSt]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Forshee, Richard [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Scott, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91620658ce0243e38241d198be1a5461-ScottJ]; Walderhaug, Mark O [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=14515448efee47098c38798d5c409b02-MWALDERH]; (b) (6)
Subject: RE: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

Dear Mr. Kirsch,

While your email was not directly addressed to FDA, we would like to note that we do not agree with the analysis put forth in your comment, as we believe the data from VAERS that you reference were not properly interpreted. This is due to the limitations of VAERS itself, as well as limitations regarding certain private patient information that is not available to individuals outside of the FDA and CDC, as we noted in our correspondence to you dated July 27, 2021.

FDA and CDC have multiple systems in place to monitor the safety of COVID-19 vaccines, including VAERS. We continue to find that the COVID-19 vaccines have a favorable benefit-risk profile, supporting their use under Emergency Use Authorization. Additionally, FDA's approval last week of Comirnaty (COVID-19 Vaccine, mRNA) followed a determination that the vaccine is safe and effective in preventing COVID-19 in individuals 16 years of age and older.

Sincerely,

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

-----Original Message-----
From: Steve Kirsch <stk@skirsch.com>
Sent: Wednesday, September 1, 2021 2:35 PM
To: Su, John (CDC) <ezu2@cdc.gov>; (b) (6)
Cc: Anderson, Steven <Steven.Anderson@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Scott, John <John.Scott@fda.hhs.gov>; Forshee, Richard <Richard.Forshee@fda.hhs.gov>; Walderhaug, Mark O

<Mark.Walderhaug@fda.hhs.gov>; (b) (6)

(b) (6)

Subject: [EXTERNAL] Please respond to my public comment submitted at the ACIP meeting ASAP

Hello,

Attached is an updated public comment I submitted at the ACIP meeting. Since you are both mentioned by name in the comment, I would like to give you an opportunity to respond before I publish this on TrialSiteNews.

To the CBER team members on the Cc: line, you should take a very close look at this. If you can find an error please let me know. If I don't hear from you, I will assume you have no objections to the methods and the conclusions.

I worked with a team of 20 scientists in putting this together... VAERS experts, statisticians, physicians, one Medical Examiner, multiple pathologists, and the inventor of the mRNA vaccine.

Thanks!

-steve

From: McNeill, Lorrie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77B0B352C9C24851BF0C7330F53E00D9-MCNEILL]
Sent: 9/27/2021 5:00:43 PM
To: Atreya, Prabhakara [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f96e446284da421a91a4479bb6e553c1-AtreyaP]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]
Subject: Re: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

You're very welcome!

Lorrie

From: Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>
Sent: Monday, September 27, 2021 4:57:45 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Subject: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Dear Lorrie,

Thank you so much for your response and keeping us in the loop.

Have a nice evening.

Prabha

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Monday, September 27, 2021 4:55 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Atreya, Prabhakara <Prabhakara.Atreya@fda.hhs.gov>
Cc: Witten, Celia (CBER) <Celia.Witten@fda.hhs.gov>
Subject: RE: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Hi Peter –

Attached is my email to Dr. Gans. I copied Prabha and Kathleen.

Thanks!

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Dear Lorrie,

Thanks so much.

Best Regards,
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Hi all –

I will respond to Dr. Gans today.

Thanks –

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Best Regards,
Prabha

From: Hayley Altman Gans (b) (6)
Sent: Sunday, September 26, 2021 6:16 PM
To: Hayes, Kathleen <Kathleen.Hayes@fda.hhs.gov>
Subject: [EXTERNAL] Fwd: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Hi Kathleen

I am not sure who to reach out to, but I am getting numerous emails from Steve Kirsch, see example below. And I am wondering if others are since the communications are to VRBPAC and ACIP.

I am curious if the FDA or CDC has any communications people that may be able to respond to him.

I would also love to know the details regarding is claims, is there a way to understand what he is seeing in VAERS that appears to be at the foundation of his claims.

Thanks for any advise or if you prefer please put me in contact with someone who may be able to address this.

Best
Hayley

Sent from my iPhone

Begin forwarded message:

From: Steve Kirsch <stk@skirsch.com>
Date: September 26, 2021 at 9:38:59 AM PDT
To: Stephanie de Garay <Shdegaray@outlook.com>
Cc: "Daniel O'Connor (doconnor@trialsitenews.com)" <doconnor@trialsitenews.com>, Patrick deGaray <pdegaray@gmail.com>
Subject: RE: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

Stephanie and Patrick,

What happened to your daughter is not right. Clearly, it wasn't "bad luck" but as you point out from identical cases, caused by the vaccines. VAERS makes this crystal clear as well.

Unfortunately, nobody cares about the fraud in the Pfizer trial. Nobody cares that the drug ruined your daughters life and the life of other kids. Or that other kids have died from the vaccine.

VAERS shows there have more deaths in kids from the vaccines than from COVID. John Su at CDC won't engage with me. He ignores all my emails and talking to him on the phone was like talking to a wall. T

he outside committees will not engage in a discussion.

NOTHING matters to them.

They are all rubber stamps of government policy. They won't pay attention to the data. They don't want to look at any peer-reviewed papers that confirm what I've been saying about the deaths.

They just don't give a shit if people die. Over 150,000 deaths using 8 different methods… doesn't matter. They can't dispute any of these methods. They pretend they don't exist.

A silicon valley billionaire who is one of the smartest people in the world spent 2 hours with me going over the data. He asked lots of questions. He could not find a hole in the analysis.

The committees? Well, they won't return a single email I sent.

I will keep trying to get their attention, but they were selected to be on the committee because they have 100% blind allegiance to the clinical trials which were gamed (but they aren't interested in hearing why) and everything that happens in the real world is ignored as anecdotal. So even though we can prove the trials were fraudulent, they aren't listening and will never listen. They are all miserable human beings.

-steve

From: Stephanie de Garay <Shdegaray@outlook.com>
Sent: Sunday, September 26, 2021 10:58 AM
To: Steve Kirsch <stk@skirsch.com>
Cc: Steve Kirsch <stk@alum.mit.edu>; Daniel O'Connor (doconnor@trialsitenews.com) <doconnor@trialsitenews.com>; Patrick deGaray <pdegaray@gmail.com>
Subject: Re: Janet Woodcock PROMISED me they'd investigate Maddie de Garay

There are two more teens with the exact same adverse reactions as Maddie. I have messaged with both parents, the sequence of events following the vaccine has been almost identical. None of us have been able to get the proper help for our daughters. All healthy, happy teenagers before they got the vaccine. This isn't right and it isn't fair. Please help our children so they can get back to who they were before the vaccine. And help prevent this from happening to more kids. That is all we want, nothing else.

https://www.facebook.com/100001699368259/posts/4517213821678552/?d=n

https://www.facebook.com/Littles-Fight-100182848984373/

Kind regards,

Stephanie de Garay
(Maddie's mom)

Sent from my iPhone

On Sep 26, 2021, at 10:28 AM, Steve Kirsch <stk@skirsch.com> wrote:

Dear VRBPAC and ACIP members:

The FDA and CDC did nothing after Janet Woodcock told me she'd investigate Maddie's paralysis that started <24 hours after her Pfizer injection.

Maddie was the 12 year old girl in the Pfizer phase 3 12-15 year old safety study with 1,100 kids in each arm.

She's paralyzed for life. She has to eat via a feeding tube. She cannot feel from the waist down. She can't hold her head up. It was reported in the trial as abdominal pain so the trial would be approved.

Janet promised to investigate and nothing happened.

I pointed this fraud out at the VRBPAC meeting when I spoke.

https://twitter.com/NeverSleever/status/1439489527094071297

Nobody cares there is clinical trial fraud in a pivotal safety study??????

Just for the record, so you all are going to do nothing, and pretend it didn't happen, RIGHT???

I wanted to give you all one last chance before I call out all of you for ignoring this. We can cripple 1 in 1,000 kids and this is OK???

-steve