From: b6
Sent: 1/24/2022 12:04:50 AM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
Subject: Re: [EXTERNAL] Post Vaccination Injury?

Good evening,
Thank you for your quick reply. Yes please, any recommendation would be much much appreciated.

Kind Regards,
b6

On Jan 23, 2022, at 3:33 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6
I am terribly sorry to hear of your illness. Sounds like you have sought consultation from all the top experts. I am not sure I have anything else to offer, but with your permission, I would like to share your email with some of my colleagues at NIH to see if they might have other suggestions.
Best.
Avi
Avindra Nath MD
Chief, Section for Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6

From: b6
Date: Sunday, January 23, 2022 at 2:20 PM
To: "Nath, Avindra (NIH/NINDS) [E]" b6
Subject: [EXTERNAL] Post Vaccination Injury?

Dear Dr. Nath,

My name is b6 I'm a b6 from b6 b6 I read the article in Science.org titled "In rare cases, coronavirus vaccines may cause Long Covid-like symptoms." I wanted to reach out to you on a personal note, ask for some

consultation/guidance if you are willing to spare some time. I was b6 working at b6 b6 until b6 when I developed intense palpitations, heat intolerance, tachycardia into the 150's, for which it would be alleviated by laying down. My vaccines were in b6 and b6 (Pfizer). I have never been diagnosed with COVID19 b6 b6 I remember feeling palpitations b6 but brushed it off as stress from working with so many ill patients. My symptoms in b6 led me to multiple ER visits and eventual admission for evaluation. My b6

b6 After visiting two different neurologists, I was told this could be b6 Symptoms fluctuated throughout summer 2021 but worsened into the Fall including lightheadedness, brain fog, profound fatigue putting me in bed, and ongoing on/off fasciculations (abdomen, limbs). I followed up with a functional internal medicine physician who did a pretty thorough workup, b6

He wasn't too convinced I had b6 stated vaccine may have lowered my immunity and caused chronic/suppressed viruses to cause symptoms. But I have no idea what organism. He labeled me as b6 and wanted to treat with b6 I ended up going to b6 in b6 and had an evaluation by b6 included b6 which revealed b6 b6 b6 I was told by him that I have b6 and that I should recondition myself and he expects improvement, albeit on a protracted timeline. I've been working hard to recondition myself since my visit In b6 and while I have had some improvements in overall fatigue, I am still struggling with dysautonomia type symptoms that have significantly impaired my quality of life. Best way I can describe is that I feel not enough blood is going to my brain, lightheaded/dizzy spells, associated nausea, brain fog, blurred vision on/off, b6 b6 I began combing through Journals, Online forums, Twitter, etc, started noticing a trend of complaints of similar symptoms, mainly from post COVID19 patients. Eventually, I started noticing similar complaints in post-vaccine patients as well. I went as far as reaching out to one group called COVIDLongHaulers.com and tested for b6 b6 They told me I'm having a b6 b6 and wanted to check b6 I reached back out to b6 to see if he wanted b6 however he said I've had a thorough workup thus far and he believes I need to stay the course. As you can tell, I have had pretty extensive workup, with the only diagnosis of b6 There is emerging literature indicating autoimmunity post-COVID, I am wondering if something similar is happening post vaccination and triggering a host of symptoms. I went to a Rheumatologist who didn't really offer any guidance. I never thought I would be writing an email to the Director of NINDS but I am desperate for answers that make sense. I apologize for the lengthy email, and appreciate your time.

Sincerely,

b6

From: b6
Sent: 1/28/2022 1:13:34 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6]
Subject: Re: [EXTERNAL] Covid Vaccine adverse event

will do thanks

b6

o.
m. b6

Please use this address for medical matters only.

On Fri, Jan 28, 2022 at 8:05 AM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Sat afternoon is fine. How about 2 pm. Call my cell when convenient. b6

Avi

From: b6
Date: Friday, January 28, 2022 at 7:22 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re: [EXTERNAL] Covid Vaccine adverse event

HI

I am sorry my wife has a medical appointment tomorrow AM anytime after 11AM can work.

However, we can reschedule this appointment if you don't have flexibility, yours can be a priority.

Sorry for inconvenience.

b6

b6

o. b6

m.

Please use this address for medical matters only.

On Thu, Jan 27, 2022 at 8:37 PM b6 wrote:

> Great. Thank you
>
> b6
>
> b6
>
> o. b6
>
> m.
>
> Please use this address for medical matters only.
>
> On Thu, Jan 27, 2022 at 5:40 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:
>
> > How about 10 am on Sat.
> >
> > My cell is b6

Avi

From: b6
Date: Thursday, January 27, 2022 at 5:33 PM
To: "Nath, Avindra (NIH/NINDS) [E]" b6
Subject: Re: [EXTERNAL] Covid Vaccine adverse event

The weekend would be perfect, we will accommodate your schedule.

b6

b6

o.
m. b6

Please use this address for medical matters only.

On Thu, Jan 27, 2022 at 10:32 AM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

> Dear b6
>
> Sorry to hear of your wife's illness. I will be glad to talk to you and your wife today after 7 pm or on the weekend. Please let me know what might be best.
>
> Avi
>
> Avindra Nath MD

Chief, Section for Infections of the Nervous System

Clinical Director,

National Institute of Neurological Disorders and Stroke

National Institutes of Health, Bethesda, MD

b6 (Office)

(cell)

b6

From: b6
Date: Thursday, January 27, 2022 at 8:50 AM
To: "Nath, Avindra (NIH/NINDS) [E]" b6
Subject: [EXTERNAL] Covid Vaccine adverse event

Hi

My name is b6 I am b6 and was referred to you by b6 in regards to my wife's reaction to covid vaccination in b6

She is b6 b6 She has suffered from b6 prior to vaccination. 20 minutes after a moderna booster b6 she had rigors, chills, and was hit with a brain fog, slurred speech, and fatigue. This was prominent for 2-3 months, but has continued to the present, though improving. She also had b6

I wonder if I can speak briefly with you about her management, or who to seek out with this regard. I do understand if you are too busy. My mobile phone is below or you can tell me when I can reach out to you.

Thank you for your attention.

b6

o. b6

m

Please use this address for medical matters only.

From: b6
Sent: 1/10/2022 7:16:50 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
Subject: Re: [EXTERNAL] Severe injury of b6

Hi Dr. Nath,

Thanks for the email. You were very clear that you were not recommending any treatment for me but appreciate suggestions of potential treatments. I would love to speak to you if you have any time in your schedule. I would also be happy to connect you with my team of wonderful doctors. I'm at the best research hospitals and they are confused and have no idea what is causing this and acknowledge it was an adverse reaction to the vaccine on a previously healthy individual. I'm not the first or the last they are seeing this with. They are waiting for direction from the FDA and NIH on what is going on as there has been no study that they know of as to why this is happening. Therefore they don't really know how to treat. It's really alarming when you take a look at how many of us are experiencing the exact same symptoms. So many people are suffering and I'm talking people out of suicide on a weekly basis who are having the same reactions and can't take it. When it happened to me b6 I thought I was just one of the unlucky ones and b6 understood that all meds and vaccines can have side effects. It wasn't until six months later that I realized how many others were suffering at an alarming rate. I'm not sure if you have been in contact with others but I'm happy to connect you. I value the research the NIH does and you are the lifeline for research and helping those injured. Are there any research investigations happening? If so I would love to be part of them. If not when will this happen? It's been a year and people can't hold on much longer. I do believe we can safely vaccinate people AND study why it's happening to so many of us at the same time. This will create trust. Is your team working with the FDA on this? I really appreciate all your time.

Sincerely,
b6

Sent from my iPhone

On Jan 10, 2022, at 2:39 AM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

I want to make sure that it is clear that I am not recommending any kind of treatment and I have absolutely no idea what might be causing your symptoms. There is no way that anyone can practice medicine via email. If there is b6
b6
Best wishes.
Avi

From: b6
Date: Monday, January 10, 2022 at 1:01 AM
To: "Nath, Avindra (NIH/NINDS) [E]" b6
Cc: b6
Subject: Re: [EXTERNAL] Severe injury of b6

Dear Dr. Nath,

Thank you so very much for the very prompt response. b6 I will definitely reach out to this this doctor b6 b6 Do you have any idea what could be causing these side effects so I could clue them in as to why b6 b6 Are you thinking autoimmune? I did b6 b6 every time I was hospitalized in the beginning. I think it's what truly saved my life. b6 don't understand what is causing it so it would be great if there was any potential lead as to your thoughts to guide them. My doctors are all wonderful and will do anything to help me. Thank you so very much.

Sincerely,
b6

Sent from my iPhone

On Jan 9, 2022, at 8:37 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6
We are terribly sorry to hear of your illness. Sounds like you have seen all the specialists that would be able to help. We are just as mystified as everyone else about these complications. We do not have any special testing or medications to offer at the moment. We know of some patients who have been treated with b6 b6 You could consider discussing it with your physicians to see if these would be appropriate for you are not. Since you are in b6 you could consider consulting b6 b6 We hope you get better soon.
With best wishes.
Avi
Avindra Nath MD
Chief, Section for Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6

From: b6
Date: Sunday, January 9, 2022 at 11:19 PM
To: "Nath, Avindra (NIH/NINDS) [E]" b6 b6
Subject: [EXTERNAL] Severe injury of b6

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

Hello Dr.Nath and Dr. Safavi,

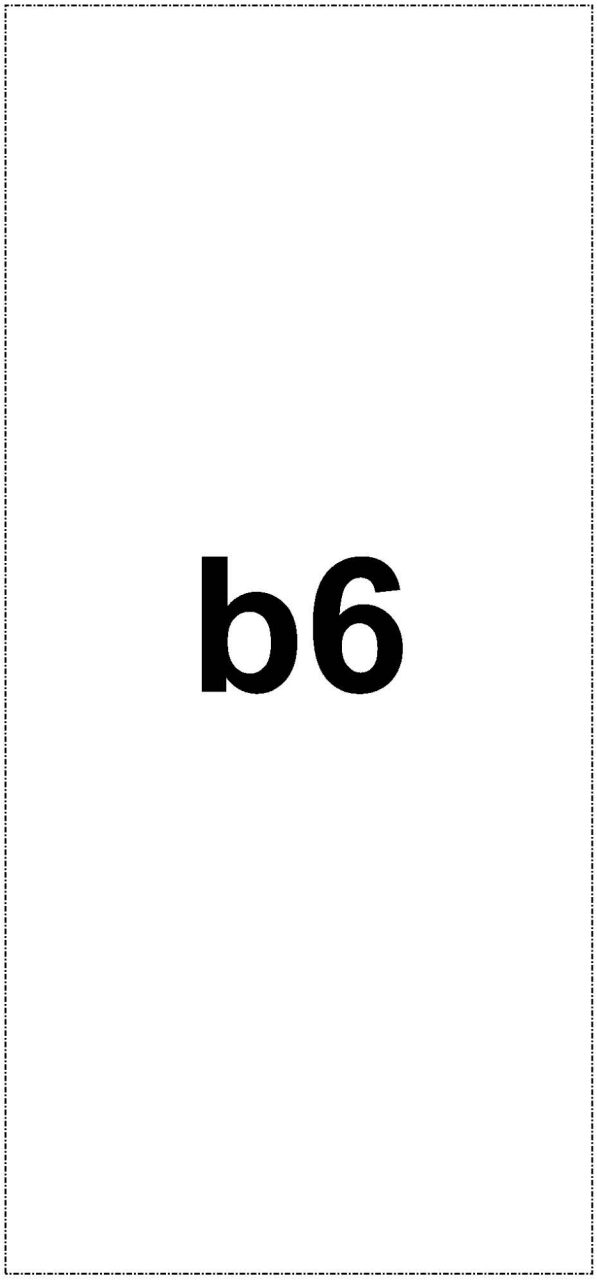
My name is b6 and I need your help desperately. I have been b6 Being b6 is part of my identity and is my life. I sent Dr. Safavi an email back in April and didn't hear a response back and I understand you were busy. I wanted to circle back around again. I was a health b6 with no medical problems and lived and active lifestyle. I was a very highly respected b6 and I will give you a few examples to show you b6

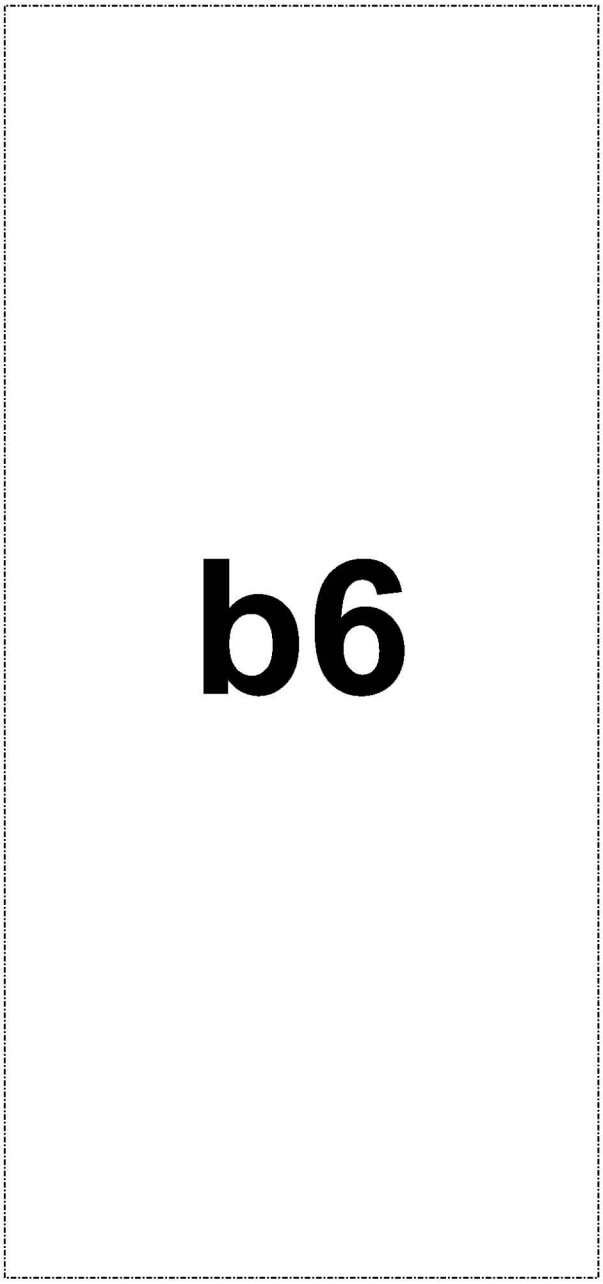
b6

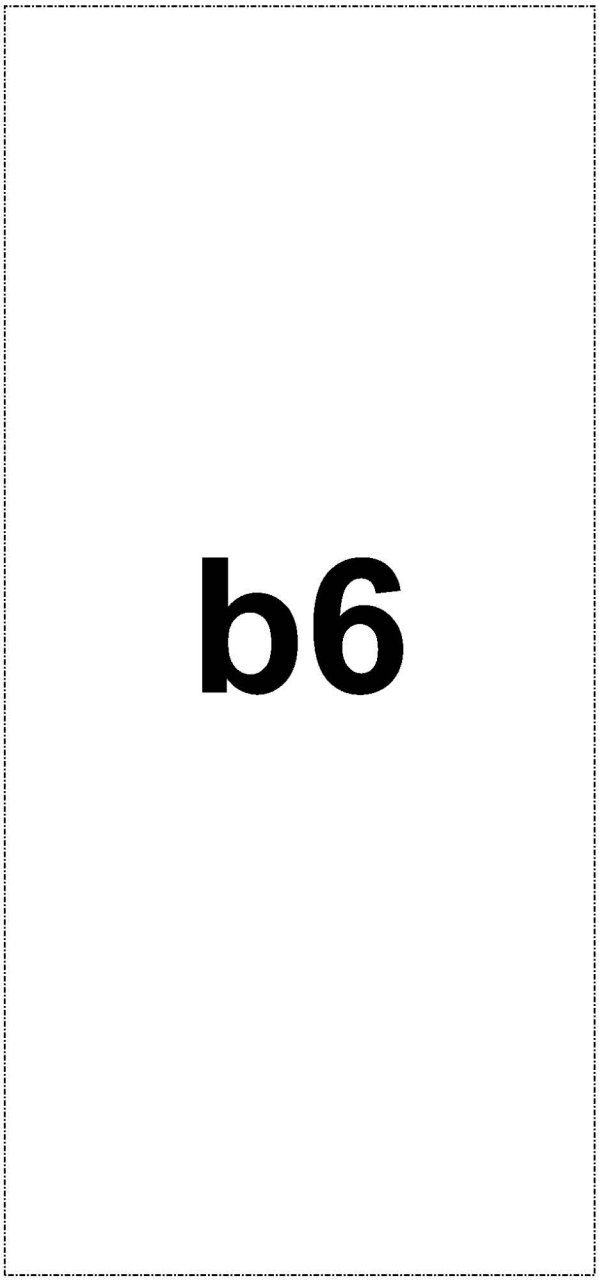
b6 and I trust the science. I took my Moderna vaccine on b6 of this year so I could b6 At the twelve minute mark my life as I knew it was gone. I had an immediate reaction and it was not anaphylactic. I wish it was because it would have been easier to treat. I was transported to the hospital to rule out a myocardial infarction as well as pulmonary emboli. I couldn't breathe and my chest was hurting. My vitals were critically unstable and my body was limp, numb and shaking. Over the following two months I had b6 couldn't eat, lost 17 lbs in three weeks and was gravely ill. I honestly didn't think I could survive it. I did a living will in case I didn't make it so my b6 would have a plan. I am one of the fortunate ones because all the doctors for the most part believed me. It's hard to argue a reaction that happens before you even leave the vaccination site. Fortunately my doctors knew my track record of being healthy and they were all terrified of what was happening to me. I rarely called in sick and never needed time off for medical care I got care almost every day in the beginning of my vaccine reaction because b6 b6 and as I said was hospitalized several times. I was seen by 7 different allergist/immunologist, cardiologist, endocrinologist, neurologist, functional medicine doctors and the list goes on. I am still dealing with cardiac issues as I was diagnosed with b6 from the b6 I have been on more meds than I could count and have to rely on cardiac meds and well as neurological meds to keep me stable. I also started developing severe neurological issues such as numbness and tingling in my legs, heavy right leg/arm and walked like I had Parkinson's. I also had tremors and jerky movements as well as weakness. I have inability to do hardly any physical exertion. My reflexes were extremely brisk and I was sent into the b6 as well as b6 I have done every expensive test imaginable. I sent labs to Germany to test for b6 and I'm awaiting results. b6 and being proactive I've sought out every workup possible. Now I need your help desperately. I'm almost at a year out and I have no answers, no real medical treatment other than masking symptoms and I want to get my life back so I can b6 I'm a prisoner of my body and I need your guidance as to what can be going on and how to help with the underlying cause. I know there are more like me and thought you might have some insight to the etiology and recommendations for treatment. I've been patient but at a year out now I'm loosing hope and I need your help and guidance. I'll share with you the type of letters from b6 and hopefully you will see why I need your help getting better so I can do what I do best which is b6 ! I appreciate your help.

Sincerely,

b6




b6



Sent from my iPhone

From: b6
Sent: 6/2/2022 9:02:22 AM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: RE: [EXTERNAL] A Vascular Disease and Multisystem Inflammatory Syndrome EUA Mandatory Report

Hello Dr. Nath,

I am following up to see if you have received my message. Dr. Woodcock said I have reached the correct contacts, so I know that you are the correct person to contact, as well as knowing you are aware of the neurological events that exist following COVID-19 vaccination, and that you have been aware of my case since April 2021. If you are no longer the correct contact, please direct me to the correct person.

Thank you,

b6

From: b6
Sent: Wednesday, May 18, 2022 2:12 AM
To: Nath, Avindra (NIH/NINDS) [E]
Subject: Re: [EXTERNAL] A Vascular Disease and Multisystem Inflammatory Syndrome EUA Mandatory Report

Hello Dr. Nath,

I am following up to see if you viewed my b6 that are both tied neurological injury from Janssen COVID19 vaccine.

If not, let me know, and I will forward it to you again. I have been in communication with you for over a year regarding neurological injury following vaccination and I am requesting a response.

Thank you,

b6

From: b6
Sent: Saturday, May 7, 2022 12:52 PM
To: Woodcock, Janet b6
Cc: Nath, Avi (NIH) b6 Richards, Paul b6 Anderson, Steven b6 Nair, Narayan b6
Subject: RE: [EXTERNAL] A Vascular Disease and Multisystem Inflammatory Syndrome EUA Mandatory Report

Thank you for your quick response.

Which of you are able to address the concerns that are causing major gaps in documentation and capturing safety signals or can provide the information I have been seeking since October 2021?

Thank you,

b6

From: Woodcock, Janet
Sent: Saturday, May 7, 2022 6:55 AM

To: Michelle Zimmerman
Cc: Nath, Avi (NIH); Richards, Paul; Anderson, Steven; Nair, Narayan
Subject: RE: [EXTERNAL] A Vascular Disease and Multisystem Inflammatory Syndrome EUA Mandatory Report

Thank you for writing. You are connected to the right people here at FDA. Janet Woodcock

---

From: b6
Sent: Saturday, May 7, 2022 2:15 AM
To: Woodcock, Janet b6
Cc: Nath, Avi (NIH) b6 Richards, Paul b6 Anderson, Steven b6 Nair, Narayan b6
Subject: RE: [EXTERNAL] A Vascular Disease and Multisystem Inflammatory Syndrome EUA Mandatory Report

Hello Dr. Woodcock,

I wanted to follow up again and am bringing back my original message of October 25, 2021 and inquiry as my concerns are still relevant and unresolved.

I have seen the updated guidelines for Janssen/J&J vaccines as of May 5, 2022, and EUA still includes a mandatory requirement to report all cases of MIS following vaccination. This was one of my initial questions for you and I offered to contact the correct people directly who had the power to update and address the gaps in information that would prevent capturing safety signals. It is May 6, 2022 and most medical providers do not know MIS is possible following vaccination. Those who do cannot diagnose MIS following vaccination because CDC has not updated their guidelines. Screen shots and links as evidence below:

SUMMARY OF INSTRUCTIONS FOR COVID-19 VACCINATION PROVIDERS

Vaccination providers enrolled in the federal COVID-19 Vaccination Program must report all vaccine administration errors, all serious adverse events, cases of Multisystem Inflammatory Syndrome (MIS) in adults, and cases of COVID-19 that result in hospitalization or death following administration of the Janssen COVID-19 Vaccine. See "MANDATORY REQUIREMENTS FOR THE JANSSEN COVID-19 VACCINE ADMINISTRATION UNDER EMERGENCY USE AUTHORIZATION" for reporting requirements.

Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)

My inquiry in the fall of 2021 requested understanding and who to contact to address major gaps in being able to identify safety signals, trusting that these gaps were merely oversights and would bring concern to the organizations I was alerting. One of these concerns was the delay in CDC updating diagnostic and case definition information for MIS.

As this is still unresolved 7 months later, I am more concerned that I am aware of who has been alerted to these gaps, and there has been ample time to address the gaps, but they have not been updated.

There is still no way for doctors to diagnose cases of MIS following vaccination because the definition provided by CDC only includes positive COVID-19 infections and has not been updated to include vaccination even though criteria have existed since February 2021 MIS-CA-vaccine-publication.pdf (brightoncollaboration.us):
Multisystem Inflammatory Syndrome in Adults (MIS-A) Case Definition Information for Healthcare Providers (cdc.gov)

I have found https://coronavirus.house.gov/subcommittee-activity/hearings/hybrid-hearing-examining-emergent-biosolutions-failure-protect-public

And have identified that the time of manufacture of my lot number coincides with the time of known contamination. I have multiple corroborating quantitative and biological data from medical and research tests for myself that show evidence of more than one type of spike protein in my blood, and antibodies to more than one type of spike glycoprotein. This should not have occurred with a single manufacture/brand, single dose, and consistent evidence of no COVID-19 infection. The only remaining logical explanation is cross contamination. In nearly 14 months of intensive searching, medical testing, and research, there are no other explanations.

I have alerted the subcommittee that all of my requests for information so far have been dismissed, denied, or absence of response despite my attempt to obtain the most accurate information to disconfirm statements that have swirled suggesting that known information has been intentionally withheld. I have alerted the subcommittee that the data on me suggests a good chance I may have received contaminated J&J along with all information of my lot number becoming disconnected from place of manufacture. I have been told by FOIA that I need to wait until J&J is FDA approved until I will be allowed to receive information, but was never provided an official letter (confirming or disconfirming) the existence of documentation I have requested, rather, I was told in 24 months, I may possibly receive a response.

This has become more concerning.

I have followed up when NIH stated they had no intention of updating public facing websites to alert doctors of the neurological risks of vaccination.

I have multiple sources of evidence now that demonstrate my neurological injury matches the pattern of other neurological vaccine injuries. I have attached the most recent as example for your review. My vision injury matches what is seen in Traumatic Brain Injury patients. I have traced my neurological, vestibular, vascular, and vision damage to a commonality as listed in research literature and a note in my b6

b6

Because FDA, CDC, NIH stated that the vaccines were safe and effective, I did not receive a diagnosis, rather, I was told by doctor after doctor and specialist after specialist that it was impossible because there are no adverse reactions from Janssen vaccination. Because of that, I did not receive early intervention for neurological injury that could have been addressed earlier.

As a result of decisions FDA, CDC, NIH have made to withhold known information from the public and from medical professionals, by not announcing a recall and by choosing to release batches for distribution, more Americans have been harmed and are being called “collateral damage” and “misinformation” despite known contamination. I have suffered disability that could have been prevented. There is an uncounted number of others who are being labeled with anxiety, rather than multisystem inflammatory syndrome when the diagnosis exists. People like me are still being turned away from medical care, denied healthcare coverage because insurance has still not been alerted that contamination existed, and that people were injured from a vaccine that was mandated to keep their jobs.

Because FDA did not ensure that informed consent consistently occurred, people are still being provided unapproved products and being told they are approved, as I was.

This goes entirely against ethical protocols for administering an unapproved product and allowing such practices to continue because the statements are not clear.

https://www.webmd.com/vaccines/covid-19-vaccine/covid-vaccines-compared

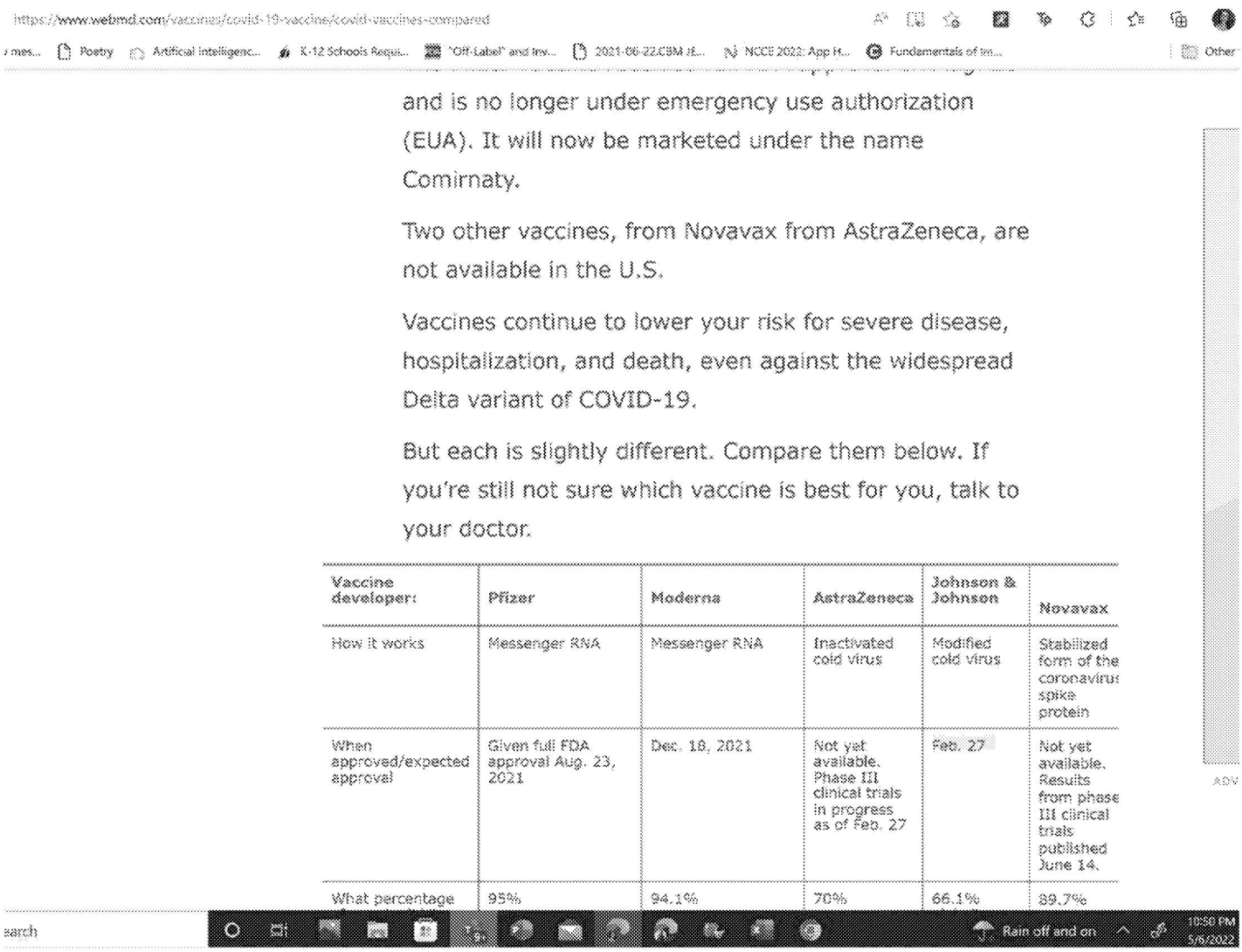
w mes... Poetry Artificial Intelligenc... K-12 Schools Requi... "Off-Label" and Inv... 2021-06-22.CBM JI


COVID Vaccines Compared

Medically Reviewed by Carol DerSarkissian, MD on March 20, 2022

There are three COVID-19 vaccines approved for use in the U.S. The Pfizer, Moderna, and Johnson & Johnson vaccines are all highly effective in protecting you from the virus that causes COVID-19.

Note J&J is listed as an FDA approved product, including WebMD stated as “medically reviewed” by an MD. I have written multiple times since they define Janssen FDA approved and stated that FDA approval occurred on February 27, 2022. After writing 3 times, they changed the fact checker and removed the year “2022” but changed no other content. While I could consider this poor journalistic practice, it has been no different than my experience with FDA, CDC, NIH, VAERS, and CICP.



https://www.webmd.com/vaccines/covid-19-vaccine/covid-vaccines-compared

and is no longer under emergency use authorization (EUA). It will now be marketed under the name Comirnaty.

Two other vaccines, from Novavax from AstraZeneca, are not available in the U.S.

Vaccines continue to lower your risk for severe disease, hospitalization, and death, even against the widespread Delta variant of COVID-19.

But each is slightly different. Compare them below. If you're still not sure which vaccine is best for you, talk to your doctor.

Vaccine developer:	Pfizer	Moderna	AstraZeneca	Johnson & Johnson	Novavax
How it works	Messenger RNA	Messenger RNA	Inactivated cold virus	Modified cold virus	Stabilized form of the coronavirus spike protein
When approved/expected approval	Given full FDA approval Aug. 23, 2021	Dec. 18, 2021	Not yet available. Phase III clinical trials in progress as of Feb. 27	Feb. 27	Not yet available. Results from phase III clinical trials published June 14.
What percentage	95%	94.1%	70%	66.1%	89.7%

The FDA has the power to stop misinformation, disinformation, and fueling vaccine hesitancy and distrust of FDA, CDC, and NIH.
I have come to you to help, and I have persisted across months because I know you are in a position to address these crucial gaps.

There is still no notification to recipients of Janssen vaccination that there was known contamination. Baby food manufacturing concerns received an alert after 4 babies were hospitalized. Vaccine recipients who are debilitated have not received the same respect, nor have their doctors.

I am offering once again to talk directly to the people in positions of authority who need to be aware of these gaps and express the seriousness of what is continuing to occur.

I am b6 over a year since vaccination, not medically cleared to b6

CICP has not provided any guideline for establishing standard for proof of causation for reviewers to review claims or for claimants prior to submitting claims, and to date, 13 claims have been denied claiming they have not met standard for proof of causation (and a standard for proof of causation does not exist, as confirmed by Captain Dale Mishler).

Due to FDA's delay in releasing information publicly and alerting recipients of Janssen/J&J vaccines during the time of manufacture that contamination existed, recipients and their doctors have not been alerted, and there is substantial underreporting. I know you are aware of this because I have brought it to your attention. This is costing people's lives. In one SAE vaccine group alone, there have been over 20 deaths by suicide because their doctors do not believe vaccines

can lead to life-threatening, debilitating effects as the messaging is only and always "safe and effective." Symptoms are not addressed, diagnosed, or believed. People are becoming homeless, losing jobs, losing vision (like me) parallel to TBI vision loss in combat veterans.

And yet, all of us who did our part, who got vaccinated, and were promised safe, effective and free, have been called collateral damage and left injured after an unapproved, experimental product, with massive financial losses, disbelief, verbal abuse.

History is repeating.
I am no longer able to assure people that there are ethical protocols in place, that people would not be given an experimental, unapproved product without their knowledge, and would not be left wounded with no help as has happened in the past.

I was not provided any informed consent. I have acquired records from Public Health. I was told the vaccine I received was FDA approved and no adverse reactions. This traces back to the FDA's failure to update known information about concerns, contamination, and failing to stop production when concerns were identified and not addressed.

In addition, my VAERS report is still inaccurate, and CDC has refused to update my report to match medically verified information including my b6 ER visits, and neurological injury persisting past a year with no safeguards for help or guidelines for any of my doctors.

I am by far not the only case, and I know you are aware of this back through October as your message of October 26, 2021 states below in this thread.

I am requesting again: If there is any documentation to provide a counterexample to any of what I have found, I am asking for it now as all other requests have been dismissed, ignored, passed off to others, or told that the information is "proprietary" and not available to anyone other than the CDC, FDA, or NIH.

There is an uneven distribution of SAE by lot number visible in VAERS. There was known contamination. There were documented increase in SAE aligned with the timing of lots produced at the time of contamination.

I still want to help. Please put me in contact with the people who will address these very concerning gaps. I would like to provide a positive report to the subcommittee I am now in contact with.

Sincerely,

b6

From: Woodcock, Janet
Sent: Tuesday, October 26, 2021 1:02 PM
To: b6
Subject: RE: [EXTERNAL] A Vascular Disease and Multisystem Inflammatory Syndrome EUA Mandatory Report

I have been looking into a variety of reports similar to yours. I will get back to you. Janet Woodcock

---

From: b6
Sent: Tuesday, October 26, 2021 3:13 PM
To: Woodcock, Janet b6
Subject: RE: [EXTERNAL] A Vascular Disease and Multisystem Inflammatory Syndrome EUA Mandatory Report

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.

Thank you for letting me know. I very much appreciate the response.

From: Woodcock, Janet
Sent: Tuesday, October 26, 2021 11:28 AM
To: b6
Subject: RE: [EXTERNAL] A Vascular Disease and Multisystem Inflammatory Syndrome EUA Mandatory Report

b6 I have received your letter and am looking through the documentation. Let me absorb this information and I will get back to you. Janet Woodcock

From: b6
Sent: Monday, October 25, 2021 10:32 PM
To: Mccluskie, Sean E (OS) b6 Walensky, Rochelle P (CDC) b6 Woodcock, Janet b6 Marks, Peter b6 Shimabukuro, Tom (CDC) b6
Subject: [EXTERNAL] A Vascular Disease and Multisystem Inflammatory Syndrome EUA Mandatory Report

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.

Xavier Becerra HHS Office of the Secretary
Secretary, Health & Human Services
200 Independence Ave., S.W. Washington, D.C. 20201
c/o Sean McCluskie
b6

Dr. Rochelle P. Walensky Director,
Centers for Disease Control and Prevention
1600 Clifton Road Atlanta, GA 30329
b6

Dr. Janet Woodcock Interim Commissioner,
Food & Drug Administration 10903 New Hampshire Ave.
Silver Spring, MD 20993
b6

Dr. Peter Marks Director,
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
10903 N.H. Ave. W071-3128 Silver Spring, MD 20993-0002
b6

Dr. Tom Shimabukuro CDC
COVID-19 Vaccine Task Force
1600 Clifton Road, NE Corporate Square,
Bldg 12
Atlanta, GA 30329
b6

I was vaccinated with Janssen/J&J on b6 to protect others and to model civic duty, to model it was safe and effective, and to lead trough action. I wanted to assure b6 b6 hesitancy based in past concerns, while valid, have been addressed since and I was determined to help do my part to stop and counter misinformation, disinformation, and hesitancy. As a b6 b6 b6 I know the rigor of ethics standards, safeguards, and panning needed, not to mention safe data collection and retention policies. I did not question any of that. I knew it was a major scientific feat to develop vaccines that quickly.

I was assured, and thankful for living in the United States where symptoms wouldn't be suppressed, censored, or hidden and dismissed. I am proud to stand behind data and b6 reopening plan was created in collaboration with epidemiologists, virologists, medical doctors and nurses who were on the front lines of treating severe COVID-19, legal, b6 and other stakeholders. The plan took the risk/benefit balance seriously for reopening b6 with multiple layers of countermeasures, including AI powered health screening, masks, ventilation, and even b6 I am proud to say b6 b6 Because of reading historical information on past pandemics, unlike b6 who believed it would be a short 2 week closure, I knew I needed to plan for a minimum of 2-5 years in advance.

Our work influenced b6 I have taken my contributions to the fight against COVID-19 with the responsibility that comes along with the enormous task. b6 I understand the magnitude of weight at the intersection of health care, education, and the incredible potential for good with artificial intelligence, and the incredible potential for destruction. I have been b6 b6 I was in progress of meeting with b6 b6 the week of my injection regarding b6 b6 b6 and collaborations I began with intelligence and defense, RAND, and MITRE. I realize the complexity of all of this, and I realize that COVID-19 is our generation's Enigma machine, mutating rather than continually changing unbreakable code. In the past b6 I have gained inside information on how to tackle vaccine hesitancy, impact of Active Measures (a book recommended by a contact in Intelligence and Defense). I have gained information into how crucial it is to tackle information warfare. I realize more than ever how important strategy will be moving forward to protect democracy with a Renewed Great Power Competition: Implications for Defense—Issues for Congress.
All of my work in the fight against COVID-19 was halted, unexpectedly. b6
I have been told I am one of the unlucky collateral damage.
I refuse to let suffering go to waste, and I will help advance accurate science knowledge, and keep breaking down misinformation.
It has become like an embedded experience into healthcare during a pandemic. I was healthy. No underlying health conditions confirmed by b6 medical testing. While I am not cleared to b6 I am still doing what I can to help – a different kind of civic duty.

Vaccination was an obvious decision for our staff as soon as possible as an additional countermeasure. I can honestly say, I never expected any of this to happen. I trusted the nurse who told me there were no adverse reactions to J&J, not even anaphylaxis.
I have learned so much in this process, and this is why I am alerting you all now of two major gaps that may be getting lost in putting out fires.

1. EUA mandates reporting all cases of MIS, but there is no guideline for clinicians to identify, define, diagnose, and treat, or report
2. A gap between research and practice – COVID-19 as a vascular disease – the research exists, but it is not making it to clinicians.

I am reaching out to each of you to alert you of a major gap preventing creating a barrier to mandatory reporting all cases of Multisystem Inflammatory Syndrome required in each of the EUA Fact Sheets for Healthcare Providers as seen below:
Janssen COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers (fda.gov)
Pfizer-BioNTech COVID-19 Vaccine EUA Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (fda.gov)
Moderna COVID-19 Vaccine EUA Fact Sheet for Health Care Providers (fda.gov)

The CDC provides Information for Healthcare Providers about Multisystem Inflammatory Syndrome in Children (MIS-C) | CDC that only defines MIS-C when a positive COVID-19 test exists. There is not provision for MIS-C/MIS-A post COVID-19 injection, nor is there ICD code for clinicians. This has major impact for healthcare coverage denials, burden of proof on the injured individual and financial losses. There are solutions to this that already exist.

UK Brighton Collaborative has extended their definition for healthcare providers to know how to diagnose MIS as a result of injection: Multisystem Inflammatory Syndrome in Children and Adults (MIS-C/A): Case Definition & Guidelines for Data Collection, Analysis, and Presentation of Immunization Safety Data - Brighton Collaboration

Additionally, British Medical Journal set precedent in defining a case and treatment procedures: Multisystem inflammatory syndrome in an adult following the SARS-CoV-2 vaccine (MIS-V) | BMJ Case Reports

While there was a response to interpret with caution: Multisystem inflammatory syndrome after SARS-CoV-2 vaccination (MIS-V), to interpret with caution | Postgraduate Medical Journal (bmj.com) , I wrote the authors addressing each of their questions of unknowns in another case, asking them to review.

This case featured:

- [redacted]

b6

While I reported to VAERS, my information was incorrect on the forward facing display. When I attempted to correct it based on medical records, it took multiple attempts until I was told it was against policy to update incorrect information.

While I reported to Janssen, my adverse reaction reports went missing each of the first three case numbers I was provided, while I was seeing reports that there were no adverse reactions reported. I filed a request for assistance to

look into the missing adverse reaction reports I kept resubmitting, and asking why I was told on three occasions there was no record of me in their system (even with audio-recorded calls). I can provide all documentation upon request.

In learning that I have not been able to be a counterexample for b6 I serve, nor have I been able to find evidence of any safeguard in existence that is functioning that I can point vaccine hesitant people to (assuring them that while experimentation may have happened on people in years past leaving people injured, ethics boards ensure that will not happen), I have become one of them. I have now seen the inside of the communities who are afraid there will be no one to help. Because it is so important for me to present counterexamples, I decided to go through the CICP process myself – surely that could be something I could point to. I learned that September 1, 2021, their website posted that no claim could be compensated as no one could meet standard of proof. I called to ask for guidelines of standard of proof as COVID-19 vaccines are not included in the table of injuries. There was no guideline or standard of proof test to measure against when preparing a claim, all without the assistance of any legal support. This is completely inaccessible to anyone without extensive knowledge in research or the ability to learn about law, proof of causation, differential diagnosis, Daubert standard, pharmacovigilance, and finding and reading scientific sources.

I gathered the majority of it at threat of my insurance company who said I had to prove I was injured from the vaccine, because they didn't hear anything about the possibility of injury.

In my goal to find logical explanations for all of these things, to present evidence to support my case, I have learned about how much was known about the structure of SARS, the mechanisms of injury with ACE2 and endothelia cells, and then about COVID-19 as a vascular disease. I learned that this gap between research and practice is in part, helping fuel conspiracy theory, misinformation, distrust, and gaps in treatment. It is a major feature in fueling extremism.

I am still doing everything in my power to contribute – a type of civic duty – as I am injured. With a background in b6 I am determined to continue helping fight this war against COVID-19 and misinformation.

You all are my last line of seeking answers and presenting what is known and what exists – in hope to see a logical explanation and know that once gaps are identified, there can be and will be change.

ICU nurses and doctors need to know the research about the vascular inflammation components of the disease. Clinicians and specialists need a guide for identifying and diagnosing MIS post COVID-19 and post vaccination. If identified and caught early, there are treatments, steroid bursts, that have been shown to blunt the severity of SAE.

We are still in EUA. There is a chance to define these things clearly. There is still time to ensure functioning safeguards. I have learned CICP and NVICP are not functioning safeguards. I am providing you with a link to the document I submitted to CICP on b6 with evidence of Multisystem Inflammatory Syndrome:

b6

I am ready and willing to help gather resources that are accurate science, that exist, and create a resource for clinicians – open access to address equity gaps in the latest research for b6. There exist cutting edge blood work panels that, if made as accessible as COVID-19 tests, could go a long way to supporting the medical field in identifying and treating Long Haul, MIS, and post vaccine reaction. And in this, in this transparency, we have a chance at helping fight the vaccine hesitancy fears there will be no help if something goes wrong.

I already have content drafted. I am happy to have any of your top experts you would recommend as peer reviewers. While researchers are focused on publishing for an academic audience.
Clinicians and specialists feel their hands are tied and want to help but don't know what to do. I have been surprised how many say "I'm just a clinician, not a researcher" and believe they do not have the skills to read or understand newly emerging research to help their patients. This is crucial during an evolving pandemic.

The added benefit is comparing the parallel symptoms in MIS-A/MIS-C/MIS-V to help separate out the mechanisms of injury related to viral load vs mechanism of injury characteristic of vascular inflammation. Helping narrow the focus through identifying vaccine injury in the absence of viral load can provide a gold mine of data to help researchers learn quickly as the virus keeps mutating. This is our enigma machine. We will crack the code, but it will take more people tackling the problem.

Please connect me with someone from: National Center for Advancing Translational Sciences | (nih.gov)

I have puzzle pieces others would not be able to have access to even in clinical trials where there are too many confounding variables.

Thank you,

b6

From: b6
Sent: 1/17/2021 6:34:39 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6]
Subject: Re: adverse reaction covid vaccine
Attachments: b6

Dear Dr. Nath:

Thank you so much for your consultation. It is greatly appreciated. I have contacted my neurologist and gave her permission to speak and consult with you. I also sent her your contact information. Below you will find attached my doctors notes and records.

On Fri, Jan 15, 2021 at 1:27 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

> Dear b6
>
> Sorry to hear of your symptoms. Lets set up some time to talk today. How about later this evening, after 6:30 pm or this weekend.
>
> Avi
>
> Avindra Nath MD
>
> Chief, Section of Infections of the Nervous System
>
> Clinical Director,
>
> National Institute of Neurological Disorders and Stroke
>
> National Institutes of Health, Bethesda, MD

b6

From: b6
Date: Friday, January 15, 2021 at 11:38 AM
To: "Nath, Avindra (NIH/NINDS) [E]" b6
Subject: adverse reaction covid vaccine

Dear Dr. Nath:

I have received your information from b6 We have in common an adverse neurological reaction to the astra zeneca covid 19 vaccine. I am seeking help as my neurological problems are worsening. I am seeing several doctors, and on different medications, but only to control some symptoms. I am needing help. Please contact me at your earliest convenience. By email or phone. Thank you

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From: Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950B4D458D74037A6A86EAD6 b6
Sent: 3/9/2022 3:51:30 AM
To: b6 Gavin, Angelique (NIH/NINDS) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e97392e947e4f7ebb17eeb8ac87c5d5 b6
NINDS Public Inquiries [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8a11837b5244c2395ed81bb7c0a65d7-NINDS Publi]
Subject: Re: Question about Evusheld [EXTERNAL] Re: NIH COVID-19 Vaccine Study

I am forwarding your email to NIH officials who might be able to help.
Avi

From: b6
Date: Tuesday, March 8, 2022 at 4:44 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Cc: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re: Question about Evusheld [EXTERNAL] Re: NIH COVID-19 Vaccine Study

Hi Angelique. Hoping you may have some info for me or can direct me to where I might find it. My doctors have me in for approval for receiving b6 As this is so new they know little to nothing about it. My research shows NIH is in its trials are in Stage 3, but I don't see data or findings. Based on my still ongoing Dysautonomia with POTS issues from the Pfizer vaccines, you can imagine I'm a bit gun shy when it comes to new Rx's, especially those under emergency approval. Is there any way to get more detailed info on the trials, or do you know who might know or have any input?
If not, thanks for taking the time to read my message.
Best Regards, b6

Sent from my iPad

On Jan 27, 2022, at 8:08 AM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:

Hello b6

I am so very sorry to hear about b6 as well as your continued efforts at recovery. Our vaccine study is still in production and we anticipate it will be a couple of months more before it is underway. We will contact you as soon as we are ready to begin recruiting participants. In the meantime, I have you on our wait list. If you speak with b6 please have her reach out to me directly. All my best to you with your efforts to find answers regarding your illness.

Sincerely,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health

10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
b6 (office)
(cell)
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Wednesday, January 26, 2022 10:22 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Cc: Nath, Avindra (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Re: NIH COVID-19 Vaccine Study

Hi Angelique. I just found out b6 here in b6 also was diagnosed with POTS after her COVID vaccine. Prior to receiving the vaccine she was a very healthy, active, b6 It's turned her world upside down. She also saw the one case study published by the NIH and would be very interested in participating in any future study. Hoping if you get enough cases reported it may advance the study, but that's just my thought. Let me know and I'll have her reach out to you directly.
And FYI, a since my vaccine and I still have not recovered. Snail snail pace recovery.
Let me know. Thank you again.
b6

> On Oct 14, 2021, at 12:35 PM, Gavin, Angelique (NIH/NINDS) [C]
> b6 wrote:
>
> Thank you b6 for checking in with us! The study is still in process and has not yet been approved to begin. No idea yet what the timeframe will be. I wish I could be of more assistance. Feel free to check back anytime.
>
> Sincerely,
> Angelique
>
> *Angelique Gavin, MS* (Contractor)
> NIH/NINDS Clinical Operations Manager
> Contractor Preferred Solutions Group
> National Institutes of Health
> 10 Center Drive
> Building 10, Room 3B19, MSC 1251
> Bethesda, MD 20814-9692
> b6 (office)
> (cell)

(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Thursday, October 14, 2021 3:15 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: NIH COVID-19 Vaccine Study

Hello. I thought I'd follow up on the study on vaccine side effects you referenced in our emails. Just curious if the study is still planned and if so, any idea when it will begin? Thank you☺

On Aug 30, 2021, at 10:04 AM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:

Thank you b6 We will contact you as soon as the study is underway. All my best to you.

Sincerely,
Angelique

Angelique Gavin, MS
Clinical Operations Manager
Contractor, PSG
National institutes of Health
10 Center Drive, Building 10
Room 3B19, MSC 1251
Bethesda, MD 20814
b6 phone
301-451-7352-fax

From: b6
Sent: Monday, August 30, 2021 12:59 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: NIH COVID-19 Vaccine Study

Angelique, thank you & Dr Nath for your quick response! I'm very interested in participating in anything that may help the medical community, and others, in researching this phenomenon.
I have not shared my story with anyone other than close friends and family, who are all pro-vaccine, as to not discourage anyone from being vaccinated. On the advise of my doctors I am holding off on the now-recommended third "booster" shot for us immunocompromised until we see how my recovery goes.
I look forward to hearing from you in the future. Thanks again!
b6

On Aug 30, 2021, at 9:26 AM, Gavin, Angelique (NIH/NINDS) [C] b6 wrote:

Dear b6

Thank you for your interest in our research. I received your inquiry from Dr. Avindra Nath. We are currently developing an online survey system to collect stories about people's complications after receiving COVID vaccines. At this time, if you are willing, we can take your name and contact information. We will reach back out to you when the survey system is completed to see if you are willing to volunteer in our on-line study.

Sincerely,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
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(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089

-

From: b6
Sent: 4/29/2022 5:24:42 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6]
CC: NINDSPostCovid19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7288bc48d86f4f5fb796620bda298e7f-nindspostco]
Subject: Re: [EXTERNAL] post-vaccine chronic issues
Attachments: b6 COVID_timeline.pdf

Dear Avi,

Thank you for the response! In case it is helpful and/or of interest, I'm attaching my vaccine/illness timeline that I prepared for my medical providers.

b6

On Thu, Apr 28, 2022 at 8:20 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6

Sorry to hear of your illness. I have copied our research team who can collect the information.

Best

Avi

From: b6
Date: Thursday, April 28, 2022 at 10:22 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: [EXTERNAL] post-vaccine chronic issues

Hello Dr. Nath,

I've read about the work you are doing regarding post-vaccine chronic health conditions, and wondered if you'd be interested in hearing about my experience.

The short version: I'm triple Moderna vaccinated, came down with a COVID-like illness b6 5 PCR tests and 1 nucleocapsid b6 yet here it is b6 and I'm still long-hauling (including loss of taste and smell, chronic fatigue, and exercise intolerance).

Any interest? If so, I'm happy to share more.

b6

b6

b6

b6

From: Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 b6]
Sent: 10/5/2021 2:56:21 PM
To: b6
Subject: RE: Request to participate in studies related to vaccines

Thank you b6

Some resources for you:

Allergic reactions: NIH Begins Study of Allergic Reactions to Moderna, Pfizer-BioNTech COVID-19 Vaccines | NIH: National Institute of Allergy and Infectious Diseases

Adverse reaction reporting: COVID-19 Vaccine Reporting Systems | CDC

The online study is not yet approved so I cannot report on what it will entail or when it will be available for recruitment.

Thank you,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
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https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Tuesday, October 5, 2021 9:55 AM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Cc: b6
Subject: Re: Request to participate in studies related to vaccines

Thanks so much, Angelique! I look forward to participating.

Could you please let us know who at the NIH we can be in touch with regarding the study details?

Thank you,
b6

On Tue, Oct 5, 2021 at 7:47 AM Gavin, Angelique (NIH/NINDS) [C] b6 wrote:

Thank you b6 for your willingness to volunteer! We will hold your information and send to the study team when it is approved. I do not have any information at this time to offer. I am simply gathering a list of interested participants to disseminate to the study team once it is underway. I am sorry I cannot be of more help to you at this time.

Sincerely,

Angelique

Angelique Gavin, MS (Contractor)

NIH/NINDS Clinical Operations Manager

Contractor Preferred Solutions Group

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https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Tuesday, October 5, 2021 8:16 AM
To: b6
Cc: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: Request to participate in studies related to vaccines

Good Morning Angelique,

I would also like to be added to the NIH's study for COVID-19 vaccine complications. Below is my contact information:

b6

Could you please answer a few questions for us regarding these studies?

1. Is the online survey system ready for use? If not, do you have an ETA on when it will be available?

2. You mentioned the possibility of an online study. What will this entail and when is the time frame that it will run?

3. How is the NIH collecting data of these extreme but rare side effects from the vaccines in the meantime?

4. Are there any current or past studies of people with neurological symptoms like ours (paresthesia, numbness, tingling, vibrating, tremors, muscle spasms) from the COVID-19 vaccines? If so, how many participants were included in these studies?

As b6 explained, we have been experiencing these neurological symptoms for b6 now following our COVID-19 vaccines, and we are looking for answers. We appreciate your support and look forward to hearing from you soon.

b6

On Fri, Sep 17, 2021 at 12:11 AM b6 wrote:

> Dear Angelique,
>
> Yes, I would love to be added to your list and will look forward to participating in your study. Below is my contact information:

b6

I'm including b6 in this chain, too, as she may also like to join.

I appreciate your quick response and I truly hope these studies start happening quickly, too. There are many of us trying to understand what has happened to our bodies over these months and how we can get help.

Sincerely,

b6

From: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Thursday, September 16, 2021 12:12 PM
To: b6
Subject: RE: Request to participate in studies related to vaccines

Dear b6

Thank you for your interest in our research. We are currently developing an online survey system to collect stories about people's complications after receiving COVID vaccines. At this time, if you are willing, we can take your name and contact information. We will reach back out to you when the survey system is completed to see if you are willing to volunteer in our on-line study.

Thanks you,

Angelique

Angelique Gavin, MS (Contractor)

NIH/NINDS Clinical Operations Manager

Contractor Preferred Solutions Group

National Institutes of Health

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Bethesda, MD 20814-9692

b6

(301) 480-5368 (efax)

b6

https://clinicaltrials.gov - study number 000089

-

From: b6
Sent: Thursday, September 16, 2021 11:23 AM
To: NINDSPostCovid19 <nindspostcovid19@ninds.nih.gov>
Subject: Request to participate in studies related to vaccines

Dear NIH,

I was referred to you and your group by Dr. Farinaz Safavi.

b6 and I have been having neurological problems since receiving our COVID-19 vaccinations this past spring, and we are desperately trying to heal and understand what has happened to us. She had both doses of Moderna b6 and I had one dose of Pfizer on b6 My b6 had Moderna, also, but no problems. She'll be getting a booster/third shot on b6

I would love to speak with someone in your department about participating in your studies. Seems we may be a unique case for you as we had/continue to have similar reactions since being vaccinated. b6 and I b6 want to do what we can to help others, understand our own problems, and be a part of the solution as we as a world try to end this pandemic. We did what we thought was right back in the spring and now we need help ourselves. The fact that you are researching gives me hope.

Sincerely,

b6

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b6

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b6

From: Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5-b6]
Sent: 2/18/2022 9:04:40 PM
To: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Thank you b6 for sharing this information!

Sincerely,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
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https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Friday, February 18, 2022 3:56 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Angelique,

Below are the links I mentioned. Some information to help others that are suffering:

https://pubmed.ncbi.nlm.nih.gov/34957554/

https://www.science.org/content/article/rare-cases-coronavirus-vaccines-may-cause-long-covid-symptoms

https://www.nature.com/articles/s41467-017-00622-4

https://onlinelibrary.wiley.com/doi/10.1002/mus.27251

https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC7046028/

I appreciate your help. And I know many others do, too.

b6

From: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Friday, February 18, 2022 10:26 AM
To: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Thank you b6

Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
b6
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Friday, February 18, 2022 12:09 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Cc: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Hi Angelique,

I appreciate your updates as to the upcoming study. I'm so glad to hear it is getting closer and b6 and I are eager to participate.

The 27 links were interesting, too, and I'm fully aware of that content. I've been researching about our illness since b6 of 2021 and the COVID virus neurological symptoms are not what we are experiencing. I will forward a few links to you in a separate email that may be helpful when you reply to others with COVID vaccine injuries.

As to the research sites, I check them periodically, as well. Still holding out hope, as you told me in the fall when we spoke by phone, that studies for vaccine injuries will most likely be plentiful in the next one to two years. A little late for those of us injured, but we do need answers.

Again, I thank you for keeping us informed and we trust that the NIH will help us as soon as possible. We did what our government asked of us and trusted that we would be safe. Unfortunately, we've had life-changing injuries from the vaccines and we desperately need to know why and what to avoid in the future. And we need to know what will help us heal.

Sincerely,

b6

From: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Thursday, January 27, 2022 9:50 AM
To: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Hello b6

Thank you for sending this update regarding your and b6 illness. Unfortunately, the vaccine study is still in process. We anticipate it will be 2-3 more months before we are ready to recruit participants. In the meantime, I have listed some resources for you. These are generally COVID-19 related but you may find something helpful here. All my best to you in your search for answers.

https://www.ninds.nih.gov/News-Events/News-and-Press-Releases/Press-Releases/Researchers-highlight-COVID-19-neurological. Additional details are provided in the following article from "Science," a publication from the American Association for the Advancement of Science: https://www.science.org/doi/10.1126/science.abm2052. That article was written by Avindra Nath, M.D., clinical director of the NINDS, and Serena Spudich, M.D., of the Yale School of Medicine.

The NINDS recognizes the need for significant research in this field and is one of many Institutes and Centers involved in the NIH PASC Initiative, now called Researching COVID to Enhance Recovery (RECOVER), which seeks to understand the prevalence of PASC and its clinical spectrum and to identify strategies to prevent and treat its complications. Information on RECOVER is available at https://recovercovid.org/. The "FAQs" portion of the site (https://recovercovid.org/faqs) includes a "How can I sign-up to join a RECOVER research study?" section that directs visitors to the following sign-up form: https://openredcap.nyumc.org/apps/redcap/surveys/?s=TYCLM7PE97.

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participating in clinical trials is available at https://www.nih.gov/health-information/nih-clinical-research-trials-you. The NIH-funded registry ResearchMatch helps connect volunteers with researchers who are seeking study participants: https://www.researchmatch.org/.

The following NINDS website, which discusses the effects of COVID-19 on the nervous system, may interest you: https://www.ninds.nih.gov/Current-Research/Coronavirus-and-NINDS/nervous-system. More information about COVID-19, including details about the Institute's efforts to invest in research that will study the neurological complications of the disease, can be accessed via the "Coronavirus and NINDS" website at https://www.ninds.nih.gov/Current-Research/Coronavirus-and-NINDS.

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The following NIH website offers information on COVID-19 that you may find useful: https://covid19.nih.gov. You can read about the NIH-wide Strategic Response to COVID-19 at https://covid19.nih.gov/nih-strategic-response-covid-19.

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Finally, you may wish to visit the NLM's MedlinePlus website, which has resources on a wide range of health topics. Information about COVID-19 is available at https://medlineplus.gov/covid19coronavirusdisease2019.html.

I hope this will be helpful to you.

Sincerely,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
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From: b6
Sent: Wednesday, January 26, 2022 4:48 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Cc: b6
Subject: [EXTERNAL] RE: Request to participate in studies related to vaccines

Hello Angelique,

I'm writing to follow up on the online study you told b6 and I about in the fall. Below I've also included our previous email dialogue.

Since our last correspondence, b6 has been diagnosed with vaccine induced b6 b6 I continue with nerve issues, as well, and has been almost b6 for both of us.

That said, we need to understand why this has happened to us so that we know what to avoid in the future, how to get appropriate medical care, and to possibly help others in our same situation. Could you please let us know where the study stands and if there is anyone else that would help us? We have b6 that your institution could study and none of us have had COVID up to this point. And I have a b6 b6 I feel understanding our experience would save many others, along with our other family members, from this life altering situation we find ourselves in.

Thank you so much and I trust you are staying well there.

Sincerely,

b6

From: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Friday, September 17, 2021 6:25 AM
To: b6
Subject: RE: Request to participate in studies related to vaccines

Thank you b6

Angelique

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Cc: b6
Subject: RE: Request to participate in studies related to vaccines

Dear Angelique,

Yes, I would love to be added to your list and will look forward to participating in your study. Below is my contact information:

b6

I'm including b6 in this chain, too, as she may also like to join.

I appreciate your quick response and I truly hope these studies start happening quickly, too. There are many of us trying to understand what has happened to our bodies over these months and how we can get help.

Sincerely,

b6

From: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Thursday, September 16, 2021 12:12 PM
To: b6
Subject: RE: Request to participate in studies related to vaccines

Dear b6

Thank you for your interest in our research. We are currently developing an online survey system to collect stories about people's complications after receiving COVID vaccines. At this time, if you are willing, we can take your name and

contact information. We will reach back out to you when the survey system is completed to see if you are willing to volunteer in our on-line study.

Thanks you,

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-

From: b6
Sent: Thursday, September 16, 2021 11:23 AM
To: NINDSPostCovid19 <nindspostcovid19@ninds.nih.gov>
Subject: Request to participate in studies related to vaccines

Dear NIH,

I was referred to you and your group by Dr. Farinaz Safavi.

b6 and I have been having neurological problems since receiving our COVID-19 vaccinations this past spring, and we are desperately trying to heal and understand what has happened to us. She had both doses of Moderna starting b6 and I had one dose of Pfizer on b6 My b6 had Moderna, also, but no problems. She'll be getting a booster/third shot on b6

I would love to speak with someone in your department about participating in your studies. Seems we may be a unique case for you as we had/continue to have similar reactions since being vaccinated. b6 and I b6 want to do what we can to help others, understand our own problems, and be a part of the solution as we as a world try to end this pandemic. We did what we thought was right back in the spring and now we need help ourselves. The fact that you are researching gives me hope.

Sincerely,

b6

From: Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 b6
Sent: 4/9/2022 11:26:10 PM
To:
CC: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Thank you b6

Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
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-

From: b6
Sent: Saturday, April 9, 2022 6:46 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Cc: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Angelique,

Again, thank you and great to hear the study will be soon. We're desperate for answers, treatment, and we need to know what to avoid in the future. Also, I have a b6
b6

I'll reach out again in May unless I hear from you first.

Sincerely,

b6

From: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Thursday, April 7, 2022 1:59 PM
To: b6

Cc: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

None yet, but very soon. Wish I could be of more help to you ☹

Angelique

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From: b6
Sent: Thursday, April 7, 2022 3:22 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Cc: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Angelique,

Thanks so much! Any idea on timelines?

b6

From: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Thursday, April 7, 2022 1:04 PM
To: b6
Cc:
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Thank you b6 We will contact you when the study is approved.

Sincerely,
Angelique

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
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Cc: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Hello Angelique,

I'm following up from my just left phone message to you with this email if it's easier for you to respond this way.

b6 and I are interested in the details for the upcoming vaccine injury study as you had previously mentioned it should be starting soon now. Please let us know what you need from us and we are eager to participate.

Thank you again for all of your help over these months.

Sincerely,

b6

From: Gavin, Angelique (NIH/NINDS) [C] b6
Sent: Friday, February 18, 2022 10:26 AM
To: b6
Subject: RE: [EXTERNAL] RE: Request to participate in studies related to vaccines

Thank you b6

Angelique

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

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The 27 links were interesting, too, and I'm fully aware of that content. I've been researching about our illness since b6 of 2021 and the COVID virus neurological symptoms are not what we are experiencing. I will forward a few links to you in a separate email that may be helpful when you reply to others with COVID vaccine injuries.

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Dear NIH,

I was referred to you and your group by Dr. Farinaz Safavi.

b6 and I have been having neurological problems since receiving our COVID-19 vaccinations this past spring, and we are desperately trying to heal and understand what has happened to us. She had both doses of Moderna starting b6 and I had one dose of Pfizer on b6 My b6 had Moderna, also, but no problems. She'll be getting a booster/third shot on b6

I would love to speak with someone in your department about participating in your studies. Seems we may be a unique case for you as we had/continue to have similar reactions since being vaccinated. b6 and I b6 want to do what we can to help others, understand our own problems, and be a part of the solution as we as a world try to end this pandemic. We did what we thought was right back in the spring and now we need help ourselves. The fact that you are researching gives me hope.

Sincerely,

b6

From: Gavin, Angelique (NIH/NINDS) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6E97392E947E4F7EBB17EEB8AC87C5D5 b6
Sent: 5/2/2022 3:35:28 PM
To: b6
Subject: RE: [EXTERNAL] post-vaccine chronic issues

Perfect. Thank you!

Angelique Gavin, MS (Contractor)
NIH/NINDS Clinical Operations Manager
Contractor Preferred Solutions Group
National Institutes of Health
10 Center Drive
Building 10, Room 3B19, MSC 1251
Bethesda, MD 20814-9692
b6
(301) 480-5368 (efax)
b6
https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Monday, May 2, 2022 11:29 AM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: [EXTERNAL] post-vaccine chronic issues

That's correct. It's 8:28am in b6 right now, and online time calculators tell me it's 11:28am on the East Coast.

On Mon, May 2, 2022 at 8:17 AM Gavin, Angelique (NIH/NINDS) [C] b6 wrote:

> Thank you b6 I believe you are 3 hours behind us. Is that correct?
>
> Angelique
>
> *Angelique Gavin, MS* (Contractor)
>
> NIH/NINDS Clinical Operations Manager
>
> Contractor Preferred Solutions Group
>
> National Institutes of Health
>
> 10 Center Drive
>
> Building 10, Room 3B19, MSC 1251

Bethesda, MD 20814-9692

b6

(301) 480-5368 (efax)

b6

https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Monday, May 2, 2022 10:15 AM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: [EXTERNAL] post-vaccine chronic issues

Thanks Angelique, Wednesday 5/4 at 12 noon Pacific works for me. I've added you to my contacts and I'll keep an eye out for your call.

b6

On Mon, May 2, 2022 at 5:37 AM Gavin, Angelique (NIH/NINDS) [C] b6 wrote:

Thank you b6 Would Wednesday, May 4 at 12:00 noon your time work for you? I'll be calling from b6 b6

Angelique

Angelique Gavin, MS (Contractor)

NIH/NINDS Clinical Operations Manager

Contractor Preferred Solutions Group

National Institutes of Health

10 Center Drive

Building 10, Room 3B19, MSC 1251

Bethesda, MD 20814-9692

b6

(301) 480-5368 (efax)

b6

https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Friday, April 29, 2022 7:45 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: [EXTERNAL] post-vaccine chronic issues

Hi Angelique,

Next week the following times (all Pacific time) work best for me:

Tuesday 12pm-2pm

Wednesday 9am-12pm

Thursday 2pm-5pm

Friday 9am-5pm

I can be reached at b6 My mobile spam filtering is pretty aggressive, so if you get sent straight to voicemail please leave a message and I will call back. Even better, if you could provide the number you'll be calling from, I can add you to my contacts and you will (hopefully) not get filtered.

b6

On Fri, Apr 29, 2022 at 4:37 PM Gavin, Angelique (NIH/NINDS) [C] b6 wrote:

Thank you b6 for your quick reply. I'd like to schedule an eligibility telephone interview for our COVID-19 study. It will take approximately 15 minutes of your time. Let me know some days and times in the next week that you would be available and I will reply with an option that works for us both. Please send me the phone number you wish for me to call and keep in mind that I am in the Eastern Time Zone. I look forward to speaking with you soon.

Sincerely,

Angelique

Angelique Gavin, MS (Contractor)

NIH/NINDS Clinical Operations Manager

Contractor Preferred Solutions Group

National Institutes of Health

10 Center Drive

Building 10, Room 3B19, MSC 1251

Bethesda, MD 20814-9692

b6

(301) 480-5368 (efax)

b6

https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Friday, April 29, 2022 3:47 PM
To: Gavin, Angelique (NIH/NINDS) [C] b6
Subject: Re: [EXTERNAL] post-vaccine chronic issues

Thank you Angelique! I would absolutely like to be placed on your wait list. I'm interested in both studies, as well as anything else COVID related that can be done online/by phone (I'm in b6 and can't travel).

b6

On Fri, Apr 29, 2022 at 12:35 PM Gavin, Angelique (NIH/NINDS) [C] b6 wrote:

Dear b6

I hope this finds you doing well. I received your inquiry from Dr. Avindra Nath. Our vaccine study is not yet approved but should be soon. We will be doing telephone interviews and online questionnaires to gather information about what vaccine recipients are experiencing. Let me know if you would like to be placed on our wait list and we will contact you as soon as recruitment begins. In addition, our COVID-19 study is recruiting. It is a similar study with interviews and online questionnaires. It may provide you access to other studies taking place at the clinical center. Let me know if you are interested in either or both studies and we can make arrangements to speak further by phone.

Thank you,

Angelique

Angelique Gavin, MS (Contractor)

NIH/NINDS Clinical Operations Manager

Contractor Preferred Solutions Group

National Institutes of Health

10 Center Drive

Building 10, Room 3B19, MSC 1251

Bethesda, MD 20814-9692

b6

(301) 480-5368 (efax)

b6

https://clinicaltrials.gov - study number 000089-N

-

From: b6
Sent: Friday, April 29, 2022 1:25 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: NINDSPostCovid19 <nindspostcovid19@ninds.nih.gov>
Subject: Re: [EXTERNAL] post-vaccine chronic issues

Dear Avi,

Thank you for the response! In case it is helpful and/or of interest, I'm attaching my vaccine/illness timeline that I prepared for my medical providers.

b6

On Thu, Apr 28, 2022 at 8:20 PM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6

Sorry to hear of your illness. I have copied our research team who can collect the information.

Best

Avi

From: b6
Date: Thursday, April 28, 2022 at 10:22 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: [EXTERNAL] post-vaccine chronic issues

Hello Dr. Nath,

I've read about the work you are doing regarding post-vaccine chronic health conditions, and wondered if you'd be interested in hearing about my experience.

The short version: I'm triple Moderna vaccinated, came down with a COVID-like illness b6 5 PCR tests and 1 nucleocapsid b6 yet here it is b6 and I'm still long-hauling (including loss of taste and smell, chronic fatigue, and exercise intolerance).

Any interest? If so, I'm happy to share more.

b6

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540-b6]
Sent: 3/24/2021 10:21:02 AM
To: b6
Subject: RE: Vaccine adverse event

Good morning b6

Dr. Safavi should be following up with you in the next couple of days. Please let me know if you haven't heard from her by the end of the week.

Thanks,
Amanda

From: b6
Sent: Tuesday, March 23, 2021 10:21 PM
To: Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Fwd: Vaccine adverse event

Hi Amanda,

Please see the below email I sent to Dr Safazi. Any help you can offer would be much appreciated

Sent from my iPhone

Begin forwarded message:

From: b6
Date: March 23, 2021 at 10:19:55 PM EDT
To: b6
Subject: Vaccine adverse event

Hi Dr Safazi

I got your info from a colleague who also has had issues since the covid vaccine.

I am a b6 in b6 I received the Pfizer vaccine on b6 and b6 Immediately after each vaccine I had flushing, tachycardia, mildly elevated BP, and dizziness. It lasted about an hour the first time. The second time I anticipated the reaction and thought maybe the first time was due to anxiety. I had the fishing again and laid down to let the tachycardia settle. It lasted 20 min. I got up and left and then it started again much more severely while I was driving home.

I felt achy and had brain fog for a few days after the 2nd shot. A few days later b6 b6 was diagnosed with b6 I am not sure if I myself contracted it. Over the next 2 weeks I felt severely fatigued, brain fog, nausea, diarrhea. I then started having severe flushing and tachycardia episodes along with diarrhea. I had two severe

episodes at work and was taken by ambulance to b6

b6

I have seen cards and been diagnosed with b6 There is some concern for b6 I was started on b6 b6 I ended up taking a b6 b6 which helped reduced the flushing and tachycardia at rest.

I continue to have intermittent neuropathy in my feet. b6 I am awaiting results of b6 Tests for b6 b6 b6 I am having b6 due to some facial numbness I have had.

I had to take b6 due to the severity of my symptoms. b6 b6 but I still struggle with b6 neuropathy, fatigue, diarrhea, and other vague symptoms.

I am hoping you can help me or shed light on this reaction. I am desperate to get my life back.

Thank you for taking the time to read my email.

Sincerely,

b6

Sent from my iPhone

From: b6
Sent: 1/19/2021 3:13:04 AM
To: Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb b6
Subject: Re: reaction to Pfizer Covid vaccine

Hi Dr. Togias,
I wanted to give you a follow up. I have been very ill with severe paresthesias of my face, tongue and extremities starting 30 minutes after receiving the Pfizer covid vaccine on b6 It can be associated with dizziness, blurred vision and tremor. I also feel a very tight band like constriction around my lower chest. I was previously in good health. I am severely debilitated and the many doctors I have seen do not know what happened to me or how to help me. b6 is still studying my blood. She has seen b6 She is looking for autoantibodies. There has been no allergic phenomenon seen. I have had b6 b6 Have you heard of similar reactions and do you know of any physician in the country who may be able to help me? I am not improving and have been barely functioning for b6 now. At times I felt like I wasn't going to make it. I desperately need medical help.
I have reported my reaction to Pfizer, VAERS, Vsafe, FDA, CDC multiple times. No one has contacted me. I wonder how many other cases there are like me since they obviously don't care about what has happened to me and are not reporting it. It is really shocking.
Thank you for any help you can give me.
Sincerely,
b6

Sent from my iPhone

> On Jan 3, 2021, at 9:14 AM, b6 wrote:
>
> Thank you. I am experiencing some type of immunological/neurological
> reaction to the vaccine. The most prominent symptom is burning and numbness of my face and tongue. I have reached out to many people and no one can help me. b6 has given up on me and I don't feel these symptoms are allergic. b6 do not help. I have reported my symptoms to VAERS, v safe, Pfizer multiple times but have had no response from anyone. This has been a very difficult experience. I just pray that this resolves. I was previously healthy and am very uncomfortable now. I feel very helpless. If you know anyone that might be able to help me I would greatly appreciate it.
> Thank you.
>
> Sent from my iPhone
>
>> On Jan 3, 2021, at 8:56 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>
>> Good morning b6
>> I am so sorry to hear that the problems continue. I have not heard of such a situation but that does not mean anything because we do not get reports from patients at NIH, nor do we see patients. Have you reported this to the VAERS website? It is important that the CDC gets these reports.
>> As I mentioned before, if I hear anything of relevance, I will let you and b6 know.
>> Kind regards,
>> Alkis Togias
>>
>>
>> On 1/2/21, 7:13 PM, b6 wrote:
>>
>> Hi Dr. Togias, I am so sorry to bother you but I am frightened and don't know what to do. I continue to be ill since I received the Pfizer Covid vaccine on b6 I was healthy prior to the vaccine. I have a remote history of b6 I was also on b6 I developed burning in my face 30 minutes after I received the vaccine and then had a pre-syncopal event with dizziness, tachycardia and chest tightness. I was basically in bed for the next six days with severe malaise, chest tightness, anorexia, burning of my face and tongue and occasional extremities. The malaise and chest tightness have resolved. Symptoms that I am left with are constant burning in my face and intermittent tingling and numbness of my face and tongue. I occasionally get burning in different areas of my arms and legs briefly. No muscle weakness. I have been on b6 b6 doesn't know what to do for me. He has spoken to b6 My labs are b6 b6 I spoke with a rheumatologist and immunologist today and b6 b6 They believe I am having some time of immunological/neurological reaction. Have you heard of this? Do you know of anyone who can help me?
>> Today is b6 and I am feeling worse today.
>> Thank you. I am trying to get help and no one knows what to do for me.
>> Sincerely,
>> b6

>> b6
>>
>> Sent from my iPhone
>>
>>>> On Dec 29, 2020, at 5:39 PM, b6 wrote:
>>>
>>> Thank you so much Dr. Togias. This has been very frightening for me. b6 seems to be easing the burning in my face. Please be in touch if you hear anything new.
>>> Sincerely,
>>> b6
>>>
>>> Sent from my iPhone
>>>
>>>>> On Dec 29, 2020, at 5:26 PM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>
>>>> Hi b6
>>>> I am very sorry to hear that things have gotten worse. I called b6 and I think he is doing the best he can for a situation that is very difficult to assess given its unusual nature and our lack of knowledge of a potential mechanism. I told b6 that I will let him know if we hear of more people having developed the type of reaction you had and how their physicians have approached it.
>>>> I hope you feel better soon.
>>>> Kind regards,
>>>> Alkis Togias
>>>>
>>>>> On 12/29/20, 7:29 PM, b6 wrote:
>>>>
>>>> Dr Togias, I am so sick. I thought I was better yesterday. Felt fine yesterday evening. Today much worse. Face and legs burning. Face felt numb and swollen. Hard to get a deep breath b6 b6 Symptoms come in waves. I am really afraid. Today is b6 since I received the Pfizer vaccine. This all started about 30 minutes after receiving it. I was fine prior. b6 is helping me but I don't think anyone knows what to do. He has spoken to b6 I have left her 2 messages. I am on b6 I have been b6 b6 I have a remote history of b6 I have been b6 b6 I just started b6 If you have any other thoughts, please let me or b6 know. His number is b6 This has been very scary for me. I am fearful that something worse will happen to me and don't know how long this will last for. So sorry to bother you.
>>>> Thank you,
>>>> b6
>>>>
>>>> Sent from my iPhone
>>>>
>>>>>> On Dec 28, 2020, at 4:48 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>
>>>>> I am glad you are seeing b6 I know him well. He may be able to contact b6 as well.
>>>>> I hope this goes away soon!
>>>>> Alkis
>>>>>
>>>>>> On 12/27/20, 8:46 PM, b6 wrote:
>>>>>
>>>>> Thank you for your kind response. I have been very ill today. An allergist, b6 has been helping me. I believe he knows you. I have had burning in my face and extremities, headache, chills, chest tightness, malaise. No fever or cough. b6 I have been taking b6 b6
>>>>> I will contact b6 and get labs drawn tomorrow. I hope this reaction that I am having ends soon. I hope I survive it. It has been quite severe.
>>>>> Sincerely,
>>>>> b6
>>>>>
>>>>> Sent from my iPhone
>>>>>
>>>>>>> On Dec 27, 2020, at 5:04 PM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>>
>>>>>> Dear b6
>>>>>> Thank you very much for your note. I am sorry to hear you experienced such a reaction with the Pfizer vaccine and I can understand your hesitancy for receiving the second dose. Not being able to assess your situation in more detail, I do not want to risk an interpretation or a recommendation. Your reaction does not sound as typical anaphylaxis although hypertensive systemic allergic reations have been described. As you have heard, we have not identified a mechanism behind reactions to the Pfizer vaccine (there has also been at least one case with the Moderna) and we hope that, if various logistical issues are addressed, we will be able to conduct the study you have probably heard about to help get more insights. Due to your reaction you would probably not qualify for that study, but I suggest you contact a specialist who may be able to do some testing that may help assess some hypotheses. The person that I know in b6 who has been actively working in this field, is b6 at b6 It may be worth contacting her.

>>>>>> With kind regards,
>>>>>>
>>>>>> Alkis Togias, M.D.
>>>>>> Branch Chief, Allergy, Asthma and Airway Biology
>>>>>> DAIT/NIAID/NIH
>>>>>>
>>>>>> 5601 Fishers Lane, Room 6B40
>>>>>> Bethesda, MD 20892-9827
>>>>>> email: b6
>>>>>> tel: b6
>>>>>>
>>>>>> For Courier Mail please use the following ZIP code: Rockville, MD 20852
>>>>>> Disclaimer: The information in this e-mail and any of its attachments is confidential and may be sensitive. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.
>>>>>>
>>>>>>
>>>>>>
>>>>>>
>>>>>>
>>>>>>> On 12/25/20, 2:11 PM, b6 wrote:
>>>>>>
>>>>>> Hi Dr. Togias,
>>>>>> My name is b6 I am a b6 in b6 I received the Pfizer BioNTech Covid vaccine the morning of b6 I left the hospital after 15 minutes feeling fine but 30 minutes after receiving the vaccine, I developed burning and tingling of my face, tightness at the base of my tongue, shortness of breath, heart racing, chest tightness and had a near syncopal event. I immediately took b6 and called 911. By the time the paramedics arrived, I felt alittle better but my BP was b6 My face continued to burn as did my arms and I felt mild chest tightness for 12 hours and stayed on b6 . By 10 pm, the symptoms completely resolved. I felt perfectly fine the next day until 10 pm when all the symptoms recurred as well as swelling and hives on my face. I have continued b6 and continue with tingling of my face and slight chest tightness. I believe I am having a significant allergic reaction to the vaccine. I did notify all the online sites including VAERS, Pfizer. I wonder if I have b6 b6 If you are interested in my case, I am happy to help. I am also very nervous about receiving the second dose of the vaccine. If you are not the appropriate person to receive this info, would you direct me to who would be interested in this info?
>>>>>> Thanks so much,
>>>>>> b6
>>>>>> b6
>>>>>>
>>>>>>
>>>>>> Sent from my iPhone
>>>>>>
>>>>>
>>>>
>>

From: b6
Sent: 3/27/2021 1:20:08 PM
To: Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb b6
Subject: Re: b6 Severe reaction to the Moderna vaccine

Thank you so much for your fast and interesting response. I appreciate it and will set up an appointment with an allergist. Have a wonderful day!

Sincerely,
b6

On Sat, Mar 27, 2021, 9:06 AM Togias, Alkis (NIH/NIAID) [E] b6 wrote:

Dear b6

Thank you for contacting me. I am very sorry to hear you are experiencing this problem. As I am not your physician, I cannot give you specific advice, but I would recommend you set up an appointment with an allergist who can do PEG testing. These tests are mostly done on the skin with medications that contain PEG. There are also blood tests used in research, but I do not know if any of those are now approved for use in clinical settings. Overall, the reliability of all this testing is not 100%. If, given your history, the tests provide evidence of allergy to PEG, one could feel relatively comfortable that this may have been the culprit behind the reaction to the Moderna vaccine. On the other hand, a negative test may not be as reliable. There are also a couple more factors that complicate the certainty of testing: a) your reaction occurred 10 days after your vaccination and most allergic reactions to PEG have been reported to occur relatively soon after exposure and b) because of your hives, it may be difficult to do the skin testing I was referring to above. Finally, there could be reasons other than PEG behind your hives that we do not yet understand and it will take more research to do so.

I apologize for not being able to give you a very specific answer, but, unfortunately, there are a lot of knowledge gaps at this time.

With kind regards,

Alkis Togias

Alkis Togias, M.D.

Branch Chief, Allergy, Asthma and Airway Biology

DAIT/NIAID/NIH

5601 Fishers Lane, Room 6B40

Bethesda, MD 20892-9827

email: b6

tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

From: b6
Date: Saturday, March 27, 2021 at 4:44 AM
To: Alkis Togias b6
Subject: b6 Severe reaction to the Moderna vaccine

Dear Dr. Togias,

I read your name in an article on www.sciencemag.org. I am having a severe allergic reaction to the Moderna vaccine. I had the vaccine on b6 and on b6 I broke out in hives all over my body. I went to my primary care doctor who put me on b6 I was seen in the ER on b6 because I was experiencing pain when breathing, no wheezing, just pain. They did b6 b6 and was sent home

I believe this reaction may be caused from polyethylene glycol. I had the same reaction from b6 b6 I also had b6 I looked up both of these meds and they both contain this chemical.

I am attaching photos so that you may see what is happening. I am b6 and still have itchy hives all over.

I am writing to you because I think this may interest you as to the safety of the vaccine for people who are allergic to this chemical. I would also like some advice as to whether you feel I should test for polyethylene glycol antibodies in my blood.

Sincerely,

b6

From: Marks, Peter [b6]
Sent: 2/21/2021 10:04:51 PM
To: [b6] [b6] Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb[b6] Beavers, Suzanne (CDC/DDPHSS/CSELS/DSEPD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffcb980af3a40189a0746a453e44921[b6] Walensky, Rochelle (CDC/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=971e7c2ce7f94e67a13565f9bfaef055[b6]
CC: McNeill, Lorrie (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fbf9dff45194f70aef59cfb59f1b9cd[b6]
Subject: RE: [EXTERNAL] RE: Adverse neurological reactions to Covid mRNA vaccines

Dear [b6]

So sorry to hear of your symptoms. We take all adverse event reports seriously. I have asked our pharmacovigilance team to follow up with you.
We certainly hope that you feel better soon.

Thanks to our NIH colleagues for forwarding your message.

Best Regards,
Peter

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
WO71-7232
Silver Spring, MD 20993
[b6] voice
301-595-1310 fax
[b6]

-----Original Message-----
From: [b6]
Sent: Sunday, February 21, 2021 5:00 PM
To: [b6] Togias, Alkis (NIH) [b6] Beavers, Suzanne (CDC) [b6] Walensky, Rochelle P (CDC) [b6] Marks, Peter [b6]
Subject: [EXTERNAL] RE: Adverse neurological reactions to Covid mRNA vaccines

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.

HI
Thanks and I forwarded your e mail to my colleagues at the FDA. I know that the NIH is interested in this and I have heard of a grant announcement to follow long term issues.
I hope you feel better and that the blood tests and research results I shared with you so far have been helpful. I am happy to speak with your rheumatologist on the phone anytime to share what we found in your blood.
All the best
[b6]

-----Original Message-----
From: [b6]

Sent: Sunday, February 21, 2021 1:03 PM
To: b6;
Alkis Togias b6
Subject: Adverse neurological reactions to Covid mRNA vaccines

Hi doctors,
As most of you know me, I am a b6 who suffered a terrible reaction 30 minutes after receiving the first dose of the Pfizer Covid vaccine. I am still very symptomatic b6 out with severe paresthesias, chest tightness, tremor, dizziness, headaches. I am on the internet seeking information and came across an article in a journal Neurology Today. b6 b6 I have subsequently been contacted by five other women who have had very similar neurological reactions to mine and are all quite ill weeks after receiving their vaccines. They have had similar difficulty in getting appropriate medical care as the medical community knows nothing about these reactions. They too have reported their reactions to the drug companies, the regulatory governmental agencies, and there has been no response or documentation of their reactions.
It is apparent that these neurological reactions are not unheard of. Why are they not being addressed? Why are our reports being ignored? We do not have any desire to frighten the public about the vaccine, but we all very much would like to get medical care and fear that we will not recover from these debilitating symptoms. We were all previously healthy. We are considering going to the media as we are terribly frustrated at the lack of transparency. Any advice from you would be greatly appreciated. Also, please pass this information on to the appropriate people. If they would like to contact me, my cell is b6
Sincerely,
b6

Sent from my iPhone

From: b6
Sent: 4/2/2021 1:44:21 AM
To: Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb b6
Subject: Re: Covid vaccine reaction

Hello,
I appreciate your response and thank you for any future assistance you can provide. Thank you very much!
b6

On Thu, Apr 1, 2021, 7:51 AM Togias, Alkis (NIH/NIAID) [E] b6 wrote:

Dear b6

Thank you for contacting me. I am very sorry to hear about the problems you've encountered after receiving the second dose of Moderna vaccine. I have been contacted by a few people who have experienced similar problems, but I cannot offer much help primarily because my expertise is in allergy (and what you describe does not sound like an allergic reaction) and because I do not see patients (I have been only doing research for more than a decade). I have tried to find out if there is a research center that has taken on this matter so that I can refer people who contact me and I have not been successful, so far. I will keep your name and contact info in my records and if I come across any knowledge related to your problem, I will let you know.

I apologize for not being able to offer you any more helpful information.

With kind regards,

Alkis Togias

Alkis Togias, M.D.

Branch Chief, Allergy, Asthma and Airway Biology

DAIT/NIAID/NIH

5601 Fishers Lane, Room 6B40

Bethesda, MD 20892-9827

email: b6

tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

From: b6
Date: Wednesday, March 31, 2021 at 7:41 PM
To: Alkis Togias b6
Subject: Covid vaccine reaction

Hello,

I have received your email from b6 I will preface it by saying I am a pretty healthy b6 and my only underlying conditions are b6 no prior neuro issues. I have been also having neurological symptoms starting shortly after my second dose of the Moderna vaccine. I received my first dose on b6 and my second on b6 The first dose was fine, just was a little tired. The second one, I had brain fog within a few hours and just didn't feel quite right and like I wasn't quite with it. Then shortly after I started with dizziness and headaches that ran across my forehead, I then had my eyes checked and all was normal. My eyes are sensitive to light and are just plain weird..Then the dizziness continued but I started to have burning in my temple area that spread around my eyes/sinuses and across my forehead. I went to see my PCP who gave me b6 b6 I had no relief from that, so the following week he put me on b6 and I had about a 2 day relief from symptoms while on b6 The symptoms continue, although I will say that the dizziness is less, but the tingling in my face is still there, along with some in my extremities, and within the past 2 weeks I have had what feels like heart palpitations, I contacted my doctor again who wanted me to go to the ER, so I did, and b6 b6 which they didn't think much about. They did the b6 tests and b6 My PCP referred me to an ENT, which I have an appointment with on Monday, next I would like to see a neurologist, unless you have any other suggestions, as I am at a loss.

Thank you,

b6

From: b6
Sent: 6/30/2021 5:47:26 PM
To: Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb b6
Subject: Update on my neuro reaction

Flag: Follow Up

Hi Dr. Togias!

I reached out several months ago regarding a strange neurological reaction to the vaccine. I'd like to give you an update.

What began as just facial paraesthesia has escalated to debilitating, full body nerve pain. After b6 b6 of suffering, my b6 showed evidence of b6 I should be starting treatment soon.

I am hopeful that I will get better. I just want to make sure people are aware of exactly how severe some of these vaccine reactions have become. My doctors ran an extensive work up on me and the only evidence they could find of b6 was b6 b6 However I did test b6 Given the timing it has become pretty obvious to those treating me that this is an immune mediated reaction to the Pfizer vaccine.

I hope this update finds you well and I appreciate your support and interest in these evolving neurological reactions.

Warmly,

b6

Sent from my iPhone

From: b6

Sent: 6/29/2021 10:12:49 PM

To: Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-b6] Marks, Peter (FDA/CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2e527dbda2b4a86b8d72f06b813d471-b6] Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb-b6] Butler, Jay C. (CDC/DDID/OD) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4d7905589004188b9d8c505514c3374-b6]

Subject: Severe neurological reaction to the Pfizer covid vaccine

I need to know what has happened to me. I have had severe burning paresthesias from head to toe since I received the Pfizer Covid vaccine b6. I am in severe pain and incapacitated. I take medications seven times a day that do nothing. b6 I have never heard of an illness like this. It is unbearable. I am barely surviving. b6 There are 1000's others like me. No one in this country knows what has happened to us. We have reached out to every expert across the country including the CDC and the NIH. It is time that we get answers. It is ridiculous and criminal that no one is talking about these reactions or trying to help us. It is time that we get the help that we need. Please. Stop gaslighting us and help us. We are innocent Americans who took the vaccine willingly with no informed consent and our lives have been taken from us. You have abandoned us. Please. It is your duty to acknowledge and help us. We are tired of writing these letters to you and pleading for help. Do your job and help us. We beg of you.

b6

b6

Sent from my iPhone

From: b6
Sent: 1/24/2022 8:04:22 PM
To: Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb b6
CC: b6
Subject: [EXTERNAL] Pfizer Vaccine Death Confirmed Via Autopsy Report
Attachments: b6
b6

Dear Dr. Alkis Togias,

Greetings. My name is b6 along with my parents b6 We are emailing to discuss my b6 who passed away on b6 We have received an extensive autopsy report and the findings concurred that his death was caused directly due to the Pfizer booster vaccine that he had received on b6 The pathologist performed scans of his heart and gathered 22 slides which confirmed that b6 had severe myocarditis from the Pfizer booster vaccine that led to his death.

Please give us answers and follow up to why this occurred. We are devastated.

Lot #'s
Pfizer 1st dose -
Pfizer 2nd dose b6
Pfizer booster -

Autopsy, death certificate, vaccine cards, and apple watch heart rate data are attached

Thank you,

b6

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From: b6
Sent: 3/27/2021 8:43:29 AM
To: Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb b6
Subject: b6 Severe reaction to the Moderna vaccine
Attachments: 20210325_081430.jpg; 20210325_083005.jpg; 20210323_192028.jpg; 20210325_081000.jpg; 20210323_201954.jpg

Dear Dr. Togias,

I read your name in an article on www.sciencemag.org. I am having a severe allergic reaction to the Moderna vaccine. I had the vaccine on b6 and on b6 I broke out in hives all over my body. I went to my primary care doctor who put me on b6 I was seen in the ER on b6 because I was experiencing pain when breathing, no wheezing, just pain. They did b6 b6 and was sent home

I believe this reaction may be caused from polyethylene glycol. I had the same reaction from b6 b6 I also had b6 I looked up both of these meds and they both contain this chemical.

I am attaching photos so that you may see what is happening. I am b6 and still have itchy hives all over.

I am writing to you because I think this may interest you as to the safety of the vaccine for people who are allergic to this chemical. I would also like some advice as to whether you feel I should test for polyethylene glycol antibodies in my blood.

Sincerely,

b6

b6

b6

b6

b6

b6

From: Togias, Alkis (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C8B85408814D496194BED8D69D6143EB-b6]
Sent: 1/23/2021 2:13:37 AM
To: b6
Subject: Re: Vaccine question

Dear b6
Thank you for contacting me and I am sorry to hear you had a bad reaction with the COVID-19 vaccine. From your description, it would be very hard for me to offer an opinion as to whether you experienced a true allergic reaction. A more detailed description of your symptoms and their timing would help. I also hope that the ED checked the level of serum tryptase within an hour or so from symptom onset. If so, have you been given the results?
As for the second vaccination, if what you experienced was a true allergic reaction, it would not be prudent to receive the second dose. Pre-treatment is not recommended by the American Academy of Allergy, Asthma and Immunology as there are no data supporting efficacy and some people are concerned that a more severe reaction may be masked and manifest itself at a later time, when you are not under medical supervision.
Whether PEG is the culprit behind vaccine-associated allergic reactions is a total unknown. Of course, if you have anti-PEG antibodies, particularly IgE, the case could be made for your reaction being related to PEG allergy. I do not know whether there are CLIA-certified labs that measure anti-PEG antibodies reliably, but one of b6 at the FDA, Dr. Steven Kozlowski, has an assay. It may be worth contacting him. Another approach would be to find out if a local allergist can skin test you with PEGs (or with PEG-containing drugs). A positive test would be indicative, but a negative may not be of much value since the negative predictive value is not known.
I hope some of this information may be of help.
Kind regards,
Alkis Togias

Alkis Togias, M.D.
Branch Chief, Allergy, Asthma and Airway Biology
DAIT/NIAID/NIH

5601 Fishers Lane, Room 6B40
Bethesda, MD 20892-9827
email: b6
tel: b6

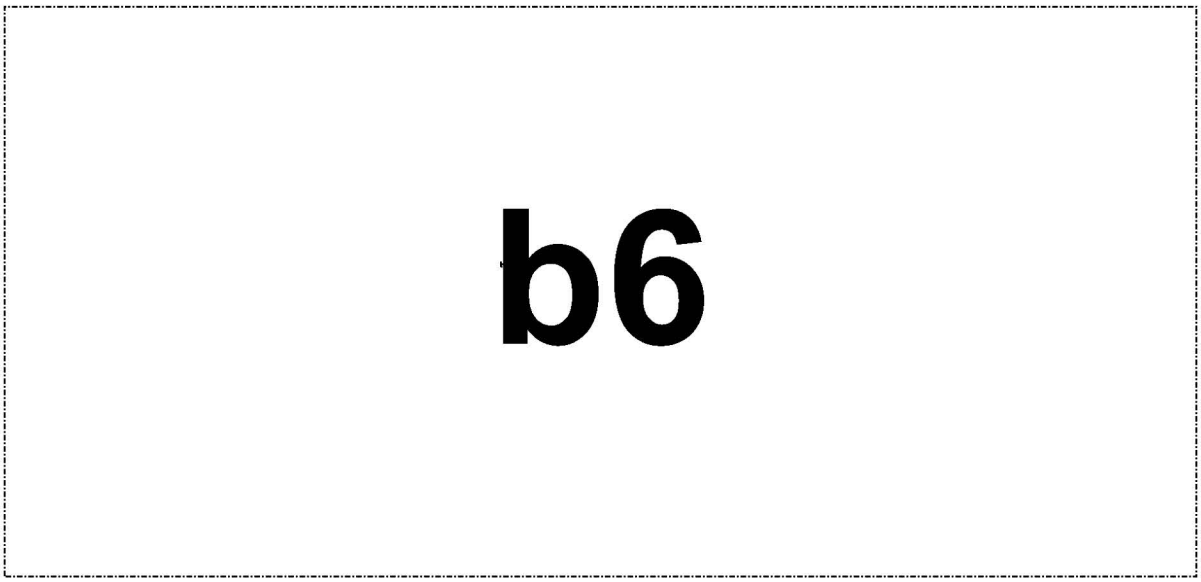
For Courier Mail please use the following ZIP code: Rockville, MD 20852

From: b6
Date: Friday, January 22, 2021 at 12:42 PM
To: Alkis Togias b6
Subject: Vaccine question

Good morning.
I found your name in an article in a Science Mag article regarding allergic reactions to the COVID vaccine from Pfizer.

I had my first shot b6 and ended up in the ER having a bad reaction to it. It was treated as an anaphylactic reaction, b6
b6
I am curious to know about the second shot, how to measure for anti-PEG antibodies, and if taking prednisone and Benadryl before would help prevent the reaction but allow me to complete the series. b6 reactions of any type. I have never had severe reactions to anything, until the last year, when I have had three: this one, b6 On reading the ingredients, there is no PEG in the b6 It's a very odd thing, and it saddens me to think I cannot be vaccinated, unless using prophylactic medications to premedicate would be okay.
What are your thoughts?
Also, if you need a test subject, I'm willing to help advance science.

Thank you for your time.



From: Togias, Alkis (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C8B85408814D496194BED8D69D6143EB b6
Sent: 2/11/2021 10:09:09 PM
To: b6
CC: b6
Subject: Re: Severe reaction to Pfizer Covid vaccine

Dear b6
Thank you for the update. I am glad you talked to b6 I know her well and I trust her judgment. I have also contacted my CDC colleagues asking about any insights with this problem. If I find something new, I will let you know.
I truly hope things will get better soon.
Kind regards,
Alkis Togias

On 2/11/21, 4:44 PM, b6 wrote:

Thank you for your reply Dr. Togias. I just had a virtual consultation with b6 at b6 I thought you might like to hear her thoughts. She has seen many cases like mine. She states I will completely recover from this. She believes I have had a b6 b6 reaction to the vaccine. In addition, my b6 and she believes I have b6 She believes some of my symptoms are related to b6 She is prescribing b6 and feels this will help me. I was so relieved to hear that I am going to be OK. She feels that I will have adequate protection from one dose of the vaccine and she definitely does not want me to receive another. She is recommending that I get b6
Thank you again for your help. You are one of the rare persons I have reached out to who has responded to me. I deeply appreciate that.
Sincerely,
b6

Sent from my iPhone

> On Feb 11, 2021, at 4:48 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>
> Dear b6
> I am truly very sorry to hear that the problems you experienced after your COVID-19 vaccination have continued. As you must be aware, problems like yours have been reported by other people; so the various agencies and the companies know about them. On the other hand, I am not aware whether any research is being conducted to understand their nature. I will continue checking with colleagues and if I hear something that could be helpful to you, I will let you know.
> With kind regards,
> Alkis Togias
>
>
> Alkis Togias, M.D.
> Branch Chief, Allergy, Asthma and Airway Biology
> DAIT/NIAID/NIH
>
> 5601 Fishers Lane, Room 6B40
> Bethesda, MD 20892-9827
> email: b6
> tel: b6
>
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>
>
>
>
> On 2/10/21, 3:08 PM, b6 wrote:
>
> Hi Dr. Togias,
> Sorry to bother you again. I am just feeling very desperate. I am still very ill with neurological symptoms b6 after receiving the Pfizer vaccine. I think I have told you about my reaction that occurred 30 minutes after receiving the vaccine in prior emails to you. Despite my

reporting this to the FDA, CDC, VAER's and Pfizer multiple times, there is no response from any agency or any documentation of my adverse reaction. b6 at b6 has reached out to the NIH as has my neurologist, b6 at b6 in b6 No one seems to know anything about this or what to do for me. I have been completely incapacitated for b6 now with severe paresthesias in my face, tongue, chest wall, limbs as well as headache, dizziness and tremor.

> Do you know anyone in the country who is studying these neurological reactions and who might be able to help me in some way recover? I would very much like to return to my prior life which was active and healthy. I feel very despondent over my prognosis. This has been devastating for me.

>

> With great appreciation for any help you can give me,

>

>

> b6

>

> Sent from my iPhone

>

>> On Jan 3, 2021, at 9:14 AM, b6 wrote:

>>

>> Thank you. I am experiencing some type of immunological/neurological

>> reaction to the vaccine. The most prominent symptom is burning and numbness of my face and tongue. I have reached out to many people and no one can help me. b6 has given up on me and I don't feel these symptoms are allergic. b6 do not help. I have reported my symptoms to VAERS, v safe, Pfizer multiple times but have had no response from anyone. This has been a very difficult experience. I just pray that this resolves. I was previously healthy and am very uncomfortable now. I feel very helpless. If you know anyone that might be able to help me I would greatly appreciate it.

>> Thank you.

>>

>> Sent from my iPhone

>>

>>>> On Jan 3, 2021, at 8:56 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:

>>>

>>> Good morning b6

>>> I am so sorry to hear that the problems continue. I have not heard of such a situation but that does not mean anything because we do not get reports from patients at NIH, nor do we see patients. Have you reported this to the VAERS website? It is important that the CDC gets these reports.

>>> As I mentioned before, if I hear anything of relevance, I will let you and b6 know.

>>> Kind regards,

>>> Alkis Togias

>>>

>>>

>>>> On 1/2/21, 7:13 PM, b6 wrote:

>>>

>>> Hi Dr. Togias, I am so sorry to bother you but I am frightened and don't know what to do. I continue to be ill since I received the Pfizer Covid vaccine on b6 I was healthy prior to the vaccine. I have a remote history of b6 I was also on b6 I developed burning in my face 30 minutes after I received the vaccine and then had a pre-syncopal event with dizziness, tachycardia and chest tightness. I was basically in bed for the next six days with severe malaise, chest tightness, anorexia, burning of my face and tongue and occasional extremities. The malaise and chest tightness have resolved. Symptoms that I am left with are constant burning in my face and intermittent tingling and numbness of my face and tongue. I occasionally get burning in different areas of my arms and legs briefly. No muscle weakness. I have been on b6 b6 doesn't know what to do for me. He has spoken to b6 My labs are b6 b6 I spoke with a rheumatologist and immunologist today and will b6 They believe I am having some time of immunological/neurological reaction. Have you heard of this? Do you know of anyone who can help me?

>>> Today is b6 and I am feeling worse today.

>>> Thank you. I am trying to get help and no one knows what to do for me.

>>> Sincerely,

>>>

>>> b6

>>>

>>> Sent from my iPhone

>>>

>>>>> On Dec 29, 2020, at 5:39 PM, b6 wrote:

>>>>

>>>> Thank you so much Dr. Togias. This has been very frightening for me. b6 seems to be easing the burning in my face. Please be in touch if you hear anything new.

>>>> Sincerely,

>>>> b6

>>>>

>>>> Sent from my iPhone

>>>>

>>>>>> On Dec 29, 2020, at 5:26 PM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:

>>>>>

>>>>> Hi b6

>>>>> I am very sorry to hear that things have gotten worse. I called b6 and I think he is doing the best he can for a situation that is very difficult to assess given its unusual nature and our lack of knowledge of a potential mechanism. I told b6 that I will let him know if we hear of more people having developed the type of reaction you had and how their physicians have approached it.
>>>>> I hope you feel better soon.
>>>>> Kind regards,
>>>>> Alkis Togias
>>>>>
>>>>>> On 12/29/20, 7:29 PM, b6 wrote:
>>>>>
>>>>> Dr Togias, I am so sick. I thought I was better yesterday. Felt fine yesterday evening. Today much worse. Face and legs burning. Face felt numb and swollen. Hard to get a deep breath but b6 b6 Symptoms come in waves. I am really afraid. Today is b6 since I received the Pfizer vaccine. This all started about 30 minutes after receiving it. I was fine prior. b6 is helping me but I don't think anyone knows what to do. He has spoken to b6 I have left her 2 messages. I am on b6 I have been b6 b6 I have taken b6 No other meds. I have a remote history of b6 b6 I have been b6 b6 I just started b6 If you have any other thoughts, please let me or b6 know. His number is b6 This has been very scary for me. I am fearful that something worse will happen to me and don't know how long this will last for. So sorry to bother you.
>>>>> Thank you,
>>>>> b6
>>>>>
>>>>> Sent from my iPhone
>>>>>
>>>>>>> On Dec 28, 2020, at 4:48 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>>
>>>>>> I am glad you are seeing b6 I know him well. He may be able to contact b6 as well.
>>>>>> I hope this goes away soon!
>>>>>> Alkis
>>>>>>
>>>>>>>> On 12/27/20, 8:46 PM, b6 wrote:
>>>>>>
>>>>>> Thank you for your kind response. I have been very ill today. An allergist, b6 b6 has been helping me. I believe he knows you. I have had burning in my face and extremities, headache, chills, chest tightness, malaise. No fever or cough. b6 I have been taking b6
>>>>>> I will contact b6 I hope this reaction that I am having ends soon. I hope I survive it. It has been quite severe.
>>>>>> Sincerely,
>>>>>> b6
>>>>>>
>>>>>> Sent from my iPhone
>>>>>>
>>>>>>>>> On Dec 27, 2020, at 5:04 PM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>>>
>>>>>>> Dear b6
>>>>>>> Thank you very much for your note. I am sorry to hear you experienced such a reaction with the Pfizer vaccine and I can understand your hesitancy for receiving the second dose. Not being able to assess your situation in more detail, I do not want to risk an interpretation or a recommendation. Your reaction does not sound as typical anaphylaxis although hypertensive systemic allergic reations have been described. As you have heard, we have not identified a mechanism behind reactions to the Pfizer vaccine (there has also been at least one case with the Moderna) and we hope that, if various logistical issues are addressed, we will be able to conduct the study you have probably heard about to help get more insights. Due to your reaction you would probably not qualify for that study, but I suggest you contact a specialist who may be able to do some testing that may help assess some hypotheses. The person that I know in b6 who has been actively working in this field, is b6 at b6 It may be worth contacting her.
>>>>>>> With kind regards,
>>>>>>>
>>>>>>> Alkis Togias, M.D.
>>>>>>> Branch Chief, Allergy, Asthma and Airway Biology
>>>>>>> DAIT/NIAID/NIH
>>>>>>>
>>>>>>> 5601 Fishers Lane, Room 6B40
>>>>>>> Bethesda, MD 20892-9827
>>>>>>> email: b6
>>>>>>> tel: b6
>>>>>>>
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for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.

>>>>>>>
>>>>>>>
>>>>>>>
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>>>>>>>
>>>>>>>> On 12/25/20, 2:11 PM, b6 wrote:
>>>>>>>
>>>>>>> Hi Dr. Togias,
>>>>>>> My name is b6 I am a b6 in b6 I received the Pfizer BioNTech Covid vaccine the morning of b6 I left the hospital after 15 minutes feeling fine but 30 minutes after receiving the vaccine, I developed burning and tingling of my face, tightness at the base of my tongue, shortness of breath, heart racing, chest tightness and had a near syncopal event. I immediately took b6 and called 911. By the time the paramedics arrived, I felt alittle better but my BP was b6 My face continued to burn as did my arms and I felt mild chest tightness for 12 hours and stayed on b6 By 10 pm, the symptoms completely resolved. I felt perfectly fine the next day until 10 pm when all the symptoms recurred as well as swelling and hives on my face. I have continued b6 and continue with tingling of my face and slight chest tightness. I believe I am having a significant allergic reaction to the vaccine. I did notify all the online sites including VAERS, Pfizer. I wonder if I have b6 b6 If you are interested in my case, I am happy to help. I am also very nervous about receiving the second dose of the vaccine. If you are not the appropriate person to receive this info, would you direct me to who would be interested in this info?
>>>>>>> Thanks so much,
>>>>>>>
>>>>>>> b6
>>>>>>>
>>>>>>>
>>>>>>>
>>>>>>> Sent from my iPhone
>>>>>>>
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>>>>>
>>>
>

From: Togias, Alkis (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C8B85408814D496194BED8D69D6143EB b6
Sent: 2/20/2021 10:54:28 PM
To: b6
Subject: Re: vaccine reaction

Hi b6
If I come across something that may be relevant to your reaction, I will keep you posted.
Alkis

From: b6
Date: Saturday, February 20, 2021 at 3:49 PM
To: Alkis Togias b6
Subject: Re: vaccine reaction

Dear Dr. Togias,

Thank you for getting back to me. If you will at least keep me in mind if anything pops up that you know of, I would greatly appreciate it. Glad you are doing research to help the community!

Sincerely,

b6

On Fri, Feb 19, 2021 at 8:37 AM Togias, Alkis (NIH/NIAID) [E] b6 wrote:

> Hello,
>
> Thank you for contacting me. I am afraid I cannot be of much help because I am a non-practicing allergist and my team is currently only focusing on research related to severe allergic reactions to the COVID-19 vaccines. The reaction you are describing is not of allergic nature. We have been informed of several reactions that resemble yours and the CDC is aware, as well. However, they have not indicated to me whether they are aware of any academic centers in the country that are conducting research to understand those reactions.
>
> My apologies for not being able to offer anything that can be of help.
>
> Alkis Togias
>
> **Alkis Togias, M.D.**
>
> Branch Chief, Allergy, Asthma and Airway Biology
>
> DAIT/NIAID/NIH

5601 Fishers Lane, Room 6B40

Bethesda, MD 20892-9827

email: b6

tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

From: b6
Date: Thursday, February 18, 2021 at 2:12 PM
To: Alkis Togias b6
Subject: vaccine reaction

Good afternoon Dr. Togias,

I am a b6 who lives in b6 and I had a reaction to my second covid vaccine within essentially an hour of receiving it. I got your information from b6 who suggested I contact you. My reaction is mostly injection side UE/LE weakness and had a burning sensation at the muscle in which the injection was placed only. I can give further details if needed. I have had other neurological things going on as well. Prior to this I was healthy with no significant medical history.

I see there are research study trials going on at NIH and I wasn't sure if there is a study going on for people like me, because I am willing to assist in research. Or if you know of someone who may be able to have answers or is conducting research. I am working with my Doctor's and as this is all new, no one seems to have answers, so far my workup has all been negative.

Please let me know and I hope to hear from you soon!

b6

From: Togias, Alkis (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C8B85408814D496194BED8D69D6143EB b6
Sent: 3/19/2021 5:47:58 PM
To: b6
Subject: Re: COVID-19 vaccine reaction

You are welcome. I hope all goes well.
Alkis Togias

From: b6
Date: Friday, March 19, 2021 at 1:37 PM
To: Alkis Togias b6
Subject: Re: COVID-19 vaccine reaction

Thank you so much for the reply and information. After researching all morning - we did find that we needed to find an allergist who could do specific testing in regards to the reaction to the vaccine. That has been hard to find. We will contact b6

Much more research needs to be conducted along with collecting the data about these vaccines. That said we need faith in the Science that is available to us at this moment.

I wish more information was being put out about the possible reactions and maybe b6 could have had some initial tests done before getting the vaccine.

Thanks for all the efforts of the NIH.

Sincerely,

b6

b6

b6

From: Togias, Alkis (NIH/NIAID) [E] b6
Sent: Friday, March 19, 2021 1:25 PM
To: b6
Subject: COVID-19 vaccine reaction

Dear b6

Dr. Hackett forwarded your e-mail to me. Dr. Rotrosen, who also received a call from b6 has asked me to respond to you, as well.

I am very sorry to hear abou b6 reaction to the COVID-19 vaccine. Of course, even if I am an allergist, I cannot offer b6 specific advise given that I am not his physician. However, I would recommend that b6 gets evaluated by an allergist in b6 preferably in one of the academic Institutions (e.g. b6), all of whom have already seen several patients who experienced reactions. Allergist may be able to get enough clinical information from b6 and even conduct a couple of tests to assess the certainly of this having been a true severe allergic reaction, in which case the recommendation by the CDC is not to receive the second injection (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html). One of the allergists with specific interest in these reactions is b6 currently the b6 b6

I am also sorry that clear information is not available. We have been aware of these reactions since the approval of these vaccines and we hope to initiate a study very soon (almost all is set to go), to understand how prevalent they are, whether people with a strong allergy background are at the highest risk and what causes these reactions. Unfortunately, this study will only involve people who have not been vaccinated yet.

I hope this is of some help.

With kind regards,

Alkis Togias

Alkis Togias, M.D.
Branch Chief, Allergy, Asthma and Airway Biology
DAIT/NIAID/NIH

5601 Fishers Lane, Room 6B40
Bethesda, MD 20892-9827
email: b6
tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

From: b6
Date: Friday, March 19, 2021 at 12:07 PM
To: Charles J HACKETT b6
Subject: Help b6 had a bad reaction to Pfizer - need information

Dr. Hackett,

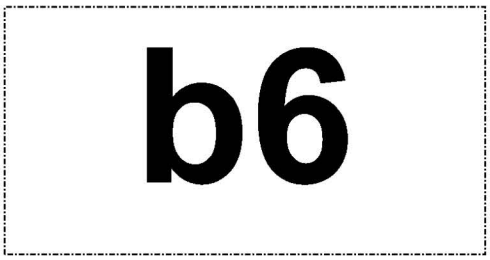
b6 had a severe reaction to the 1st Pfizer vaccine. He broke out in full body hives. b6 where he got the shot and had no information. He went to his primary doctor and she had no information - but put him on b6 We are having had time finding information on whether he should take the second shot.

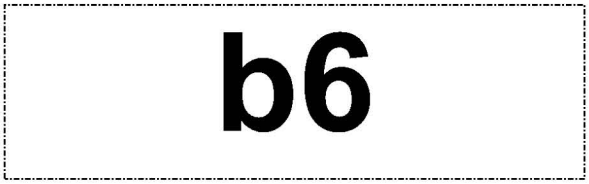
He has b6 We are very concerned. We have researched online but no clear information about what to do.

Why is it so hard to get clear information?

Thank you for getting back to us with information or where we can get the information.

b6





From: Togias, Alkis (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C8B85408814D496194BED8D69D6143EB b6
Sent: 3/24/2021 10:46:23 PM
To:
CC: b6
Subject: Re: COVID-19 vaccine reaction

I totally agree. Unfortunately, VAERS is based on self-reporting and it misses a tremendous amount of information that would have been so helpful to everybody.
A lot more work is needed!
Alkis Togias

From: b6
Date: Wednesday, March 24, 2021 at 6:28 PM
To: Alkis Togias b6
Cc: b6
Subject: Re: COVID-19 vaccine reaction

Understood.
It would be helpful if VAERS and CDC could collect
even preliminary data and advise on this.

Best,

On Mar 24, 2021, at 5:57 PM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:

Dear b6
Thank you for your note. I am glad you managed to get evaluated by an allergist in b6 and that you have already been b6 There is no knowledge so far, as to what else could have caused a reaction if not PEG. The field, as you understand, is brand new and we have no good research at this stage. Still waiting for our study to be initiated that could potentially give us more insight. Furthermore, there is no study that I am aware of that has carefully followed people who had a reaction to the first shot and received the second shot. As a result of this lack of knowledge, I do not think that anybody can advise you with major certainly as to whether to proceed with the 2nd dose. However, if you fulfill the criteria for a severe allergic reaction as defined in the CDC guideline (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html), you should not be receiving the second dose. I cannot make that determination since I am not your physician, but I was hoping your allergist would have been able to help you make that decision.
Overall, the lack of clear answers to your questions reflects our lack of knowledge and that is not surprising given the speed at which these vaccines came out.
With kind regards,
Alkis Togias

Alkis Togias, M.D.
Branch Chief, Allergy, Asthma and Airway Biology
DAIT/NIAID/NIH

5601 Fishers Lane, Room 6B40
Bethesda, MD 20892-9827
email: b6
tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

From: b6
Date: Wednesday, March 24, 2021 at 2:16 PM
To: Alkis Togias b6
Cc: b6
Subject: Re: COVID-19 vaccine reaction

Hi, Dr. Togias,

b6 had forwarded this to me based on our phone calls to NIH.
I had a hives/rash 4 days after the Pfizer shot #1. While I do have an appt scheduled with b6 b6 - it is not until 4/30. My scheduled shot #2 is b6
I just went to another local allergist here b6 b6
but obviously something caused the hives/ rash reaction, and nobody seems to know what, and could occur again. ***Do you or any of your team(s) have current updated data on reactions for 2nd Pfizer shot in people who had this type of reaction to the first shot?*** Am still on the fence about taking the 2nd, and my doc says wait at least for the reaction to clear up. What happens if I go beyond the 3 week schedule? Is it still effective? Nobody out there seems to give very clear answers on any of this stuff. Anything you can share is appreciated as far as data at least per my above question, thanks.

b6

From: Togias, Alkis (NIH/NIAID) [E] b6
Sent: Friday, March 19, 2021 1:25 PM
To: b6
Subject: COVID-19 vaccine reaction

Dear b6

Dr. Hackett forwarded your e-mail to me. Dr. Rotrosen, who also received a call from b6 has asked me to respond to you, as well.

I am very sorry to hear about b6 reaction to the COVID-19 vaccine. Of course, even if I am an allergist, I cannot offer b6 specific advise given that I am not his physician. However, I would recommend that b6 b6 gets evaluated by an allergist in b6 preferably in one of the academic Institutions (e.g. b6), all of whom have already seen several patients who experienced reactions. Allergist may be able to get enough clinical information from your husband and even conduct a couple of tests to assess the certainly of this having been a true severe allergic reaction, in which case the recommendation by the CDC is not to receive the second injection (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html). One of the allergists with specific interest in these reactions is b6 currently the b6

I am also sorry that clear information is not available. We have been aware of these reactions since the approval of these vaccines and we hope to initiate a study very soon (almost all is set to go), to understand how prevalent they are, whether people with a strong allergy background are at the highest risk and what causes these reactions. Unfortunately, this study will only involve people who have not been vaccinated yet.

I hope this is of some help.

With kind regards,

Alkis Togias

Alkis Togias, M.D.
Branch Chief, Allergy, Asthma and Airway Biology
DAIT/NIAID/NIH

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tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

accept liability for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.

From: b6
Date: Friday, March 19, 2021 at 12:07 PM
To: Charles J HACKETT b6
Subject: Help b6 had a bad reaction to Pfizer - need information

Dr. Hackett,

b6 had a severe reaction to the 1st Pfizer vaccine. He broke out in full body hives. b6 where he got the shot and had no information. He went to his primary doctor and she had no information - but put him on b6 We are having had time finding information on whether he should take the second shot.

He has b6
b6 We are very concerned. We have researched online but no clear information about what to do.

Why is it so hard to get clear information?

Thank you for getting back to us with information or where we can get the information.

b6

b6

b6

From: Togias, Alkis (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C8B85408814D496194BED8D69D6143EB-b6]
Sent: 3/29/2021 6:50:18 PM
To: b6
Subject: Re: Urgent issue re Pfizer Vaccine

You're welcome and I hope you will recover soon!
Alkis Togias

From: b6
Date: Monday, March 29, 2021 at 1:18 PM
To: Alkis Togias b6
Subject: Re: Urgent issue re Pfizer Vaccine

That is very interesting! At least I can throw that theory out the window! I really appreciate the insight and that is very good to know.

Thank you so much!

Sent from my iPhone

> On Mar 29, 2021, at 10:03 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>
> b6
> Inhaled corticosteroids b6 at regular doses should not interfere with the immune response to any vaccine. Theoretically, very high doses, above those recommended by what is approved, could suppress a vaccine response, but not alter it in any way that the vaccine produces side effects. Years ago, during the H1N1 pandemic, we did a study comparing people with severe asthma on very high doses of inhaled steroids (many also on oral steroids) to people with mild asthma and we found no differences in their H1N1 influenza vaccine response. Of course, here we are talking about different vaccines, but I just gave you this example to indicate that I do not believe b6 should be a concern.
> Alkis Togias
>
> ---
>
> **From:** b6
> **Date:** Monday, March 29, 2021 at 10:52 AM
> **To:** Alkis Togias b6
> **Subject:** Re: Urgent issue re Pfizer Vaccine
>
> I so appreciate your getting back to me and understand there's a lack of information.
>
> Perhaps interestingly for you to note, I b6 have wondered whether I have a compromised immune system because of the b6 I take. Obviously that is my own completely unscientific guesswork but I figure the more open I am about sharing info with the experts, the more likely we will be to evolve science in the right direction!
>
> Thank you again so much for responding and I will be sure to let you know as I find answers.
>
> I really appreciate it!

Best,

b6

Sent from my iPhone

On Mar 29, 2021, at 5:41 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:

Dear b6
Thank you for your note. I am very sorry to hear that you are experiencing such a problem and I fully understand your frustration. Unfortunately, I cannot give you much advice because I am not your physician and have little information about your condition, but also because I have stopped seeing patients for many years and all my work is in allergy research. The symptoms you are describing are not commonly seen with allergic reactions, which almost invariably begin with skin and respiratory manifestations occurring within minutes-hours after the administration of a vaccine and dissipating soon thereafter. I have received e-mails from people who have experienced symptoms similar to yours and I have tried to relate those to colleagues at the CDC, but I do not know if any action has been taken to investigate their nature. I am wondering whether contacting the National Institute of Neurologic Disorders and Stroke (NINDS) (https://www.ninds.nih.gov/Disorders/All-Disorders/Peripheral-Neuropathy-Information-Page) may be of help. The clinical director of NINDS is Dr. Avindra Nath (b6). I know he has been investigating brain involvement in COVID-19, but I do not know if he or his team are looking into neurologic complications possibly associated with the vaccines.
I apologize for not being able to offer you any more helpful information.
With kind regards,
Alkis Togias

Alkis Togias, M.D.
Branch Chief, Allergy, Asthma and Airway Biology
DAIT/NIAID/NIH

5601 Fishers Lane, Room 6B40
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email: b6
tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

From: b6
Date: Monday, March 29, 2021 at 12:32 AM
To: Alkis Togias b6
Subject: Urgent issue re Pfizer Vaccine

Hi Dr. Togias,

My name is b6 I am a b6 in b6 who has suffered a severe neurological reaction to the Pfizer vaccine.

After receiving it, I developed extreme and unrelenting paraesthesia and sensory neuropathy in my face and my head.

I've been told it's potentially an "immune-mediated antibody response that led to inflammation of the trigeminal nerve," though there is very little research available to understand why this happened and how to treat it.

Not only is my brain spasming and my eye clawing as I write this, but my hands are also shaking to the point where typing these words is a challenge. As a b6 it's made my work near impossible.

The medical community is at a total loss as to what to do, even though the correlation to the vaccine could not be more obvious. There are many of us who have reported these symptoms to VAERS, many of us who are finding ways to help each other through support groups, who are on a relentless search for answers to treat our disabling conditions. The burden should NOT be on us to figure out why this vaccine has caused us so much suffering.

I hope you may have some guidance for me as I endure this terrible condition.

Respectfully yours,

b6

From: Togias, Alkis (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C8B85408814D496194BED8D69D6143EB-b6]
Sent: 4/1/2021 12:27:21 PM
To: b6
Subject: Re: Moderna Adverse Reaction

Dear b6
Thank you for your note. I am very sorry to hear about the problems you have experienced after receiving the first dose of the Moderna vaccine. A few people with similar problems have contacted me and I have not been able to offer any help because this is not my area of expertise (my work is in allergy research). There have been allergic reactions to either the Pfizer or the Moderna vaccines and we are beginning a large study next week to find out how frequent these reactions are and what causes them. The study I am referring to will only recruit people who have not yet been vaccinated but have a history of severe allergic reactions to foods, insect stings or drugs.
There is a small possibility that what happened to you very early after receiving the vaccine was an allergic reaction and some allergists are testing for one of the vaccine components (polyethylene glycol). However, what you have experienced afterwards and are still experiencing is not at all characteristic of allergy. As I have mentioned to other people who have contacted me, I keep my eyes open for any researcher who is looking into this matter and I will keep your name in file to inform you, if anything comes up.
I apologize for not being able to offer more help.
With kind regards,
Alkis Togias

Alkis Togias, M.D.
Branch Chief, Allergy, Asthma and Airway Biology
DAIT/NIAID/NIH

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Bethesda, MD 20892-9827
email: b6
tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

From: b6
Date: Tuesday, March 30, 2021 at 5:27 PM
To: Alkis Togias b6
Subject: Moderna Adverse Reaction

My name is b6 and I am writing to you in regards my Moderna adverse reaction. I got your information from a small Facebook group that's going through the same issues as me. On b6 I received my first shot of Moderna. I was told to stay 30min because b6 I also received a flu shot 3 weeks prior. After 15 min I started to feel tingling in my face and throat tightness. As time passed, I started to feel like I couldn't breathe at one point. As I

continued to have issues breathing and started getting nauseous and lightheaded, they informed a nurse to look over me. The nurse had a student nurse do my vitals manually. She gives out b6 heart rate and b6 blood pressure. My normal blood pressure is b6 I had to be picked up due to feeling unwell. I went home took Tylenol and slept.

The next few weeks I kept feeling zaps of sharp pain in my chest area. On the 12th day after the vaccine, I had a panic attack. The panic attack started with a sharp pain in my neck and when I inhaled it hurt. I got heart palpitations and again felt like I couldn't breathe. I never suffered from a panic attack, so we called 911. The EMTs came my blood pressure was b6 It was suggested I go to the ER since b6 In the ER I told the doctor about my vaccine incident. They b6 and she decided to b6 I am working on getting that info). My b6 I was then diagnosed with b6 I was sent home and after a few hours I started to feel an internal tremor.

I describe the tremor as having a cell phone on vibrate its usually is in my lower abdomen to pelvic area. My blood pressure b6 I kept reaching out for help by going to ER once more, 3 urgent care visits and my primary. No one could help me, and I kept getting labeled as b6 My primary doctor said I could be having adverse reaction to the vaccine, but I just have to wait it out. The internal tremor I feel constantly and sometimes it's in my chest. I have muscle twitching, tingling in my lower limbs, muscle pain, and b6 b6 I do feel like my symptoms cause anxiety because ill have these spells where I feel adrenaline running through me which will cause anxiousness. My b6 s getting better, but I still b6 and have had another panic attack.

I have been on b6 During that time, my symptoms have not improved. I will be b6 I never had any of these issues prior. I don't drink, smoke or do any drugs besides the medication prescribed.

On 3/30/21, I reached out to my psychiatrist again and went into more detail about everything and she said she believes me about the vaccine side effects. She recommended I go back to my primary care doctor and ask to be referred to UCSD covid long haulers study to see if they can help me.
I wanted to share my information to see if it might be help to your research.

Thank you for your time, b6 Here is my phone number if you need anymore information b6

From: Togias, Alkis (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C8B85408814D496194BED8D69D6143EB-b6]
Sent: 1/30/2022 7:16:48 PM
To:
CC: b6
Subject: Re: [EXTERNAL] Pfizer Vaccine Death Confirmed Via Autopsy Report

Dear b6

Thank you for your note and I apologize for my late response. Please accept my sincere condolensces fo the loss of b6 b6 This is such a devastating event for the family!

During the pandemic, as an allergist, I have been involved in efforts to assess the cause(s) behind allergic reactions to the mRNA vaccines. However, neither I or my team at NIH have been involved in other aspects of vaccine safety, including myocarditis. Therefore, I am not the right person to offer you more information on this matter. As you may know, myorcarditis caused by SARS-CoV-2 vaccines, although rare (5-6 per 100,000 vaccinations), is more commonly seen in young males. The vast majority of people who develop this complication recover and it is double devastating that your brother was in the very, very small group of people who lost their lives.

If you have not already done so, you or b6 healthcare provider may wish to file a report through the Vaccine Adverse Event Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html. VAERS was created by the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC) to receive reports about and document adverse events that may be associated with vaccines. FDA is the regulatory agency responsible for assuring that all vaccines are safe and effective, and CDC is the federal agency responsible for tracking and controlling infectious diseases. Further questions may be directed to VAERS at https://vaers.hhs.gov/contact.html.

Again, I am very sorry for your loss.

With kind regards,

Alkis Togias

Alkis Togias, M.D.
Branch Chief, Allergy, Asthma and Airway Biology
DAIT/NIAID/NIH

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tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

From: b6
Date: Monday, January 24, 2022 at 3:06 PM
To: Alkis Togias b6
Cc: b6
Subject: [EXTERNAL] Pfizer Vaccine Death Confirmed Via Autopsy Report

Dear Dr. Alkis Togias,

Greetings. My name is b6 along with my parents b6 We are emailing to discuss b6 who passed away on b6 We have received an extensive autopsy report and the findings concurred that his death was caused directly due to the Pfizer booster vaccine that he had received on b6 The pathologist performed scans of his heart and gathered 22 slides which confirmed that b6 had severe myocarditis from the Pfizer booster vaccine that led to his death.

Please give us answers and follow up to why this occurred. We are devastated.

Lot #'s
Pfizer 1st dose -
Pfizer 2nd dose b6
Pfizer booster -

Autopsy, death certificate, vaccine cards, and apple watch heart rate data are attached

Thank you,

b6

From: b6
Sent: 2/11/2021 10:07:55 PM
To: b6 Togias, Alkis (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c8b85408814d496194bed8d69d6143eb b6
CC: b6
Subject: RE: Severe reaction to Pfizer Covid vaccine

Dear b6
Thanks so much and it is great to hear from you and when b6 would like, I can share the results of the tests we performed on your blood. You and I had spoken about the fact that b6 b6 which is what is likely leading to your symptoms. And you and I had talked about these symptoms likely taking a while to resolve. I spoke to the rheumatologist you had been referred to b6 and he said he would try to see you.
All the best
b6

-----Original Message-----
From: b6
Sent: Thursday, February 11, 2021 1:44 PM
To: Togias, Alkis (NIH/NIAID) [E] b6
Cc: b6
Subject: Re: Severe reaction to Pfizer Covid vaccine

Thank you for your reply Dr. Togias. I just had a virtual consultation with b6 at b6 I thought you might like to hear her thoughts. She has seen many cases like mine. She states I will completely recover from this. She believes I have had a b6 b6 reaction to the vaccine. In addition, my b6 and she believes I have b6 She believes some of my symptoms are related to b6 She is prescribing b6 and feels this will help me. I was so relieved to hear that I am going to be OK. She feels that I will have adequate protection from one dose of the vaccine and she definitely does not want me to receive another. She is recommending that I get b6
Thank you again for your help. You are one of the rare persons I have reached out to who has responded to me. I deeply appreciate that.
Sincerely,
b6

Sent from my iPhone

> On Feb 11, 2021, at 4:48 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>
> Dear b6
> I am truly very sorry to hear that the problems you experienced after your COVID-19 vaccination have continued. As you must be aware, problems like yours have been reported by other people; so the various agencies and the companies know about them. On the other hand, I am not aware whether any research is being conducted to understand their nature. I will continue checking with colleagues and if I hear something that could be helpful to you, I will let you know.
> With kind regards,
> Alkis Togias
>
>
> Alkis Togias, M.D.
> Branch Chief, Allergy, Asthma and Airway Biology DAIT/NIAID/NIH
>
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> 20852
> Disclaimer: The information in this e-mail and any of its attachments is confidential and may be sensitive. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.
>
>
>
>
> On 2/10/21, 3:08 PM, b6 wrote:

>
> Hi Dr. Togias,
> Sorry to bother you again. I am just feeling very desperate. I am still very ill with neurological symptoms b6 after receiving the Pfizer vaccine. I think I have told you about my reaction that occurred 30 minutes after receiving the vaccine in prior emails to you. Despite my reporting this to the FDA, CDC, VAER's and Pfizer multiple times, there is no response from any agency or any documentation of my adverse reaction. b6 at b6 has reached out to the NIH as has my neurologist, b6 b6 at b6 in b6 No one seems to know anything about this or what to do for me. I have been completely incapacitated for b6 now with severe paresthesias in my face, tongue, chest wall, limbs as well as headache, dizziness and tremor.
> Do you know anyone in the country who is studying these neurological reactions and who might be able to help me in some way recover? I would very much like to return to my prior life which was active and healthy. I feel very despondent over my prognosis. This has been devastating for me.
>
> With great appreciation for any help you can give me,
>
> b6
>
>
> Sent from my iPhone
>
>> On Jan 3, 2021, at 9:14 AM, b6 wrote:
>>
>> Thank you. I am experiencing some type of immunological/neurological
>> reaction to the vaccine. The most prominent symptom is burning and numbness of my face and tongue. I have reached out to many people and no one can help me. b6 has given up on me and I don't feel these symptoms are allergic. b6 do not help. I have reported my symptoms to VAERS, v safe, Pfizer multiple times but have had no response from anyone. This has been a very difficult experience. I just pray that this resolves. I was previously healthy and am very uncomfortable now. I feel very helpless. If you know anyone that might be able to help me I would greatly appreciate it.
>> Thank you.
>>
>> Sent from my iPhone
>>
>>>> On Jan 3, 2021, at 8:56 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>
>>> Good morning b6
>>> I am so sorry to hear that the problems continue. I have not heard of such a situation but that does not mean anything because we do not get reports from patients at NIH, nor do we see patients. Have you reported this to the VAERS website? It is important that the CDC gets these reports.
>>> As I mentioned before, if I hear anything of relevance, I will let you and b6 know.
>>> Kind regards,
>>> Alkis Togias
>>>
>>>
>>>> On 1/2/21, 7:13 PM, b6 wrote:
>>>
>>> Hi Dr. Togias, I am so sorry to bother you but I am frightened and don't know what to do. I continue to be ill since I received the Pfizer Covid vaccine on b6 I was healthy prior to the vaccine. I have a remote history of b6 I was also on b6 I developed burning in my face 30 minutes after I received the vaccine and then had a pre-syncopal event with dizziness, tachycardia and chest tightness. I was basically in bed for the next six days with severe malaise, chest tightness, anorexia, burning of my face and tongue and occasional extremities. The malaise and chest tightness have resolved. Symptoms that I am left with are constant burning in my face and intermittent tingling and numbness of my face and tongue. I occasionally get burning in different areas of my arms and legs briefly. No muscle weakness. I have been on b6 b6 doesn't know what to do for me. He has spoken to b6 b6 b6 I spoke with a rheumatologist and immunologist today and will b6 b6 They believe I am having some time of immunological/neurological reaction. Have you heard of this? Do you know of anyone who can help me?
>>> Today is b6 and I am feeling worse today.
>>> Thank you. I am trying to get help and no one knows what to do for me.
>>> Sincerely,
>>> b6
>>>
>>> Sent from my iPhone
>>>
>>>>> On Dec 29, 2020, at 5:39 PM, b6 wrote:
>>>>
>>>> Thank you so much Dr. Togias. This has been very frightening for me. b6 seems to be easing the burning in my face. Please be in touch if you hear anything new.
>>>> Sincerely,
>>>> b6
>>>>
>>>> Sent from my iPhone

>>>>
>>>>>> On Dec 29, 2020, at 5:26 PM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>
>>>>> Hi b6
>>>>> I am very sorry to hear that things have gotten worse. I called b6 and I think he is doing the best he can for a situation that is very difficult to assess given its unusual nature and our lack of knowledge of a potential mechanism. I told b6 that I will let him know if we hear of more people having developed the type of reaction you had and how their physicians have approached it.
>>>>> I hope you feel better soon.
>>>>> Kind regards,
>>>>> Alkis Togias
>>>>>
>>>>>> On 12/29/20, 7:29 PM, b6 wrote:
>>>>>
>>>>> Dr Togias, I am so sick. I thought I was better yesterday. Felt fine yesterday evening. Today much worse. Face and legs burning. Face felt numb and swollen. Hard to get a deep breath b6 Bp and hr normal. Symptoms come in waves. I am really afraid. Today is b6 since I received the Pfizer vaccine. This all started about 30 minutes after receiving it. I was fine prior. b6 is helping me but I don't think anyone knows what to do. He has spoken to b6 I have left her 2 messages. I am on b6 I have been b6 b6 I have b6 No other meds. I have a remote history of b6 I have been b6 b6 I just started b6 If you have any other thoughts, please let me or b6 know. His number is b6 This has been very scary for me. I am fearful that something worse will happen to me and don't know how long this will last for. So sorry to bother you.
>>>>> Thank you,
>>>>> b6
>>>>>
>>>>> Sent from my iPhone
>>>>>
>>>>>>> On Dec 28, 2020, at 4:48 AM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>>
>>>>>> I am glad you are seeing b6 I know him well. He may be able to contact b6 as well.
>>>>>> I hope this goes away soon!
>>>>>> Alkis
>>>>>>
>>>>>>> On 12/27/20, 8:46 PM, b6 wrote:
>>>>>>
>>>>>> Thank you for your kind response. I have been very ill today. An allergist, b6 has been helping me. I believe he knows you. I have had burning in my face and extremities, headache, chills, chest tightness, malaise. No fever or cough. b6 I have been taking b6 b6
>>>>>> I will contact b6 I hope this reaction that I am having ends soon. I hope I survive it. It has been quite severe.
>>>>>> Sincerely,
>>>>>> b6
>>>>>>
>>>>>> Sent from my iPhone
>>>>>>
>>>>>>>>> On Dec 27, 2020, at 5:04 PM, Togias, Alkis (NIH/NIAID) [E] b6 wrote:
>>>>>>>
>>>>>>> Dear b6
>>>>>>> Thank you very much for your note. I am sorry to hear you experienced such a reaction with the Pfizer vaccine and I can understand your hesitancy for receiving the second dose. Not being able to assess your situation in more detail, I do not want to risk an interpretation or a recommendation. Your reaction does not sound as typical anaphylaxis although hypertensive systemic allergic reations have been described. As you have heard, we have not identified a mechanism behind reactions to the Pfizer vaccine (there has also been at least one case with the Moderna) and we hope that, if various logistical issues are addressed, we will be able to conduct the study you have probably heard about to help get more insights. Due to your reaction you would probably not qualify for that study, but I suggest you contact a specialist who may be able to do some testing that may help assess some hypotheses. The person that I know in b6, who has been actively working in this field, is b6 at b6 It may be worth contacting her.
>>>>>>> With kind regards,
>>>>>>>
>>>>>>> Alkis Togias, M.D.
>>>>>>> Branch Chief, Allergy, Asthma and Airway Biology DAIT/NIAID/NIH
>>>>>>>
>>>>>>> 5601 Fishers Lane, Room 6B40
>>>>>>> Bethesda, MD 20892-9827
>>>>>>> email: b6
>>>>>>> tel: b6
>>>>>>>
>>>>>>> For Courier Mail please use the following ZIP code: Rockville,
>>>>>>> MD 20852

>>>>>>> Disclaimer: The information in this e-mail and any of its attachments is confidential and may be sensitive. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error, please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.
>>>>>>>
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>>>>>>>
>>>>>>>
>>>>>>>> On 12/25/20, 2:11 PM, b6 wrote:
>>>>>>>
>>>>>>> Hi Dr. Togias,
>>>>>>> My name is b6 I am a b6 in b6 I received the Pfizer BioNTech Covid vaccine the morning of b6 I left the hospital after 15 minutes feeling fine but 30 minutes after receiving the vaccine, I developed burning and tingling of my face, tightness at the base of my tongue, shortness of breath, heart racing, chest tightness and had a near syncopal event. I immediately took b6 and called 911. By the time the paramedics arrived, I felt alittle better but my BP was b6 My face continued to burn as did my arms and I felt mild chest tightness for 12 hours and stayed on b6 By 10 pm, the symptoms completely resolved. I felt perfectly fine the next day until 10 pm when all the symptoms recurred as well as swelling and hives on my face. I have continued b6 and continue with tingling of my face and slight chest tightness. I believe I am having a significant allergic reaction to the vaccine. I did notify all the online sites including VAERS, Pfizer. I wonder if I have b6 b6 If you are interested in my case, I am happy to help. I am also very nervous about receiving the second dose of the vaccine. If you are not the appropriate person to receive this info, would you direct me to who would be interested in this info?
>>>>>>> Thanks so much,
>>>>>>> b6
>>>>>>>
>>>>>>>
>>>>>>> Sent from my iPhone
>>>>>>>
>>>>>>
>>>>>
>>>
>

From: b6
Sent: 2/8/2021 5:56:22 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6
Subject: b6 Rare Side Effects from Covid Vaccine

Hi, Dr. Fauci,

My name is b6 and I am an b6 at b6 b6 I have had rare side effects from the Covid vaccine after my 2nd shot that I think you would find interesting and fascinating.

I am b6
b6

I received my 2nd shot b6 and 16 hours later developed severe lymphadenopathy in my neck, chest and axilla (which is still present 5 weeks later), fever b6 (for over a week and a half), myalgias, arthralgias, peteachie to my left flank, headache, severe spine and neck pain and BILATERAL upper arm weakness. The upper arm weakness did not present b6 rather is presented approx 2 weeks after the shot. My bilateral upper arm weakness extends from my anterior shoulder to my AC. My forearms and hands do not have any weakness. My feet, calves, thighs, buttox, abdomen, flank do not have any weakness or fatigue.

I have been to 2 ID doctors, 2 Rheum doctors, 1 neurologist and 1 hematologist. I have had b6
I have had b6
None of these doctors can figure out why I am having bilateral upper arm weakness which I explain as a "jello" type feeling. The furthest we can get is SIRS response to the covid vaccine.

b6
b6

I feel that I need to see a research based immunologist who can explore why I have this bilateral upper arm weakness and lymphadenopathy that has been persistent for more than 5 weeks.

If you are interested in my case I will be happy to share my information with you and your team. I know we do not have a lot of information about short or long term side effects from the covid vaccine and I could be an interesting and educational research case for the nation.

Please let me know if you have interest in my case. I am currently living and working in the b6 area and living in b6

Thank you for your attention.

b6

From: b6
Sent: 2/21/2021 9:11:49 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-b6]
Subject: Fwd: Adverse neurological reactions to Covid mRNA vaccines

Sent from my iPhone

Begin forwarded message:

From: b6
Date: February 21, 2021 at 1:02:46 PM PST
To: b6
b6 Alkis Togias b6
b6
Subject: Adverse neurological reactions to Covid mRNA vaccines

Hi doctors,
As most of you know me, I am a b6 who suffered a terrible reaction 30 minutes after receiving the first dose of the Pfizer Covid vaccine. I am still very symptomatic b6 with severe paresthesias, chest tightness, tremor, dizziness, headaches. I am on the internet seeking information and came across an article in a journal Neurology Today. b6 b6 I have subsequently been contacted by five other women who have had very similar neurological reactions to mine and are all quite ill weeks after receiving their vaccines. They have had similar difficulty in getting appropriate medical care as the medical community knows nothing about these reactions. They too have reported their reactions to the drug companies, the regulatory governmental agencies, and there has been no response or documentation of their reactions.
It is apparent that these neurological reactions are not unheard of. Why are they not being addressed? Why are our reports being ignored? We do not have any desire to frighten the public about the vaccine, but we all very much would like to get medical care and fear that we will not recover from these debilitating symptoms. We were all previously healthy. We are considering going to the media as we are terribly frustrated at the lack of transparency. Any advice from you would be greatly appreciated. Also, please pass this information on to the appropriate people. If they would like to contact me, my cell is b6
Sincerely,
b6

Sent from my iPhone

From: b6
Sent: 12/27/2020 3:18:04 AM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6
Subject: Re: Anaphylactoid reaction to Pfizer vaccine

I think you should read my email. The website does not help me.
Thanks
b6

Sent from my iPhone

On Dec 26, 2020, at 7:05 PM, Fauci, Anthony (NIH/NIAID) [E] b6 wrote:

My work with the Coronavirus Task Force and the large volume of incoming emails precludes me or my staff from answering each individual message. I would encourage you to visit www.coronavirus.gov for the latest information and guidance related to COVID-19.

Thank you, and best regards.

Anthony S. Fauci, M.D.

From: b6
Sent: 12/27/2020 3:04:52 AM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-b6
Subject: Anaphylactoid reaction to Pfizer vaccine

Hello Dr. Fauci,
My name is b6
I am a b6 in b6
I received the Pfizer BioNTech Covid-19 vaccine b6 in b6 Approximately 30 minutes later, I developed burning and tingling in my face. By the time I got home I felt slightly short of breath, tachycardia and had a near syncopal event. The paramedics were called. b6 b6 Since then, I have had intermittent burning, redness, swelling and tingling of my face, occasional fine papular rash on my face, occasional burning in my arms and legs and occasional chest tightness and mild shortness of breath. The symptoms stay for hours and disappear for hours. b6 b6

b6

I believe that I have had an anaphylactoid reaction to the vaccine. I have alerted my hospital, Pfizer, VAER and VSafe online reporting sites and have had no response from anybody.
I thought maybe you or someone might want to know about my reaction. I have spoken to an allergist, b6 who has given me instructions and ordered lab work. If anyone is interested in my case, I would be happy to help.

b6

I am not planning to get the second dose of the vaccine at this point.
Any input from you or one of your colleagues would be most appreciated
Thank you for your time,

b6

Sent from my iPhone

From: b6
Sent: 9/14/2021 4:51:20 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6
Subject: complicated vaccine question

Dear Dr. Fauci,

This is a shot-in-the-dark (writing you, that is). I have exhausted my resources on this question—with contradicting advice. To get straight to the point, my question is, ***generally speaking***, for someone who had heart issues for 4 months after receiving the first Moderna (no diagnosed myocarditis or pericarditis—but no testing), would you recommend getting Pfizer, Moderna – or avoiding the mRNA and getting the Johnson & Johnson?

Background is below, though I understand both that you are not my doctor and that your time is precious. IF you read it, the most important of these *optional* details is in blue.

I am a b6 I received the **first dose** of the Moderna vaccine b6 Four hours after receiving the first dose and for four months following, I experienced racing heart/heart palpitations. It was enough to curtail my exercise (with shortness of breath), make me take frequent rest breaks during the day, disrupt sleep patterns, and cause me a tremendous amount of anxiety. I spoke to a number of doctors about this who seemed to dismiss it as anxiety in the beginning. The only testing I received was from an at-home b6 I bought on amazon—and that wasn't until it had almost resolved, in b6.

Advice I received:

- First - wait at least 4 months on the 2nd dose (was still going on at that point—it has now been b6 b6 since the 1st)
- Second – get the Pfizer as second dose
- Third – don't get the second dose
- Fourth – monitor b6 and get the Johnson & Johnson when they begin to dip too low (I don't know what level that is—feels risky)

The last (4th) is the advice am following. I had b6 —the doctor said my b6 I also get weekly covid tests (I am b6 provides these for free). My only b6 is conducted outside.

As they are everywhere, cases are rising in our area b6 is vaccinated, I have b6 with mandated masks for all). They are obviously not. I also have b6 b6

I am reading a lot (news not journals) about Johnson & Johnson's lack of efficacy against the Delta variant but nothing approaching definitive. Just not sure what I should do. There doesn't seem to be a lot in medical journals on this scenario. No doctor knows what to do. I called the CDC hotline, they did not know how to guide me.

NO EXPECTATION of response, here. This is almost like a message in a bottle. If you do get this at the very least let me say ***THANK YOU***—for ***ALL*** that you do!!!!!!!!!!

With warmth and respect (every ounce of it),
b6

b6

b6

From: b6
Sent: 8/6/2021 12:38:27 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6
Subject: b6 Death from enlarged heart post vaccine shots

Dear Dr. Fauci,

My b6 died b6 in b6 from an enlarged heart issue. He had received both doses of the Pfizer vaccine - his last shot being on b6 I've read about the possibility of myocarditis being a possible side effect of the vaccine and was curious of how it would be determined whether or not this played a part in b6 death. We're awaiting further results from the autopsy, but I wanted you to be aware of his death just in case the vaccination could have been a possible cause. He was b6 an athlete in good shape, a big believer in science as are his mother and I(we've been vaccinated as well) - he wanted to get the shots to help get everything back to normal. I'm not sure you'll even get a chance to read this email as I'm sure you're inundated daily - but if there's a chance that it could have caused his death, perhaps people should be made aware to hopefully avoid future incidents.
There's a chance it was hereditary as well - hopefully we'll find out soon.I wanted to thank you and your colleagues for your work trying to fight the virus and wish you continued success. I realize there's nothing that can be done for b6 at this point - I'm not sure what compelled me to type this email - other than to let you be aware of the possibility of issues with the vaccine(I'm sure you're already aware).

Thanks for your time - keep up the fight,

b6

From: b6
Sent: 9/21/2021 7:07:03 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-b6]
Subject: Pfizer vaccination reaction concerns for adolescents

Dr. Fauci:
I am a b6 in b6 I have b6 b6 and am vaccinated. Our b6 received both doses of Pfizer's vaccine in August. She experienced chest discomfort and some fatigue with the first dose with no sequelae. The second dose, within 12 hours, resulted in severe chest pain, hypotension and a syncopal episode that resulted in an ambulance trip to the emergency department. Her parents let us know that b6 b6 She responded well to b6 and was cleared after 72 hours by her pediatrician to resume participation with b6 at the end of the following week. I have pulled out and sent to b6 the VAERS website information and form to report this reaction and have encouraged them to report this adverse event or notify b6 where she received her shots and/or her pediatrician to report it as well. My question and concern deals with future vaccinations and possible administration of a booster shot to her. If appropriate to direct me to any links as to ongoing studies involving children, adolescents regarding boosters, perhaps not being administered the mRNA vaccines in the future, but being able to take the J&J vaccine, would be appreciative of that information. I pulled up a publication referencing UK's Dr. Finn/JCVI in https://apple.news/A0CljhAK_RGy-lyLDcDYQhg, where it is mentioned but not specific that the Pfizer dosing was smaller, understandably in 5-11 yr. olds – could that be applied in adolescents or with any adverse events that could be indicative of acute myocarditis – or should it just not be re-looked at? Am thankful for your service whether a response is received or not; trying always feels better.

Please take care.
Sincerely,
b6

b6

From: b6
Sent: 12/16/2021 3:06:33 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6
Subject: [EXTERNAL] Booster Shot and Myocarditis?

Honorable Dr. Fauci,

Seven months ago I was hospitalized for five days from myocarditis seven days after my second dose of Pfizer. I fear going back to the hospital for an even worse case of myocarditis from a booster shot. I understand the need for boosters is urgent, especially with Omicron. I do want to receive a booster, but I feel that my case is being overlooked.

Should I forgo the booster? Should I request to receive the Johnson & Johnson booster instead? Should I receive a booster at a hospital and be observed until side effects subside?

Thank you so much for your insight. I hope this answer not only helps me but for all those who share the same frightening experience.

--
b6

From: b6
Sent: 12/4/2021 1:28:35 AM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-b6]
Subject: Booster Shot for Someone that Experience Myocarditis after Second Shot

Hello Dr. Fauci,

Of all the people that speak about Covid vaccines on TV, and all the articles on the internet, I have not heard anyone or seen any articles that specifically address the issue of whether a person (that might have experienced myocarditis after the second covid shot) should take the booster shot for Covid.

b6 had no real symptoms to speak of after the first shot, but after the second shot, like most people, she felt worse the night of the shot. But, in addition to the normal symptoms of immune response, she also experience what she described as an elephant sitting on her chest. When she started feeling this chest discomfort, she got out of bed and when to the kitchen. Once there, the she felt bad enough that she laid on the floor and then did not have the strength to talk or get up for about an hour. After that the chest symptoms subsided to where she could get up, and the symptoms continued to subside throughout the night, and was no longer an issue in the morning, or ever since. She has not had any previous heart issue. All this occurred a few weeks to a month prior to the news releases about some young boys having a myocarditis, so we had no idea that this was a possibility. Now b6 b6 after that second shot, b6 is wondering if she should get the Covid booster shot, but is afraid of the possible consequences.

b6 has not received a satisfactory answer from her doctor on what to do, so I am hoping that you can help. By the way, the shot she had was the Pfizer vaccine.

1) Should someone in her position take the Covid booster shot? Or any future Covid shot?
2) Is there anything that can be done in preparation of the booster so that if she has a similar reaction she can mitigate the effect (e.g., have some medicine on hand to take)?

And if you can, I think it would be worth addressing this to the public in one of you news briefings.

Thank you for your time,

b6

From: b6
Sent: 7/30/2021 1:57:48 AM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6
Subject: Question on adverse reaction to Pfizer vaccine in older adult and second dose

Dr. Fauci,

It was suggested emailing you regarding a possible adverse reaction to the Pfizer Vaccine. I received the first dose b6 at b6 in b6 A few days after I began having ongoing generalized chest pains. Due to my insurance I could not see a doctor since I was out of state, and the chest pains did not quite match descriptions of a heart attack.

I called the pharmacist, who said myocarditis has been reported in some people after the vaccine. She recommended reporting my case on VAERS. I did so, but was wondering if my case was actually reported, since the news is focused on cases in younger adults. I was wondering if cases in older adults are being accurately reported.

My primary question is on getting the second vaccine. The pharmacist recommended not getting the second dose, since the incidence of myocarditis is higher with the second dose. The chest pains have almost gone away, but I am concerned about getting a second dose.

I am b6 but am very active, eat a good diet, and have not had the cold or flu in something like 15 years or more. I appreciate any feedback you may have, about the pharmacist's advice not to get the second dose, and on how accurately adverse reactions are being reported related to myocarditis in older adults. The news and research in this area has been very conflicting.

I appreciate your attention to this matter.

b6

From: b6
Sent: 1/30/2022 12:32:51 AM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6
Subject: [EXTERNAL] Myocarditis question from a b6

Dear Anthony and Sanjay,

My name is b6 and I am b6 affected by myocarditis as a result of getting the second shot of Pfizer vaccine. b6 spent five days in b6 ICU recovering after the shot. I would be more than happy to share more details about b6 well being upon request; I am sure you have the study that was published since then. The reason I am reaching out is because there has been no updates whatsoever on the subject matter. We received a call from CDC months back just to interview b6 As it stands right now, everyone but b6 and we are very concerned since the second shot t b6 was administered b6

We are afraid of a repeat scenario if we "boost" b6 but we are scared of not doing so at the same time. If you have any additional information on the subject matter that could help us make a decision, would you please let me know?

Thank you in advance,

b6

From: b6
Sent: 1/11/2022 12:54:34 AM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6]
Subject: [EXTERNAL] IMPORTANT Seriously injured b6

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

Dear Dr. Fauci,

I want to thank you for what you do and the very tough job you have working tirelessly through this pandemic. I know it's not easy. I have been a b6 in b6 for b6 years at b6 I will include some letters b6 wrote about me as well as my boss so you have an understanding of the type of b6 I am. I have been a b6 for b6 b6 as well part of b6 After seeing friends and loved ones die of covid I got vaccinated on b6 b6 as I take covid very serious. I am a pro vaxer and have taken every vaccine including the flu shot every year to protect b6 I was a young, fit, healthy b6 with no medical problems. That ended twelve minutes after my moderna vaccine. I was on the ground, my body went numb, was shaking and my vitals were critically unstable. I was taken away by ambulance to rule out myocardial infarction and pulmonary emboli. I had chest pain and difficulty breathing. Over the following two months I had b6 calls and was hospitalized 5 times. I lost seventeen pounds in three weeks and was in my doctors or urgent care 3-5 times a week if I was not in the hospital. Fortunately because I'm known in my community for b6 doctors took me seriously and were terrified. They worked hard to keep me alive with b6 and ordered testing that the majority of vaccine injured are still waiting to get. I also dealt with numbness, tingling, Parkinson's like walk and jerky body movements. I have the best of the best doctors at b6 trying to help me figure this out. They believe me and know I was vaccine injured. There's no denying it when it happened before I could even leave the vaccination site. The problem is my top notch doctors don't know what to do. This is where I desperately need your help. Dr. Nath at the NIH is aware of my case and he is great and feels terrible for what has happened to me. He is just as mystified as all my doctors as to what is causing this. We need help and we need research. I believe we can do this at the same time as vaccinating people. This will build trust. We can't leave the wounded behind when they did what you asked of them. Also when this happened to me I assumed I was just an unlucky one with an adverse reaction as I was b6 b6 I realize all meds and vaccines can have side effects. But at the six month mark I realized I wasn't rare and there were tens of thousands just like me with my same symptoms or worse. That's when I realized this was so much bigger than a few isolated cases. I have been b6 all my career and even though I know vaccine reactions exist, I had never seen one. There must be something that is causing these reactions with the covid vaccines and we need to figure it out before more lives are damaged or lost. I can also tell you that I have talked injured out of committing suicide weekly because I promise them help will be on the way and to please hold on. I need you to hold this promise to them too because I believe in you and know in your heart you would never want this to happen. I know of 7 so far that have ended their life because they couldn't handle the side effects as well as b6 that tried recently but was fortunately unsuccessful. I had to talk to a b6 to cancel her flight to b6 where she was going to undergo legal euthanasia because she couldn't suffer any longer. The doctors at b6 couldn't help her any longer and they didn't know what was wrong. I am just one person and If I know that many I can't imagine how many more there are. Not to mention the economic disaster this has caused us. This has cost me my income as well as my medical bills which I would gladly show you that aren't covered. I trust that you can help us in working with Dr. Nath and the FDA and CDC. I know Dr. Nath wants to help us. My doctors would be more than happy to speak with you as well from b6 team. They have seen many like me. I am almost at one year post injury and spent my Christmas in bed unable to ambulate for one week due to cardiac instability/autonomic dysfunction. I have missed my b6 being in hospital and I just missed Christmas with her. She is suffering and crying over this b6 . My identity is b6 and I need to get back to what I love and was born to do. b6 b6 We have a huge shortage of nurses right now California. I also have a doctor b6 who has my same

injury that spoke with the FDA.) She was a b6 as well as a b6 I can supply you with many more injured nurses and doctors not to mention non medical people. Will you please help me/us? You would be a true hero if you could help facilitate that. I am open to any confidential communication from your team to help me help the injured Americans. My cell is b6 and I'm available anytime by phone, email, zoom meetings and collaborating with expert physicians. I know your heart is in the right place and I have faith you can do this. Thank you so much for all you do and hopefully working with us.

Sincerely,

b6

b6

b6

b6

Sent from my iPhone

From: Wiebold, Amanda (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4491EE2AE9804610899C741100150540 b6
Sent: 3/10/2021 7:16:44 PM
To: Safavi, Farinaz (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246 b6
b6
Subject: RE: Covid-19 Vaccine Adverse Reaction

Hi b6

I will be sending you a secure email shortly.

Thanks,
Amanda

From: Safavi, Farinaz (NIH/NINDS) [E] b6
Sent: Wednesday, March 10, 2021 1:29 PM
To: b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Covid-19 Vaccine Adverse Reaction

Dear b6
Hope all is well.
I am copying our research nurse Amanda in this email to coordinate receiving your medical record and send you a kit for serum collection.
Please let me know if you have any questions.
Best
Farinaz

From: b6
Sent: Thursday, March 4, 2021 2:04:41 PM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Subject: Re: :Covid-19 Vaccine Adverse Reaction

I just received it. That works great too!
Again thank you so much!

b6

On Thu, Mar 4, 2021, 12:45 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

> Our research nurse(Amanda) already sent you a televisit link for Tuesday 3pm ET.
>
> Best
>
> Farinaz

From: b6
Sent: Thursday, March 4, 2021 9:33 AM
To: Safavi, Farinaz (NIH/NINDS) [E]
Subject: Re: :Covid-19 Vaccine Adverse Reaction

If Friday March 5th is still available I will take it. If not, I can do any of the other 2.

Thank you...thank you...thank you!

b6

On Wed, Mar 3, 2021, 10:25 PM Safavi, Farinaz (NIH/NINDS) [E] b6 wrote:

Dear b6

I am really sorry to hear about your illness. We started an effort at NIH to look at neurological side effects of COVID19 vaccines. I suggest we set a time and have a televisit to discuss your symptoms.

I have availabilities on

Friday 3/5 4-5pm ET

Tuesday 3/9 3-5pm ET

Thursday 3/11 3-5pm ET

Please let me know which date/time works for you and one of our team member will send you MS teams link.

Best Regards,

Farinaz Safavi MD, PhD

Section of Infections of Nervous System

Division of Neuroimmunology and Neurovirology

NINDS, NIH, Bethesda, MD

From: b6
Sent: Wednesday, March 3, 2021 11:00 PM
To: Safavi, Farinaz (NIH/NINDS) [E]; Nath, Avindra (NIH/NINDS) [E]; Wiebold, Amanda (NIH/NINDS) [E]; Smith, Bryan (NIH/NINDS) [E]
Subject: Potential SPAM:Covid-19 Vaccine Adverse Reaction

To whom this may concern,

Good evening,

My name is b6 I am a b6 that lives in b6 I am a b6 that willing received my Pfizer covid-19 vaccine b6 I have sent messages to the CDC, FDA, Pfizer, and VAERS. No answers to date from any government or pharmaceutical agencies, but I did get an acknowledgment email from VAERS. I have emailed direct person's with each agency as well, with still no answers.

I have also found information, and been in contact with others experiencing this same reaction, one of which is b6 b6 who has been in contact with you also. All of these person's have been ignored by government and pharmaceutical agencies as well. We want to tell our stories in hopes for answers. We have gone from scared, to frustrated, and now to being angry.

I want to tell you my story...

b6 I was inoculated with the Pfizer covid-19 vaccine in my left deltoid. The day I received the vaccine I had an immediate reaction, but I didn't realize it at the time. I thought I was having a hot flash/slight panic attack. My blood pressure spiked, I was hot, felt like I couldn't breathe, and had instant heart palpitations, fast heart rate and respirations. This resulted in me being monitored an extra 30 minutes. I have never been afraid of vaccines, and willingly get the flu shot every year, so this reaction seemed "off."

In the middle of the night of b6 I woke up and thought the bed was vibrating, and I had a sharp pain in my left scapula. I tried to go back to sleep thinking that the heater kicked on and was making the wall vibrate, and that I was sleeping in a wrong position that my scapula area was sore.

I wake up b6 and as I am drinking my coffee, I notice this vibrating sensation was coming from inside me. I can feel it from my scapula down my left arm. It continues all day, so I now think I have a rib out of place and it has pinched a nerve.

I wake up b6 and the vibrations have started down my right arm as well. This continues for a few days, until I can see a chiropractor. I get in b6 get adjusted, and think I have a little relief, but it was only momentarily. That afternoon and evening still no improvement.

b6 I'm in urgent care. I am miserable at this point, because now I have vibrations running up and down my whole spine, up my neck, and still down both arms. The UC physician gives me flexeril and prednisone, tells me I'm having muscle spasms.

b6 I proceeded to the ER in the morning. I can't sleep, no appetite, constant vibrations everywhere now, tremors, and my poor family has not had b6 for days now. They do b6 Tell me to see my PCP. Well, my PCP unfortunately passed away this last year, so now I get to find someone new that knows nothing about me, and I have this weird reaction going on in my body. ER says b6 refers me to see a neurologist, and sends me on my way.

Go to PCP, b6 and she prescribed me b6 Gives the referral to see the neurologist. Go to neurologist, and she says I am fine, but wants to b6 b6 I should interject, that my lower lumbar region at this time, has massive mobile and slightly tender lymph nodes present. Then she puts me on b6

Flash forward to today. I have seen the chiropractor, PCP, urgent care doctor, ER NP, and now the neurologist. No one knows what is wrong. My chiropractor is the only one that is listening to me. She is 100% with me that the covid vaccine has caused this. My other providers are not dismissing that it was the vaccine, but want to rule everything else out first. But... I was a perfectly healthy b6 with no med hx of anything, b6 b6

I had my b6 I don't think it will really show anything, but I just keep trying to get answers, or rule things out at least. I feel these vibrations all the time! It is like an electric current runs through my body. It makes me feel like I am in someone else's body. This is not the b6 I was. It has been b6 that I have had to live like this.

I have seen videos of people with the same reactions I have going on. Some are the same, some are lighter, and some are more severe. I consider myself lucky that I am in the middle of the road category. I can still do most day to day functions, as well as, be present for b6 But some days I can't do anything, because I am mentally, physically, and emotionally exhausted. Spiritually I know God is weathering this storm with me, and that he is the ultimate physician.

I tell you my story, because I am a real person, with a very real adverse reaction to the covid-19 vaccine. I need help!! I would not be pursuing so many people for help if I were not 100% certain of this. I am a b6 b6 There is a face to my name that carries multiple facets. Others have stories just like mine as well. I plead with you to listen and ask for your help. Thank you!

Sincerely,

b6

Farinaz

From: Nath, Avindra (NIH/NINDS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B81CA051950B4D458D74037A6A86EAD6-b6]
Sent: 11/1/2022 11:29:21 PM
To: b6
CC: Wiebold, Amanda (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4491ee2ae9804610899c741100150540-b6] Gustafson, Lindsey (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bcc895932d544e4a2f36eb6f9388adb-b6] Safavi, Farinaz (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=94807ce146e045d4b61655da26a0c246-b6]
b6
Subject: Re: [EXTERNAL] Re: I still am not better-b6 R side weakness R face, hand, arm, leg. My Dr wants b6 he will do any recommended tests. Can you suggest some?

Dear b6
Please see email trail below. I would be glad to talk to you if we can be of any further help.
Thanks.
Avi
Avindra Nath MD
Chief Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health

From: b6
Date: Tuesday, November 1, 2022 at 6:30 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: Wiebold, Amanda (NIH/NINDS) [E] b6 Gustafson, Lindsey (NIH/NINDS) [E] b6 Safavi, Farinaz (NIH/NIAID) [E] b6
b6
Subject: Re: [EXTERNAL] Re: I still am not better-b6 R side weakness R face, hand, arm, leg. My Dr wants b6 he will do any recommended tests. Can you suggest some?

Dear Doctors,

Thank you. I really appreciate all your help. I will share your contact info with b6 my neurologist.

His email is b6
b6

Best regards,

b6

b6

b6

b6

b6

On Mon, Oct 31, 2022 at 10:32 AM Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6

Thanks for the update. I am uncertain why you have persistent symptoms. We will be glad to discuss with your neurologist to see what we can do to help. OK to share our contact information who him/her.

Best.

Avi

Avindra Nath MD

Chief Section of Infections of the Nervous System

Clinical Director,

National Institute of Neurological Disorders and Stroke

National Institutes of Health

From: b6

Date: Tuesday, October 25, 2022 at 1:53 PM

To: Wiebold, Amanda (NIH/NINDS) [E] b6 Nath, Avindra (NIH/NINDS) [E] b6

Cc: Gustafson, Lindsey (NIH/NINDS) [E] b6 Safavi, Farinaz (NIH/NIAID) [E] b6

Subject: [EXTERNAL] Re: I still am not better- b6 R side weakness R face, hand, arm, leg. My Dr wants b6 he will do any recommended tests. Can you suggest some?

Dear Doctors and All,

Thanks for your help in the past. I hope that you are doing well.

I am still about the same,but I was able to get b6 b6 and started b6 even through my constant vertigo, headache, R side weakness etc (yay for face masks to hide my face!).

Same meds as below, and b6

b6 helps a lot,but wears off. I also fluctuate in severity with all my symptoms getting worse and it is quite dramatic.

My neurologist has b6 He said I can ask.around and he will add in any suggestions for b6 so I hope that you can help with ideas.

I told him to go big and order anything that may help, since I don't want b6 ☺

There has been discussion of other treatments b6 but my neurologist wants more tests, and I want to clear that with b6

In other news, b6

b6

Then b6

b6

b6

b6

b6

Sorry for the detailed updates,but I had not been in touch for almost a year!

Also, the CDC VAERS is asking for more from me too,and I am waiting to submit more days b6 b6 **that is the** b6 **immunologist has** b6

b6

Your help and suggestions are welcome.

You have my permission to share with other Drs that may be of help for my case b6

Thank you,

b6

On Fri, Nov 5, 2021, 9:04 AM b6 wrote:

Dear Doctors,

Thanks so much for all your help. A special thanks to Dr Safafi for the phone appointment almost a month ago. I wanted to get you b6

I got b6 These were done before b6 but my b6 and these are b6 b6 b6

I am b6 and it helps with the Right sided weakness and droop in my face to get to a much better, almost 90% or more of normal look in the eye and mouth area, and improvement w/ my R hand grip and R arm strength, and R upper leg too, and it helps to reduce my constant vertigo and headache, but by b6 then I regress with progressively more vertigo, headache, R side weakness and progressively worse facial droop and need for a cane or forearm crutch to manage to get around due to the issues, and terrible vertigo at times.

I have asked to be referred to immunology and rheumatology, and b6 b6 b6 but when the vertigo is bad, it is harder, but I push on. Still taking b6 b6 and to be strong, and doing things daily to get better. Hopefully I can get b6

b6

Thanks,

b6

b6

b6

b6

b6

On Mon, Oct 4, 2021 at 12:14 PM b6 wrote:

Dear All,

I have had b6
b6

My neurologist located some b6
b6

b6

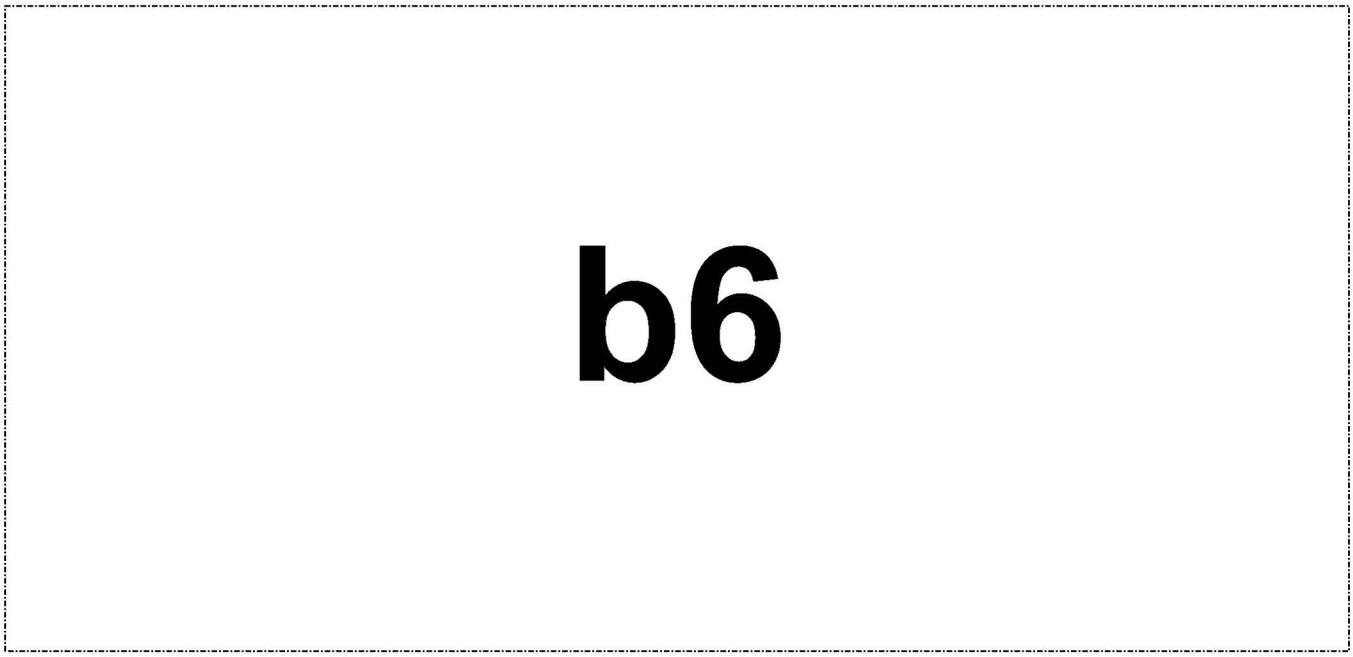
b6

b6 helps with the vertigo, headache, brain fog, Right sided weakness and especially fixes my R face droop dramatically each time, but it wears off starting before 2 weeks post dose, and gets worse until b6 b6 but now that I am getting it b6 I think that it has helped more. I can send photos if you want to see the progression, and how things reverse with my face after b6 Let me know and I can send some. If we are on zoom, you will see me looking in my better form, since I b6 b6

Thanks,

b6

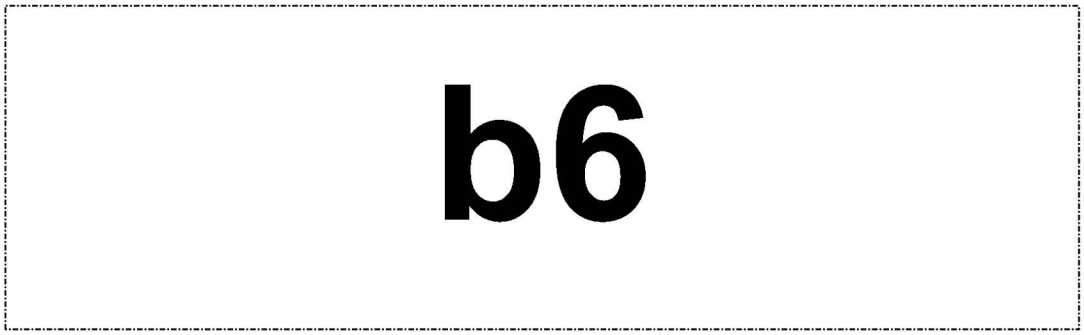
b6



On Mon, Sep 13, 2021 at 2:06 PM b6 wrote:

Dear Doctors,

I am devastated to let you know that I did all the recommended Mayo sendout labs before b6 and my hospital had tried to find out what happened as the reports said FInal, but I had to do my own work to find these labs, and got this message today from Mayo:



I am so sorry, and absolutely devastated. I have all the other labs ordered from b6 below this note. I wanted to contact you sooner, but had been trying to get all the results for you. I hope that you can still help me. Sorry for all the info below, but I wanted to update you, and ask for your help. Thank you for all you have done, and for your consideration.

I now have very little to give you from most of the tests you wanted, and I am not sure if your lab samples that were sent to you were able to be used.

Also, I am advised to get a booster dose #3 of my Pfizer COVID vaccine, yet I had all these now chronic neuro issues arise, starting with the vaccine, and some respiratory issues hit with each dose that were not long, but notable.

I am still not able to b6 **due to my continued, chronic and regressive neuro issues**
b6

I do not know what to do for a booster dose! I need some help on sorting out the next steps, and really, really wanted to see the results of those Mayo COVID-19 labs you had ordered. I need help. Not getting much help on this, and I am asking for a referral to an immunologist, and would like some advice on next steps on b6

I am now getting b6 **how can I go about more testing?** b6 offered me a booster COVID vaccine dose this week, and I said I needed more advice before doing that, and with my history, I am not sure I should do that with b6 but no one really seems to want to sort me out. I am so sorry. I am devastated.

The CDC VAERS wanted more of my files months ago, as I still have issues, and they were sent everything that I had before June. They have not responded, not asked for more info, and never got back to me for a referral to the CDC CISA program.

I have asked my neurologist to refer me to b6 **, and immunologist and vaccine specialist at the** b6 b6 **that manages the west coast CDC CISA-no word on that. I have tried to call, but have not yet emailed, as I want to see if my Dr will try first.**

The only good news is that b6 ve

b6

b6

b6

b6

LABS THAT WE DID GET b6

b6

Please note that these were done at Quest, and their reference range in NOT the same as Mayo, and on their site, they say to use their reference range for this test.

My neurologist has not really pursued b6 and I think it is worth sorting out. I really need to sort out my unusual past medical history, even before last year and the current issues since my Pfizer COVID-19 vaccine b6

It was sent there by our lab, vs Mayo but I guess that is a blessing, since I got at least that lab result, and I would like more help on that.

Please help me if possible! I am b6 but need to be better for me too, and also not get sick from COVID, and I just do not know my risk.

b6

I have had a history of b6

b6

I have never been offered b6 I know that is used for immune studies. I will try to pursue this more.

Even b6 **has not been helpful for years, as I have felt that the** b6

b6

b6

b6

b6

b6

b6

b6

b6

b6

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

From: b6
Sent: 6/2/2021 11:13:29 AM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
CC: b6
Subject: Re: Covid 19 Pfizer vaccine myelitis??

Thanks!
I Understand.

Sent from my iPhone

b6

On Jun 2, 2021, at 12:51 AM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Unfortunately, I am not allowed to give medical advice over the internet. Best to contact the doctors at b6 directly.

From: b6
Date: Tuesday, June 1, 2021 at 10:17 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6
Subject: Re: Covid 19 Pfizer vaccine myelitis??

Thanks! Dr. Avindra Nath

Please connect me to them through common email. Perhaps exchange numbers to discuss.

I will include b6 who is ID with b6 I had requested him to assist me in Early May to sort this out with me.

We plan to have collaborative discussion at the end of this week. I am very concerned of ongoing LUE, face neck and mid back to neck paresthesias (hot-cold and stabbing needles) still ongoing though lesser than 5/25 migratory LE resolved but LUE spastic with endurance still there though much reduced since 5/25.

Hope we can do it in a collaborative manner before another major event.

Sent from my iPhone

b6

On Jun 1, 2021, at 8:13 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

If you want to be treated at b6 you can contact b6
b6 is not against a particular molecule.
b6 is fine too. There should be no concern about loss of antibodies to other viruses.
Avi

From: b6
Date: Tuesday, June 1, 2021 at 6:17 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re: Covid 19 Pfizer vaccine myelitis??

Thanks for quick response.
I think it will be good if we discuss further details. I just want to try to understand b6 against what molecule. I declined
b6

Should we hold a zoom or FaceTime meeting. I can fly and come there if needed after that. But I noted you b6
b6 Who will be my Neuro-virologist.

Sent from my iPhone
b6

On May 31, 2021, at 10:31 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6
Sorry to hear of your illness. We have seen several patients with neurological complications following the COVID vaccine. Some have responded to treatment b6 Wonder if you might consider such intervention
Avi

From: b6
Date: Monday, May 31, 2021 at 10:44 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Covid 19 Pfizer vaccine myelitis??

Hi
I wonder if you remember me. I had discussed with you about b6
b6

Guess what! I may need a personal favor about me. I am b6
b6

Recently on 5/25/21, I developed suddenly L.sided "heaviness" with mild weakness with spasticity (endurance) from head to toe with neck stiffness and some immediate memory of "names". I already had ongoing waxing-waning stabbing-burning patches that were migratory on my bilateral UE and LE since 4th day of my Pfizer #1 vaccine on b6 b6 However this time 2 days before that my above paresthesia had increased to trunk, neck, face and head on left side.

History is that right at 24hrs after #1 vaccine I suddenly developed total weakness all over and somnolence, unable to continue to type or walk with foggy brain. I took b6 and slept for 2hrs in my office and felt fine. But at day 4, developed migratory and fleeting stabbing-burning paresthesia patches on my UE and LE but no motor function issue. Looking back I do have issues in memory of names (recalling a name) but could be age. Other complication is that I get these weird initially bulae 1-2 on my LLE which became bil UE in 4/26/21 and then 5/25 I had it on my upper Thorax near neck.
I improved with b6 but not resolved totally in 48hrs.

However the bulae 1-2 occurred before the vaccine but I was b6 First occurred since July 21 2020, post severe gastroenteritis (woken from sleep) with nausea b6 or so. So I got tested since I still had issues and found b6 or so. I kept having 1-2 blisters/bulae that I would find during shower since warm water would make it sting and forced me to see. I also had episode of b6

So in short, I felt I have reactivation of done "dormant infection" causing recurrent blister and an autoimmune mimicry molecule attacking my nervous system.
Here are some timelines>>>
-migratory paresthesias started only after vaccine day 4 b6 after extreme weakness 24hrs.
-However blisters/bulae first time occurred July 21 2020 after severe diarrhea and after that intermittently occurred from Oct 2021 w/o diarrhea issues.
- b6
-Severe Diarrhea with nausea needing hospitalizations First occurred Oct 2018 (moved to new city and drank tap water or ate fruit??) almost every month until Jan 2020 when I took b6 I didnot have any episode for 1 year until July-Sept 2020 when workup confirmed b6 No diarrhea after that.

Hope to hear soon as to which direction to go for further workup. I really had to steer this myself with ID and neurology. I have been reading extensively since b6 I am in the process of b6
b6 Hopefully I can sort my personal adverse event from Pfizer (I anticipated due to b6 as we continue thinking out of box. Working diagnosis is b6

b6

Hope to hear from you soon and help me link to right time to figure this before it worsens or I get paralyzed.

Sent from my iPhone

b6

From: b6
Sent: 6/18/2021 7:35:36 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6
CC: b6
Subject: Pfizer Vaccine Paresthesia

Dear Dr. Fauci,

I have been experiencing paresthesia (head, arms, legs mostly) since day 2 after my 1st dose of the Pfizer COVID-19 vaccine. It becomes worse with exertion. I was first sent to the ER where my symptoms were dismissed as possibly from the vaccine but b6 as this side effect is not listed by the CDC. After this "diagnosis" I did some online investigation, and it turns out that many people are experiencing tingling/paresthesia/peripheral neuropathy after receiving the Pfizer vaccine. I followed up with my family doctor and allergist and was referred to a neurologist who said this is from the vaccine and that I am experiencing b6 b6 She advises not to get the 2nd dose until this issue resolves, and to limit my exercise to walking on flat surfaces at a slow pace as the issue is worse with exertion and my heart rate increases greatly unlike before the vaccine when I could work out without any issues.

My research unearthed a plethora of information on this side effect. It is noted as an adverse event in Pfizer's clinical trials (.04%). In Israel 474 people have been found to experience this side effect at the time of publishing in the article I read. I have seen a doctor on Twitter asking if people in the U.S. are experiencing this as many people in Italy have experienced this side effect there. I also found a clinical study identifying small fiber neuropathy in a 57-year-old woman after receiving the 2nd dose of the Pfizer vaccine. I see in the comments on a neurology site that there are doctors experiencing this – one said he has repeatedly tried to contact the CDC, FDA, and Pfizer and is being ignored. I have reported my side effects to Pfizer and have not heard from them.

We need someone to investigate this and help us figure out why this is happening to us and if it safe to get the 2nd dose of the vaccine. I have found many online comments with people experiencing this same tingling sensation and no one knows what is happening to them.

I have included links to my findings below and hope that you will be able to help me or at least get Pfizer, the FDA, and the CDC to acknowledge this side effect and investigate its cause. We need help and answers as soon as possible.

https://www.dovepress.com/minor-to-moderate-side-effects-of-pfizer-biontech-covid-19-vaccine-amo-peer-reviewed-fulltext-article-IJGM

https://onlinelibrary.wiley.com/doi/10.1002/mus.27251?af=R

https://twitter.com/mraffatellu/status/1371980769506168832 (Click on "more comments" under the replies as there are many people reporting this)

https://journals.lww.com/neurotodayonline/blog/breakingnews/pages/post.aspx?PostID=1075 (Scroll to comments to read about Doctors with this side effect)

https://www.jpost.com/health-science/covid-19-vaccination-73-cases-facial-paralysis-7-anaphylactic-shock-661073 (474 people with paresthesia)

https://www.i24news.tv/en/news/coronavirus/1611650805-covid-19-side-effects-unknown-to-pfizer-detected-in-israel (Read comments of people with this side effect)

https://www.openaccessgovernment.org/what-are-the-side-effects-of-the-pfizer-vaccine/104380/ (Scroll down to the comments)

https://vestibular.org/forum/dizziness/covid-19-vaccine-side-effects/paged/54/

Sincerely,

b6

From: b6
Sent: 7/21/2021 11:22:10 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94 b6
Subject: Vaccine Adverse Events and Hesitancy

Dr. Fauci,
I listened to your hearing today with the US Senate Committee. I applaud you in your efforts to use science and precision to get us out of the pandemic. I would like to express gratitude on your organization's efforts to seek for truth and answers.
I myself have been there to the NIH to participate in research in regards to the unfortunate life-altering experience I have had during this time.

I also am writing to ask for HELP. I now am representing thousands, like me, who have experienced severe reactions to the Covid vaccines that is extremely similar to what is seen in long-covid. Individually and collectively, we have been reaching out to the CDC and FDA (some of us having extensive dialogue with the top officials) since last December. Obviously no substantiative response has been made, none of these adverse reactions (yes, rare) are known to the public, and more and more people are piling onto this sinking ship with absolutely NO HELP from the appropriate agencies. I myself have been there to the NIH to participate in the research in this arena, however like everyone else, my home medical team outright refuses to acknowledge this is happening and I am unable to obtain any medical care here locally.

We are educated, science-loving, mask-wearing, honest Americans who jumped at the chance to get our shot. Most are medical care workers. Now our lives have dramatically changed and are severely debilitated. And worse, to be abandoned by our country, when we did our part to help end the pandemic.

This is not right. We are good people. WE NEED HELP.

One mention of this, even though it is rare…a single mention, would change the game for these suffering, alone and afraid. To be able to tell our doctors that yes, this is a possibility and to finally get these people on the path of healing.

Had our pleas for help been answered months ago by the appropriate agencies, I do believe there may be a different discord in this country in regards to vaccine hesitancy. Unfortunately, social media is FULL of these types of injuries, everybody knows somebody who has experienced a "scary" reaction, with still no acknowledgment or response from the CDC and FDA. The people see this, they know this. There is no amount of money the government is going to be able to put into this that will change what these people are seeing with their own eyes.
These are ALL being reported to VAERS and also directly to the CDC. Yet, nothing is mentioned anywhere publicly by trusted officials. Which leaves us literally completely unable to get medical care.

The best way to calm fears surrounding the vaccines is to be upfront with possible adverse events, start a program similar to the Canadian COVID Task Force and start researching this openly. This should be studied, so when these individuals do appear in ERs and hospitals they are met with physicians equipped with the knowledge and tools to help them. It is not fair to these individuals, but it also is not fair to these physicians.

Instead, we have been abandoned and are now desperate for help.

You and your staff are good people. I am asking for anything…please help us to start the conversation with the medical community.

I absolutely believe we can vaccinate and help the injured. This doesn't need to be an either-or thing. My husband and family were all vaccinated after this happened to me. But I can't bear to see this adverse reaction happen to more and more people without the medical community being aware that this even exists.

Please, please help us.

b6

From: b6
Sent: 6/1/2021 2:45:32 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: Re: Severe Covid Vaccine Reaction from b6 in Pfizer Trial for b6
Attachments: 2021-06-01 09-52.pdf

Attached is the consent that I signed for the doctors, the doctor that will be calling is b6 b6

Sent from my iPhone

On May 27, 2021, at 11:00 AM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Sorry for what you are going through. Hope b6 gets better soon.
Best wishes.
Avi

From: b6
Date: Thursday, May 27, 2021 at 8:48 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Cc: Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Severe Covid Vaccine Reaction from b6 in Pfizer Trial for b6 b6

Hi Dr. Nash,

Thank you for following up so quickly. I shared your information with her neurologist but I haven't heard back from him yet. We met with b6 Inpatient Rehabilitation doctors yesterday and they said they were not willing to call you and were standing firm on the b6 but we were welcome to get a second opinion. However in her MyChart notes it said b6 b6

Unfortunately, our only option now is to have her transferred to b6 for their b6 clinic to work on her b6 so she doesn't have to rely on b6 At least then they will be able to help monitor and possibly help resolve the problems she is having with b6

After b6 she is very close to being able to walk on her own and can walk with a walker. She suffered for b6 while they dismissed her symptoms and deteriorating health.

My frustration is that b6 has the same symptoms and recovery as the diagnosis's other people who have had adverse reactions to the vaccine. They are unwilling to look any further into this because then they would have to admit the vaccine caused her reaction. This is happening over and over to other people to this day and healthy people (soon to include children) are

having their lives ruined forever. Kids 12-15 have only had their first dose and soon will have their second dose, their immune responses are stronger than adults and if they have any autoimmune disorders many of them are not aware of it yet which could be one of the many things that they were unwilling to figure out with b6 who is in a trial at their hospital. They just want to slap a psychological sticker on her so they don't have any accountability to this and it is wrong.

Thank you from the bottom of my heart for being so willing to help out when you are inundated to begin with, I really appreciate it. I pray you are able to figure out why this is happening to so many people and the public is informed so they can be prepared if this happens to them and they don't have to go through what b6 went through.

Kind regards,

b6

Sent from my iPhone

On May 26, 2021, at 9:35 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Thanks for the additional information. Due to HIPPA b6 would need to give consent to her physicians to talk to me about her. Then the physicians would need to contact me. Sorry, I am not allowed to contact the physicians directly. OK to share my contact information below with them.
Avi

From: b6
Date: Wednesday, May 26, 2021 at 10:57 AM
To: Nath, Avindra (NIH/NINDS) [E]
Cc: Safavi, Farinaz (NIH/NINDS) [E] b6
b6 Wiebold, Amanda (NIH/NINDS) [E]
b6
Subject: Re: Severe Covid Vaccine Reaction from b6 in Pfizer Trial for b6

Hi Dr. Nath,

Thank you for the quick response, I know you are very busy. Thank you for offering to talk to her neurologist. I am going to email him your contact information, his name is b6 Right now she is inpatient rehabilitation for walking and her doctors are b6 b6 and b6 b6

She was diagnosed with b6 shortly after she started having her symptoms. They have done b6 They have not done b6 If she can't walk today without a walker b6 then they are discharging her). She still has b6

b6

b6

b6 She also has numbness from her waist down but does have some feeling coming back.

I am sharing a summary of her test results, ER visits and hospitalizations. I also have a document hat gives more details of her symptoms as they progressed that is a work in progress. My concern is she was tagged with b6 early on and there has been an unconscious bias from that point forward by specialists she has seen and the ER doctors. Additionally all of the doctors are from the hospital that she participated in the Pfizer trial and from the beginning no one was even willing to talk about the vaccine as the trigger for this.

From what I have read, the peripheral immune response and psychiatric disease can produce the same type of Neurologic symptoms. My concern is they are treating her symptoms and not the underlying cause.

I am extremely concerned about her health and the discharge plan they have for her which is b6 which she does not have. I am not fully confident they will reach out to you but my plan is to refuse to let her be discharged until they do.

I appreciate your help, we are desperate to get b6 better. She has developed b6 due to her experience.

b6

Kind regards,

b6

Sent from my iPhone

On May 25, 2021, at 10:27 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6

Sorry to hear of b6 illness. Sounds like she has been through a lot and been investigated extensively. It is hard to make a diagnosis over emails, but if it would help we would be glad to talk to her physicians or the neurologist who took care of her. We have certainly heard of a lot of cases of neurological complications form the vaccine and will be glad to share our experience with them. You are welcome to share my contact information.
Best wishes.
Avi

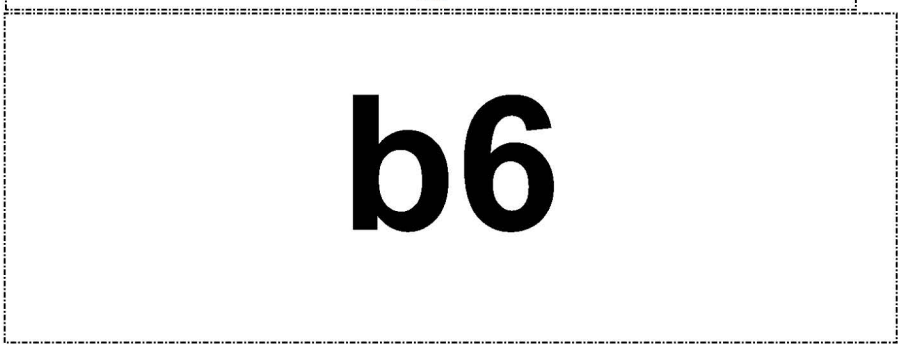
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD
b6

From: b6
Date: Monday, May 24, 2021 at 12:36 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6
Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Severe Covid Vaccine Reaction from b6 in Pfizer Trial for b6

Hello Dr. Nath and Dr. Safavi,

b6 shared your contact information and recommended reaching out to you for help b6 b6 was a healthy b6 with no major medical issues, the only things on her medical chart were b6 She participated in the Pfizer vaccine trial for b6 at b6 b6 and was confirmed that she got the vaccine on Monday by b6 She received her first dose in the trial on b6 The next day she had a fever of 101, felt tired, and had swelling at the injection site but all of these resolved within a couple of days. She received her second dose on b6 She had immediate pain at the injection site which didn't happen with the first dose. About 18 hours after receiving the vaccine, she developed the following: severe muscle/nerve pain, painful electrical shocks down her neck and spine which caused her to walk hunched over, severe chest pain that felt like her heart was being pulled out, numbness, and swelling in her vaccine arm (left), her

fingers and toes turned white and were ice cold to the touch, the pain in her toes was so bad she walked on her heels, severe abdominal pain (especially on the lower right side) and a fever of 101.4. We were instructed to take her to the ER at b6 where they did b6 b6



Over the next b6 her severe abdominal pain along with the muscle and nerve pain persisted plus she new symptoms including fatigue, nausea, vomiting, abdominal distension, regurgitation of food, and eventually the inability to swallow food or liquids, itchy rash on her arms, peeling skin on her feet, unexplained painful cysts on her vagina and then her head, tinnitus, vision problems, headaches, dizziness, erratic blood pressure, and heart rate, memory loss, brain fog, verbal and motor tics, fainting/seizures (10+ a day), loss of feeling from the waist down then paralysis of her legs, inability to walk, muscle weakness, abnormal gait, gastroparesis, urinary retention, anxiety, and medical PTSD. Additionally, she b6 menstrual cycle on b6 which continued off and on for over a month with clumps of blood and then off and on spotting until b6 and nothing since then. Between b6 we had to take her to the ER nine (9) times and she was admitted to the hospital 3 times. In between hospital visits she has seen multiple specialists at b6 and had b6 b6 instead she continued to decline.

After several desperate calls to multiple doctors expressing our concern for her declining health and more ER trips we finally got help from our new Care Coordinator to have neurology guarantee, she would be admitted if we went to the ER on b6 When she got to the ER on b6 she could not walk, was unable to feel or move below her waist, had tachycardia and her blood sugar was at b6 Once she was stable they admitted her to neurology and then transferred her to Inpatient Rehabilitation on b6 As of today, b6 she is finally close to being

able to walk without a walker but she still has an abnormal gait. She also still has b6 and continued problems with urination and gastroparesis, not to mention the PTSD from this experience with doctors, especially in the ER and Pfizer Vaccine Trial, doubting her and treating her like a mental patient. Right now every Wednesday and Friday, she has to b6

b6

b6 NOTE: the words in italics are directly from her medical chart.

b6 has gone from being a typical healthy b6 b6 who worried about doing well in school and loved hanging out with friends to being so ill she had to b6 b6 She has been in the hospital for b6 b6 where she b6. She is the strongest person I know and I am so proud of her for pushing through this nightmare and never giving up. There is no doubt in my mind that the vaccine caused this. All of these medical problems started less than 24 hours after the second dose of the Pfizer covid vaccine and did not just go away within 72 hours like they say. She was not forced to do the vaccine trial, she asked to do it along with b6 b6 so she could help get our world back to normal. The only diagnosis we have been given is

b6

b6

b6 no explanation as to why the vaccine triggered it They have dismissed her having b6

b6

Once she was given the b6 diagnosis they stopped any further testing that could and should have been done. We have had issues with doctors avoiding vaccine conversations and the immunologist/allergist who saw her for 15 minutes is the doctor who "told" b6 her symptoms were likely not due to the vaccine. She is not even close to being functional and that is with b6

b6

b6 And no one can explain or improve her urinary and GI issues. We have a family meeting today to discuss her discharge on b6 We are desperate to get her treatment that will help her get back to

the healthy b6 she was before she got the Pfizer vaccine. I was told her case was included in Pfizer's final report on the trial b6 but they did not share the end diagnosis and all of her symptoms. They summed it up as b6 b6 it was MUCH more than that! We do not want this to happen to more innocent people, especially children!

Kind regards,

b6

b6

b6

From: b6
Sent: 12/13/2021 3:56:51 AM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6 b6
Subject: [EXTERNAL] Re: VAERS reports of myelitis after COVID-19 vaccination

Thank you. I will let you know if b6 receives Evusheld and how he tolerates the injections.

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Sunday, December 12, 2021 9:46 PM
To: b6
Subject: Re: VAERS reports of myelitis after COVID-19 vaccination

No, not yet
Avi

From: b6
Date: Sunday, December 12, 2021 at 10:45 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Re: VAERS reports of myelitis after COVID-19 vaccination

Thanks for you quick response. Have you seen patients with a previous severe neurologic adverse reaction , e.g GBS or transverse myelitis, after COVID 19 vaccination and subsequently received Evusheld successfully?
b6

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Sunday, December 12, 2021 9:42 PM
To: b6
Subject: Re: VAERS reports of myelitis after COVID-19 vaccination

We or others have not had the chance to study patients with myelitis to know what the pathophysiology might be. In general if there are enhancing lesions or swelling of the spinal cord a cell mediated pathophysiology is more likely. Having said that T and B cells interact with one another. Evusheid is a combination of two monoclonal antibodies so reacts against specific epitopes on the virus which is very different from the antibody response to the vaccine where the antibodies are formed against multiple epitopes of the spike protein.
Avi

From: b6
Date: Sunday, December 12, 2021 at 10:28 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: [EXTERNAL] Re: VAERS reports of myelitis after COVID-19 vaccination

Dear Dr. Nath,

Previously you were very helpful in providing advice on the care of b6 who was hospitalized with transverse myelitis within 2 days after his 2nd Moderna COVID-19 vaccination. As you may know, AstraZeneca received Emergency Use Authorization for their antibodies that are used for COVID-19 prophylaxis including individuals who previously had a severe adverse reaction to a COVID-19 vaccine. The data from the trial is not published and the attached EUA factsheet does not provide details on subjects who previously had an adverse reaction. As I consider whether it is safe to administer Evusheld to b6 I think it is wise to consider whether his previous myelitis is mediated by antibodies or whether it was T cell mediated , i.e. is there a chance that the antibodies in Evusheld may react to a self antigen in the spinal cord. Do you have any opinion or insights on whether myelitis after vaccination is mediated by antibodies or is it T cell mediated?

Thanks for your important advice.

Best regards,
b6

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Sunday, June 13, 2021 10:03 AM
To: b6
Subject: Re: VAERS reports of myelitis after COVID-19 vaccination

Not sure. Some would argue that even a 100 cases after administration of nearly a billion doses of the vaccine still makes it a very rare complication. Further the reliability of the VAERS database is poor since anyone can enter the information and there may even be duplication of entries.
Avi

From: b6
Date: Sunday, June 13, 2021 at 10:41 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: VAERS reports of myelitis after COVID-19 vaccination

Dear Dr.. Nath,

After posting b6 case report of myelitis after the Moderna vaccine (attached), I have queried the VAERS WONDER database and found over 110 reports of either myelitis or transverse myelitis after COVID-19 vaccine. Also I have heard from b6 after vaccination but the CDC omitted some of her data on the VAERS report and mistakenly classified it as b6 Many of the descriptions of cases sound similar to b6

Do you believe that myelitis should be more formally evaluated as a safety signal after COVID-19 vaccination? Is there anything more we could/should do to raise awareness of this potential adverse event while ensuring it is placed in the right context of benefit:risk?

Thanks for your expert insight.

Best regards,

b6

From: b6
Sent: 6/13/2021 2:41:22 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
Subject: VAERS reports of myelitis after COVID-19 vaccination
Attachments: CaseReportOfMyelitis-SSRN.pdf

Dear Dr.. Nath,

After posting b6 case report of myelitis after the Moderna vaccine (attached), I have queried the VAERS WONDER database and found over 110 reports of either myelitis or transverse myelitis after COVID-19 vaccine. Also I have heard from b6 after vaccination but the CDC omitted some of her data on the VAERS report and mistakenly classified it as b6 Many of the descriptions of cases sound similar to b6

Do you believe that myelitis should be more formally evaluated as a safety signal after COVID-19 vaccination? Is there anything more we could/should do to raise awareness of this potential adverse event while ensuring it is placed in the right context of benefit:risk?

Thanks for your expert insight.

Best regards,
b6

Sudden onset of myelitis after COVID-19 vaccination: An under-recognized severe rare adverse event

William E. Fitzsimmons, Pharm.D., M.S. and Christopher S. Nance, M.D.

Abstract

Myelitis has been reported as a complication of COVID-19 infection. However, it has rarely been reported as a complication of COVID-19 vaccination, and this may be the first case report following an mRNA vaccine. A 63 yo, otherwise healthy male, received his second dose of the Moderna vaccine on 08 April 2021. He had some initial pain and soreness at the injection site. Seventeen hours post dose, he reported pain and numbness in both calves which progressed to lower back pain, paresthesia in both feet, and pain in lower extremities. Over the day post- vaccination the patient's condition worsened and he was unable to walk and unable to urinate voluntarily. On the second day post- vaccination he presented to the Emergency Department and was admitted to the University of Iowa hospital unable to walk with severe pain in lower back, legs and feet, and numbness in buttocks. Laboratory findings were unremarkable and lumbar puncture was not diagnostic. MRI revealed increased T2 cord signal seen in the distal spinal cord and conus. Initial treatment included IV Immunoglobulin for 2 days, followed by methylprednisolone 1000 mg/day IV for 5 days. Discharge from the hospital occurred on 16 April 2021 to inpatient rehabilitation. Treatment consisted of oral prednisone 60 mg/day with a tapering schedule. The patient slowly improved and was able to ambulate unassisted at 25 days post -vaccination. This case represents one of the first cases of myelitis reported in the literature after COVID-19 mRNA vaccination. As of 27 April 2021 the FDA VAERS system has 45 reports of transverse myelitis after COVID-19 vaccination (21 after Moderna vaccine, 19 were after Pfizer vaccine, and 5 occurred after Janssen vaccine).

Key Words: COVID-19 vaccine, myelitis, transverse myelitis, serious adverse event

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Introduction

Transverse myelitis has been reported as a complication of COVID 19 infection.[1-5] However, case reports describing myelitis after COVID-19 vaccination have been rare and primarily after vaccination with the AstraZeneca/Oxford ChAdOx1 nCoV-19 vaccine, an adenovirus vector vaccine.[6,7] Goss et al reported that there were 9 cases of transverse myelitis in the Centers for Disease Control (CDC) Vaccine Adverse Event Reporting System (VAERS) database as of March 2, 2021.[8] To our knowledge, this is the first detailed case report of myelitis after the Moderna mRNA-1273 vaccine.

Case Report

A 63 yo, otherwise healthy male received his first vaccination in left deltoid with Moderna Lot 036A21A on 11 Mar 2021. Soreness at the injection site was the only adverse event. On 8 April 2021 at 1230 he received his 2nd injection in the left deltoid with Moderna 028A21A . 15 minutes after vaccination he noticed low level pain (1 on a 0-10 scale) around the injection site. This persisted throughout the day and evening. On 9 April 2021, 0515 while walking from bedroom to bathroom he noticed aching and slight numbness in calves of both legs, more prominent in left leg. At 0700 he developed lower back pain (3 out of 10) and aching and numbness extended from his calves to ankles. Over the next few hours lower back pain and leg aches persisted. At 1100 he experienced an involuntary erection lasting 5-10 minutes. During the afternoon, pain in the lower back increased to 6 out of 10, pain in lower legs increased (severity 2 out of 10), and he had paresthesias in both feet. At 1800 he had difficulty with ambulation and his feet became increasingly numb. Pain in lower legs and ankles persisted at level 4. At 1900 he noted his last voluntary urination before hospitalization. Over the next several hours he experienced greater difficulty walking and inability to sleep. On 10 April 2021 (day 2 post- vaccination) at 0100 he experienced sharp shooting pain from the buttocks down through the legs into bottoms of the feet lasting several seconds with greater severity in the left leg. The pain in the lower legs and ankles increased to level 5 and numbness in the buttocks and back of thighs started. The shooting pain persisted and at 0600 while attempting to get out of bed, he could not stand. His left calf, both ankles and both feet were completely numb. He was unable to urinate and was constipated. The patient arrived at University of Iowa Hospital Emergency Department at approximately 0830. At that time, his buttocks was completely numb, pain in the lower back, lower legs ankles and feet persisted (level 6). He was admitted to the hospital. At 1300 his pain levels suddenly and severely spiked, pain in lower back, legs, ankles and feet were all at level 10. Approximately 45 minutes after administration of narcotic analgesics pain decreased to level 8 and over the course of the next few hours decreased to 6. Over the next 4 days pain levels diminished. During his hospitalization, the patient continued to experience urinary retention and constipation along with other buttocks and lower extremity symptoms but no symptoms above the waist. He had left foot drop and brisk patellar and Achilles reflexes. The patient was discharged from the hospital to inpatient rehabilitation on 15 Apr 2021 (7 days of hospitalization). At that time the patient was voiding urine on his own with straight catheterization for retention as needed. He continued to experience bilateral lower extremity numbness and was walking with a walker or physical therapist. Inpatient treatment consisted of IVIG 0.5 g/kg on 10 Apr and 11 Apr (2 doses); Methylprednisolone IV

1 G/day 11-15 Apr (5 doses) followed by oral prednisone. He reported sporadic shooting pain in soles of feet and was discharged after 7 days in hospital. Discharge medications included prednisone 60 mg/day on a slow tapering schedule.

After 7 days of inpatient rehabilitation he was discharged to home, ambulating with two canes. He is now able to walk in his home without assistance, canes, or walker and continues to improve but some numbness continues in his feet and ankles. His current prednisone dose is 40 mg/day.

Laboratory tests

On admission

CBC and chemistries were within normal limits.

COVID-19 PCR test negative.

ESR 16 mm/hr (normal < 15)

C-reactive protein <0.5

PTT 23 sec

C3 and C4 complement normal

Rapid plasma reagin titer 1:1

During hospitalization:

Neuromyelitis Optica/Aquaporin-4-IgG – Serum- Negative

MOG FACS – Serum- Negative

MS screen- negative

SS A antibody 1.9AI (positive)- drawn 12 Apr after two doses of IVIG

SS B antibody negative

ANCA negative

Rheumatoid Factor negative (<10 IU/ml)

ANA <1:80

Imaging

MRI on 11 Apr 2021 of cervical thoracic and lumbar spine

Cervical and lumbar spines appear within normal limits. Increased T2 cord signal seen in the distal spinal cord and conus with questionable associated enhancement suggestive of myelitis.

MRI on 13 Apr 2021 of brain

Few punctate T2/FLAIR signal hyperintensities in bilateral corona radiata, nonspecific. No enhancing or restricting lesion.

CSF

Lumbar Puncture on 12 Apr 2021

Aerobic and anaerobic cultures negative; meningitis/encephalitis panel negative; glucose 74 mg/dL(40-75); total protein 37 mg/dL (15-45); cell count and differential normal; total nucleated cell count 3

Autoimmune Myelopathy Evaluation performed by Mayo Clinic labs was negative for all autoantibodies tested.

EMG

14 Apr 2021 No clear evidence for demyelinating polyradiculoneuropathy. One positive sharp wave in left gastrocnemius muscle.

Discussion

Two cases of transverse myelitis were reported with the ChAdOx1n CoV-19 vaccine (AZD1222), a replication-deficient chimpanzee adenoviral vector vaccine, from the four randomized controlled trials in Brazil, South Africa, and the UK which triggered a temporary pause in enrollment. One case was reported 14 days after booster vaccination and one case 10 days after a first vaccination.[6] Additionally Sing Malhotra et al reported a case of a 36 yo male who received the ChAdOx1n CoV-19 vaccine and on the 8th day post vaccination presented with abnormal sensations in both lower limbs. MRI on the 13th day post vaccination showed a T2-hyperintense lesion in the dorsal aspect of the spinal cord at the C6 and C7 vertebral levels. The patient responded well to IV methylprednisolone 1G/day for 5 days.[7]

As of April 27, 2021, VAERS has 133,321 reports for all adverse events after COVID-19 vaccine. Of these, 45 (0.03%) are reports of transverse myelitis. The ages of the patients with transverse myelitis ranged from 27 to 88 years with a median of 62 years, with symptoms beginning within 14 days for 71% of the reports. Twenty one of the reports were after the Moderna vaccine, 19 were after the Pfizer vaccine, and 5 occurred after the Janssen vaccine.[9] This case report is consistent with those in VAERS given the patient is 63 yo and the

onset was within 14 days of the second vaccine dose. In this case, no other etiology for lumbar spine myelitis was identified and the temporal association to the second dose of the Moderna vaccine was clear. Transverse myelitis is a very rare event in the population and has been reported after other types of vaccines (e.g. hepatitis B virus, measles-mumps-rubella, diphtheria-tetanus-pertussis) but the reports describe very few cases. Baxter et al described 7 cases after nearly 64 million doses of vaccine.[10] Agmon-Levin et al found 37 cases reported in the literature between 1970-2009.[11] Therefore, serious adverse events occurring soon after COVID-19 vaccination should be reported to the VAERS system and formally assessed as a potential safety signal with communication to health care providers. Given that myelitis has been associated with both COVID-19 infection and with COVID-19 vaccination, there may be an immunologic reaction to the spike protein that is misdirected to the spinal cord in these patients.

Ethics approval and consent to participate - Not applicable

Consent for publication - Informed consent obtained.

Competing interests - The author declares no competing interests.

Funding - The author has not received any funding from any intramural or extramural source.

Acknowledgements:

The authors would like to acknowledge and thank:

-The patient for the detailed description of symptomatology and review of the case report

-Avindra Nath MD, Chief, Section of Infections of the Nervous System, Clinical Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health, Bethesda, MD

-Carlos A. Pardo, MD, Johns Hopkins Myelitis & Myelopathy Center, Divisions of Neuroimmunology and Neuroinfectious Disorders & Advanced Clinical Neurology, Johns Hopkins University School of Medicine

-Benjamin M. Greenberg, MD, MHS, FANA, FAAN, CRND, Distinguished Teaching Professor, Vice Chair of Research, Department of Neurology; Director, Perot Foundation Neurosciences Translational Research Center, O'Donnell Brain Institute, University of Texas Southwestern

M. Roy First, MD, Sef Kurstjens, MD, PhD, and Kenneth Johnson, Pharm.D., for review and editorial assistance with the case report.

References

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From: b6
Sent: 12/13/2021 3:27:39 AM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
Subject: [EXTERNAL] Re: VAERS reports of myelitis after COVID-19 vaccination
Attachments: Microsoft Word - HCP Fact Sheet.docx.pdf

Dear Dr. Nath,

Previously you were very helpful in providing advice on the care of b6 who was hospitalized with transverse myelitis within 2 days after his 2nd Moderna COVID-19 vaccination. As you may know, AstraZeneca received Emergency Use Authorization for their antibodies that are used for COVID-19 prophylaxis including individuals who previously had a severe adverse reaction to a COVID-19 vaccine. The data from the trial is not published and the attached EUA factsheet does not provide details on subjects who previously had an adverse reaction. As I consider whether it is safe to administer Evusheld to b6 I think it is wise to consider whether his previous myelitis is mediated by antibodies or whether it was T cell mediated , i.e. is there a chance that the antibodies in Evusheld may react to a self antigen in the spinal cord. Do you have any opinion or insights on whether myelitis after vaccination is mediated by antibodies or is it T cell mediated?

Thanks for your important advice.

Best regards,
b6

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Sunday, June 13, 2021 10:03 AM
To: b6
Subject: Re: VAERS reports of myelitis after COVID-19 vaccination

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From: b6
Date: Sunday, June 13, 2021 at 10:41 AM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: VAERS reports of myelitis after COVID-19 vaccination

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Do you believe that myelitis should be more formally evaluated as a safety signal after COVID-19 vaccination? Is there anything more we could/should do to raise awareness of this potential adverse event while ensuring it is placed in the right context of benefit:risk?

Thanks for your expert insight.

Best regards,
b6

FACT SHEET FOR HEALTHCARE PROVIDERS: EMERGENCY USE AUTHORIZATION FOR EVUSHELD™ (tixagevimab co-packaged with cilgavimab)

HIGHLIGHTS OF EMERGENCY USE AUTHORIZATION (EUA)
These highlights of the EUA do not include all the information needed to use EVUSHELD™ under the EUA. See the FULL FACT SHEET FOR HEALTHCARE PROVIDERS for EVUSHELD.

EVUSHELD (tixagevimab) injection; (cilgavimab) injection, co-packaged for intramuscular use
Original EUA Authorized Date: 12/2021

----------EUA FOR EVUSHELD----------
The U.S. Food and Drug Administration has issued an EUA for the emergency use of the unapproved product EVUSHELD (tixagevimab co-packaged with cilgavimab), SARS-CoV-2 spike protein-directed attachment inhibitor, for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination **or**
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

EVUSHELD has been authorized by FDA for the emergency use described above. EVUSHELD is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19. (1)

EVUSHELD is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of EVUSHELD under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

LIMITATIONS OF AUTHORIZED USE

- EVUSHELD is not authorized for use in individuals:
  - For treatment of COVID-19, or
  - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

See Full Fact Sheet for Healthcare Providers for examples of medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination, the justification for emergency use of drugs during the COVID-19 pandemic, information on available alternatives, and additional information on COVID-19. (1)

----------DOSAGE AND ADMINISTRATION----------
The dosage of EVUSHELD for emergency use is 150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate consecutive intramuscular injections. See Full Fact Sheet for Healthcare Providers for detail on preparation and administration. (2)

----------DOSAGE FORMS AND STRENGTHS----------
Injection:

- tixagevimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial. (3)
- cilgavimab 150 mg/1.5 mL (100 mg/mL) in a single-dose vial. (3)

----------CONTRAINDICATIONS----------
EVUSHELD is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of EVUSHELD. (4)

----------WARNINGS AND PRECAUTIONS----------

- Hypersensitivity Including Anaphylaxis: Serious hypersensitivity reactions, including anaphylaxis, have been observed with IgG1 monoclonal antibodies like EVUSHELD. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur, immediately discontinue administration and initiate appropriate medications and/or supportive therapy. Clinically monitor individuals after injections and observe for at least 1 hour. (5.1)
- Clinically Significant Bleeding Disorders: As with any other intramuscular injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder. (5.2)
- Cardiovascular Events: A higher proportion of subjects who received EVUSHELD versus placebo reported myocardial infarction and cardiac failure serious adverse events. All of the subjects with events had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events, and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event. (5.3)

----------ADVERSE REACTIONS----------
Most common adverse events (all grades, incidence ≥3%) are headache, fatigue, and cough. (6.1)

You or your designee must report all SERIOUS ADVERSE EVENTS or MEDICATION ERRORS potentially related to EVUSHELD (1) by submitting FDA Form 3500 online, (2) by downloading this form and then submitting by mail or fax, or (3) contacting the FDA at 1-800-FDA-1088 to request this form. Please also provide a copy of this form to *AstraZeneca* by Fax at 1-866-742-7984 or call 1-800-236-9933. (6.4)

See PATIENT AND PARENTS/CAREGIVER FACT SHEET.

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* Sections or subsections omitted from the EUA are not listed

FULL FACT SHEET FOR HEALTHCARE PROVIDERS

1 EMERGENCY USE AUTHORIZATION

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for the emergency use of the unapproved product EVUSHELD (tixagevimab co-packaged with cilgavimab) for the pre-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and pediatric individuals (12 years of age and older weighing at least 40 kg):

- Who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS-CoV-2 **and**
  - Who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments **and** may not mount an adequate immune response to COVID-19 vaccination[1] **or**
  - For whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (e.g., severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s).

EVUSHELD has been authorized by FDA for the emergency use described above. EVUSHELD is not FDA-approved for any use, including use for pre-exposure prophylaxis of COVID-19.

EVUSHELD is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of EVUSHELD under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Medical conditions or treatments that may result in moderate to severe immune compromise and an inadequate immune response to COVID-19 vaccination include but are not limited to[1]:

- Active treatment for solid tumor and hematologic malignancies
- Receipt of solid-organ transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell or hematopoietic stem cell transplant (within 2 years of transplantation or taking immunosuppression therapy)
- Moderate or severe primary immunodeficiency (e.g., DiGeorge syndrome, Wiskott-Aldrich syndrome)
- Advanced or untreated HIV infection (people with HIV and CD4 cell counts <200/mm^3, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV)
- Active treatment with high-dose corticosteroids (i.e., ≥20 mg prednisone or equivalent per day when administered for ≥2 weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor-necrosis (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell depleting agents)

LIMITATIONS OF AUTHORIZED USE

- EVUSHELD is not authorized for use in individuals:
  - For treatment of COVID-19, or

[1] For additional information please see https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.Healthcare providers should consider the benefit-risk for an individual patient.

    - For post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.
- Pre-exposure prophylaxis with EVUSHELD is not a substitute for vaccination in individuals for whom COVID-19 vaccination is recommended. Individuals for whom COVID-19 vaccination is recommended, including individuals with moderate to severe immune compromise who may derive benefit from COVID-19 vaccination, should receive COVID-19 vaccination.
- In individuals who have received a COVID-19 vaccine, EVUSHELD should be administered at least two weeks after vaccination.

Justification for Emergency Use of Drugs During the COVID-19 Pandemic
There is currently an outbreak of COVID-19 caused by SARS-CoV-2, a novel coronavirus. The Secretary of HHS has declared that:

- A public health emergency related to COVID-19 has existed since January 27, 2020.
- Circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic (March 27, 2020 declaration).

An EUA is a FDA authorization for the emergency use of an unapproved product or unapproved use of an approved product (i.e., drug, biological product, or device) in the United States under certain circumstances including, but not limited to, when the Secretary of HHS declares that there is a public health emergency that affects the national security or the health and security of United States citizens living abroad, and that involves biological agent(s) or a disease or condition that may be attributable to such agent(s). Criteria for issuing an EUA include:

- The biological agent(s) can cause a serious or life-threatening disease or condition;
- Based on the totality of the available scientific evidence (including data from adequate and well-controlled clinical trials, if available), it is reasonable to believe that
    - The product may be effective in diagnosing, treating, or preventing the serious or life-threatening disease or condition; and
    - The known and potential benefits of the product - when used to diagnose, prevent, or treat such disease or condition - outweigh the known and potential risks of the product, taking into consideration the material threat posed by the biological agent(s);
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating the serious or life-threatening disease or condition.

Information Regarding Available Alternatives for the EUA Authorized Use
There are no adequate, approved and available alternatives to EVUSHELD for the pre-exposure prophylaxis of COVID-19 in individuals who may not mount an adequate immune response to COVID-19 vaccination or for whom COVID-19 vaccination is not recommended due to a history of severe adverse reaction to a COVID-19 vaccine or its components.

For information on clinical studies of EVUSHELD and other therapies for the prophylaxis of COVID-19, see www.clinicaltrials.gov.

2 DOSAGE AND ADMINISTRATION

2.1 Dosage for Emergency Use of EVUSHELD

The dosage of EVUSHELD in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) is 150 mg of tixagevimab and 150 mg of cilgavimab administered as two separate consecutive intramuscular (IM) injections.

Repeat Dosing
Longer term data from the study PROVENT indicate that EVUSHELD may be effective for pre-exposure prophylaxis for 6 months post-administration *[see Clinical Studies (14)]*. While SARS-CoV-2 remains in circulation, individuals who qualify for EVUSHELD, per the conditions of the EUA, can be redosed every 6 months.

EVUSHELD has only been studied in single-dose studies. There are no safety and efficacy data available with repeat dosing. The recommendation for repeat dosing is based on the totality of the scientific evidence including clinical pharmacology data and clinical trial data *[see Clinical Pharmacology (12.3) and Clinical Studies (14)]*.

2.2 Dosage Adjustment in Specific Populations

No dosage adjustment is recommended in pregnant or lactating individuals, in geriatrics, and in individuals with renal impairment *[see Use in Specific Populations (8)]*.

2.3 Dose Preparation and Administration

Each EVUSHELD carton contains two vials; one of each antibody. Each vial contains an overfill to allow the withdrawal of 150 mg (1.5 mL).

Table 1. Dosage of Tixagevimab and Cilgavimab

EVUSHELD* (tixagevimab co-packaged with cilgavimab)	Antibody dose	Number of vials needed	Volume to withdraw from vial(s)
	tixagevimab 150 mg	1 vial (dark grey vial cap)	1.5 mL
	cilgavimab 150 mg	1 vial (white vial cap)	1.5 mL

* 150 mg of tixagevimab and 150 mg of cilgavimab are to be administered as separate, consecutive intramuscular injections

Preparation

- Tixagevimab and cilgavimab must be prepared by a qualified healthcare provider.
- Tixagevimab and cilgavimab are each supplied in individual single-dose vials. Do not shake the vials.
- Visually inspect the vials for particulate matter and discoloration. Tixagevimab and cilgavimab are clear to opalescent, colorless to slightly yellow solutions. Discard the vials if the solution is cloudy, discolored or visible particles are observed.
- Withdraw 1.5 mL of tixagevimab solution and 1.5 mL of cilgavimab solution into TWO separate syringes (see Table 1). Discard unused portion in vials.

- This product is preservative-free and therefore, the prepared syringes should be administered immediately. If immediate administration is not possible, and the prepared tixagevimab and cilgavimab syringes need to be stored, the total time from vial puncture to administration must not exceed 4 hours:
    - in a refrigerator at 2°C to 8°C (36°F to 46°F), or
    - at room temperature up to 25°C (77°F).

Administration

- Tixagevimab and cilgavimab must be administered by a qualified healthcare provider.
- Administer the two components of EVUSHELD consecutively.
- Administer the IM injections at different injection sites, preferably one in each of the gluteal muscles, one after the other.
- Clinically monitor individuals after injections and observe for at least 1 hour *[see Warnings and Precautions (5.1)]*.

3 DOSAGE FORMS AND STRENGTHS

EVUSHELD is available as an individual single-dose vial of tixagevimab as a clear to opalescent, colorless to slightly yellow solution co-packaged with an individual single-dose vial of cilgavimab as a clear to opalescent, colorless to slightly yellow solution as:

- Injection: 150 mg/1.5 mL (100 mg/mL) of tixagevimab
- Injection: 150 mg/1.5 mL (100 mg/mL) of cilgavimab

4 CONTRAINDICATIONS

EVUSHELD is contraindicated in individuals with previous severe hypersensitivity reactions, including anaphylaxis, to any component of EVUSHELD *[see Warnings and Precautions (5.1)]*.

5 WARNINGS AND PRECAUTIONS

There are limited clinical data available for EVUSHELD. Serious and unexpected adverse events may occur that have not been previously reported with EVUSHELD use.

5.1 Hypersensitivity Including Anaphylaxis

Serious hypersensitivity reactions, including anaphylaxis, have been observed with Human immunoglobulin G1 (IgG1) monoclonal antibodies like EVUSHELD *[see Adverse Reactions (6.1)]*. If signs and symptoms of a clinically significant hypersensitivity reaction or anaphylaxis occur while taking EVUSHELD, immediately discontinue administration and initiate appropriate medications and/or supportive care. Clinically monitor individuals after injections and observe for at least 1 hour.

5.2 Clinically Significant Bleeding Disorders

As with any other intramuscular injection, EVUSHELD should be given with caution to individuals with thrombocytopenia or any coagulation disorder.

5.3 Cardiovascular Events

In PROVENT there was a higher rate of cardiovascular serious adverse events (SAEs), including myocardial infarction (one fatal SAE) and cardiac failure, in subjects who received EVUSHELD compared to placebo *[see Adverse Reactions (6.1)]*. All subjects who experienced cardiac SAEs had cardiac risk factors and/or a prior history of cardiovascular disease, and there was no clear temporal pattern. A causal relationship between EVUSHELD and these events has not been established. There was no signal for cardiac toxicity or thrombotic events identified in the nonclinical studies.

Consider the risks and benefits prior to initiating EVUSHELD in individuals at high risk for cardiovascular events, and advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event.

6 ADVERSE REACTIONS

6.1 Adverse Reactions from Clinical Studies

The following adverse events have been observed in the clinical studies of EVUSHELD that supported the EUA. The adverse event rates observed in these clinical studies cannot be directly compared to rates in the clinical studies of other products and may not reflect the rates observed in clinical practice. Additional adverse events associated with EVUSHELD may become apparent with more widespread use.

Approximately 4,220 subjects have been exposed to EVUSHELD (tixagevimab 150 mg and cilgavimab 150 mg) in clinical trials.

The safety of EVUSHELD is based on analyses from two ongoing Phase III trials, PROVENT and STORM CHASER. In both studies, adults received EVUSHELD (150 mg of tixagevimab and 150 mg of cilgavimab) administered as two separate consecutive IM injections or placebo *[see Clinical Studies (14)]*.

The primary safety analysis was based on data through to an event driven efficacy data cut-off, such that individual subjects had variable follow-up times *[see Clinical Studies (14)]*, with a median (range) of follow-up of 83 days (3-166 days) for PROVENT and 49 days (5-115 days) for STORM CHASER. An additional data cut-off was conducted to provide updated analyses with a median (range) of follow-up of 6.5 months (3-282 days) for PROVENT and approximately 6 months (5-249 days) for STORM CHASER. The median and range of follow-up times were similar between EVUSHELD and placebo recipients in each trial.

PROVENT

PROVENT enrolled adults ≥18 years of age who were either ≥60 years of age, had pre-specified co-morbidities *[see Clinical Studies (14)]*, or were at increased risk of SARS-CoV-2 infection due to their living situation or occupation. Subjects could not have previously received a COVID-19 vaccine or have known prior or current SARS-CoV-2 infection. Subjects received a single dose of EVUSHELD (N= 3,461) or placebo (N= 1,736).

Adverse events were reported in 1,221 (35%) subjects receiving EVUSHELD and 593 (34%) receiving placebo. SAEs were reported in 50 (1%) subjects receiving EVUSHELD and 23 (1%) receiving placebo. There was 1 adverse event reported as anaphylaxis among subjects who received

EVUSHELD. The event began within minutes of EVUSHELD administration and was treated with epinephrine. The event resolved.

Of the reported adverse events (N= 4,507), the majority were mild (73%) or moderate (24%) in severity. All adverse events, occurring in at least 1% of subjects, were reported at similar incidence rates among subjects receiving EVUSHELD compared to those receiving placebo (difference <1%). The most common treatment-emergent adverse events, occurring in at least 3% of subjects receiving EVUSHELD or placebo are shown in Table 2.

Table 2 Adverse Events (All Grades) Regardless of Causality Occurring in at Least 3% of Subjects Receiving EVUSHELD or Placebo in Primary Safety Analysis

	EVUSHELD N= 3,461	Placebo N= 1,736
Headache	6%	5%
Fatigue	4%	3%
Cough	3%	3%

At the additional data cut-off (median follow-up 6.5 months), the overall adverse event profile for subjects who received EVUSHELD remained similar to events displayed in Table 2.

Cardiac Serious Adverse Events

Through the additional data cut-off in PROVENT, a higher proportion of subjects who received EVUSHELD versus placebo in PROVENT reported myocardial infarction SAEs, one of which resulted in death, and cardiac failure SAEs (see Table 3 below). All subjects who experienced cardiac SAEs had cardiac risk factors and/or a prior history of cardiovascular disease at baseline. There was no clear temporal pattern, with events reported from several hours after EVUSHELD receipt through the end of the follow-up period.

Table 3 Cardiac SAEs Regardless of Causality in PROVENT with Onset Prior to Day 183 Using the Median 6-Month Data Cut-off Date

	EVUSHELD N= 3,461	Placebo N= 1,736
Subjects with any cardiac SAE*	22 (0.6%)	3 (0.2%)
SAEs related to coronary artery disease or myocardial ischemia†	10 (0.3%)	2 (0.1%)
Myocardial infarctions‡	8 (0.2%)	1 (0.1%)
SAEs related to cardiac failure§α	6 (0.2%)	1 (0.1%)
SAEs related to an arrhythmia¶	4 (0.1%)	1 (0.1%)
Other (cardiomegaly, cardiomyopathy, and cardio-respiratory arrest)	3 (0.1%)	0

* One EVUSHELD recipient and one placebo recipient had two cardiac SAEs each.
† Includes the preferred terms angina pectoris, coronary artery disease, arteriosclerosis, troponin increased, acute myocardial infarction, and myocardial infarction.
‡ Includes the preferred terms acute myocardial infarction, myocardial infarction, and troponin increased (with a discharge diagnosis of myocardial infarction).
§ Includes the preferred terms cardiac failure congestive, acute left ventricular failure, cardiac failure, and cardiac failure acute.
¶ Includes the preferred terms atrial fibrillation, arrhythmia, paroxysmal atrioventricular block, and heart rate irregular.

STORM CHASER

STORM CHASER enrolled adults ≥18 years of age following potential exposure (within 8 days) to an identified individual with a laboratory-confirmed SARS-CoV-2 infection (symptomatic or asymptomatic). Subjects could not have previously received a COVID-19 vaccine, have symptoms consistent with COVID-19, or have a known prior SARS-CoV-2 infection. Subjects received a single dose of EVUSHELD (N= 749) or placebo (N= 372).

Adverse events were reported in 162 (22%) subjects receiving EVUSHELD and 111 (30%) receiving placebo. SAEs were reported in 5 (<1%) subjects receiving EVUSHELD and 3 (<1%) receiving placebo. Of the reported adverse events (N= 777), the majority were mild (75%) or moderate (23%) in severity.

At the additional data cut-off (median follow-up approximately 6 months), the overall adverse event profile for subjects who received EVUSHELD remained similar to earlier results. EVUSHELD is not authorized for post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2 *[see Emergency Use Authorization (1)]*.

Cardiac Serious Adverse Events

In STORM CHASER (N= 1,121) no cardiac SAEs were reported (median follow-up approximately 6 months). Compared to PROVENT, the subjects in STORM CHASER were younger (median age 48 versus 57 years) and had fewer baseline cardiac risk factors (24% versus 36% with hypertension, 11% versus 14% with diabetes, and 3% versus 8% with cardiovascular disease in STORM CHASER versus PROVENT, respectively).

6.4 Required Reporting for Serious Adverse Events and Medication Errors

The prescribing healthcare provider and/or the provider's designee is/are responsible for mandatory reporting of all serious adverse events* and medication errors potentially related to EVUSHELD within 7 calendar days from the healthcare provider's awareness of the event, using FDA Form 3500 (for information on how to access this form, see below). The FDA recommends that such reports, using FDA Form 3500, include the following:

- Patient demographics and baseline characteristics (e.g., patient identifier, age or date of birth, gender, weight, ethnicity, and race)
- A statement "EVUSHELD use for COVID-19 under Emergency Use Authorization (EUA)" under the "**Describe Event, Problem, or Product Use/Medication Error"** heading
- Information about the serious adverse event or medication error (e.g., signs and symptoms, test/laboratory data, complications, timing of drug initiation in relation to the occurrence of the event, duration of the event, treatments required to mitigate the event, evidence of event improvement/disappearance after stopping or reducing the dosage, evidence of event reappearance after reintroduction, clinical outcomes)
- Patient's preexisting medical conditions and use of concomitant products
- Information about the product (e.g., dosage, route of administration, NDC #)

Submit adverse event and medication error reports, using Form 3500, to FDA MedWatch using one of the following methods:

- Complete and submit the report online: www.fda.gov/medwatch/report.htm

- Complete and submit a postage-paid FDA Form 3500 (https://www.fda.gov/media/76299/download) and return by:
  - Mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or
  - Fax to 1-800-FDA-0178, or
- Call 1-800-FDA-1088 to request a reporting form

In addition, please provide a copy of all FDA MedWatch forms to AstraZeneca:
- Fax 1-866-742-7984

and to report adverse events please:
- Visit https://contactazmedical.astrazeneca.com, or
- Call AstraZeneca at 1-800-236-9933.

The prescribing healthcare provider and/or the provider's designee is/are to provide mandatory responses to requests from FDA for information about adverse events and medication errors associated with EVUSHELD.

*Serious adverse events are defined as:

- Death or a life-threatening adverse event;
- A medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions; or
- A congenital anomaly/birth defect.

7 DRUG INTERACTIONS

Drug-drug interaction studies have not been performed.

Tixagevimab and cilgavimab are not renally excreted or metabolized by cytochrome P450 (CYP) enzymes; therefore, interactions with concomitant medications that are renally excreted or that are substrates, inducers, or inhibitors of CYP enzymes are unlikely *[see Clinical Pharmacology (12.3)]*.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary
There are insufficient data to evaluate a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. EVUSHELD should only be used during pregnancy if the potential benefit outweighs the potential risk for the mother and the fetus.

Nonclinical reproductive toxicity studies have not been conducted with tixagevimab and cilgavimab. In a tissue cross-reactivity study assessing off-target binding of tixagevimab and cilgavimab to human fetal tissues no binding of clinical concern was observed. Human immunoglobulin G1 (IgG1) antibodies are known to cross the placental barrier; therefore, tixagevimab and cilgavimab have the

potential to be transferred from the mother to the developing fetus. It is unknown whether the potential transfer of tixagevimab and cilgavimab provides any treatment benefit or risk to the developing fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

8.2 Lactation

Risk Summary

There are no available data on the presence of tixagevimab or cilgavimab in human milk or animal milk, the effects on the breastfed infant, or the effects of the drug on milk production. Maternal IgG is known to be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for EVUSHELD and any potential adverse effects on the breastfed infant from EVUSHELD.

8.4 Pediatric Use

EVUSHELD is not authorized for use in pediatric individuals under 12 years of age or weighing less than 40 kg. The safety and effectiveness of EVUSHELD have not been established in pediatric individuals. The dosing regimen is expected to result in comparable serum exposures of tixagevimab and cilgavimab in individuals 12 years of age and older and weighing at least 40 kg as observed in adults, since adults with similar body weight have been included in the trials PROVENT and STORM CHASER *[see Adverse Reactions (6.1) and Clinical Studies (14)]*.

8.5 Geriatric Use

Of the 2,029 subjects in the pooled pharmacokinetics (PK) analysis (Phase I and Phase III studies), 23% (N= 461) were 65 years of age or older and 3.3% (N= 67) were 75 years of age or older. There is no clinically meaningful difference in the PK of tixagevimab and cilgavimab in geriatric subjects (≥65 years) compared to younger subjects.

8.6 Renal Impairment

Tixagevimab and cilgavimab are not eliminated intact in the urine, renal impairment is not expected to affect the exposure of tixagevimab and cilgavimab. Similarly, dialysis is not expected to impact the PK of tixagevimab and cilgavimab.

8.7 Hepatic Impairment

The effect of hepatic impairment on the PK of tixagevimab and cilgavimab is unknown.

8.8 Other Specific Populations

Based on a population PK analysis, the PK profile of tixagevimab and cilgavimab was not affected by sex, age, race, or ethnicity. Population PK model-based simulations suggest that body weight had no

clinically relevant effect on the PK of tixagevimab and cilgavimab in healthy adults over the range of 36 kg to 177 kg.

10 OVERDOSAGE

Treatment of overdose with EVUSHELD should consist of general supportive measures including the monitoring of the clinical status of the individual. There is no specific treatment for overdose with EVUSHELD.

11 DESCRIPTION

Tixagevimab, a SARS-CoV-2 spike protein-directed attachment inhibitor, is a human immunoglobulin G1 (IgG1κ) monoclonal antibody produced in Chinese hamster ovary (CHO) cells by recombinant DNA technology. The molecular weight is approximately 149 kDa.

Tixagevimab injection is a sterile, preservative-free, clear to opalescent and colorless to slightly yellow solution supplied in a single-dose vial for intramuscular use. The vial stoppers are not made with natural rubber latex. Each 1.5 mL contains 150 mg tixagevimab, L- histidine (2.4 mg), L- histidine hydrochloride monohydrate (3.0 mg), polysorbate 80 (0.6 mg), sucrose (123.2 mg), and Water for Injection, USP. The pH is 6.0.

Cilgavimab, a SARS-CoV-2 spike protein-directed attachment inhibitor, is a human IgG1κ monoclonal antibody produced in CHO cells by recombinant DNA technology. The molecular weight is approximately 152 kDa.

Cilgavimab injection is a sterile, preservative-free, clear to opalescent and colorless to slightly yellow solution supplied in a single-dose vial for intramuscular use. The vial stoppers are not made with natural rubber latex. Each 1.5 mL contains 150 mg cilgavimab, L- histidine (2.4 mg), L- histidine hydrochloride monohydrate (3.0 mg), polysorbate 80 (0.6 mg), sucrose (123.2 mg), and Water for Injection, USP. The pH is 6.0.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tixagevimab and cilgavimab are two recombinant human IgG1κ monoclonal antibodies with amino acid substitutions to extend antibody half-life (YTE), reduce antibody effector function, and minimize the potential risk of antibody-dependent enhancement of disease (TM). Tixagevimab and cilgavimab can simultaneously bind to non-overlapping regions of the receptor binding domain (RBD) of SARS-CoV-2 spike protein. Tixagevimab, cilgavimab, and their combination bind to spike protein with equilibrium dissociation constants of K_D = 2.76 pM, 13.0 pM and 13.7 pM, respectively, blocking its interaction with human ACE2, the SARS-CoV-2 receptor, which is required for virus attachment. Tixagevimab, cilgavimab, and their combination blocked RBD binding to human ACE2 with IC_{50} values of 0.32 nM (48 ng/mL), 0.53 nM (80 ng/mL), and 0.43 nM (65 ng/mL), respectively.

12.3 Pharmacokinetics

A summary of PK parameters and properties of tixagevimab and cilgavimab following administration of a single EVUSHELD (150 mg of tixagevimab and 150 mg of cilgavimab) intramuscular dose is provided in Table 4.

Table 4 Summary of PK Parameters and Properties of Tixagevimab and Cilgavimab Following a Single EVUSHELD Intramuscular Dose

PK Parameters	Tixagevimab	Cilgavimab
C_{max} (µg/mL)*	16.5 (35.6)	15.3 (38.5)
T_{max} (day)†	14.0 (3.1 – 30)	14.0 (3.1 – 60)
C_1 (µg/mL)‡	4.4 (92.2)	3.9 (94.4)
C_{150} (µg/mL)§	6.6 (25.6)	5.5 (35.2)
C_{210} (µg/mL)¶	4.0 (31.6)	3.9 (37.1)
AUC_{inf} (day•µg/mL)	2529 (30.2)	2133 (31.7)
Absorption		
Bioavailability#	68.5	65.8
Distribution		
Apparent Volume of Distribution (L)#	7.7 (1.97)	8.7 (2.73)
Elimination		
Half-life (days)#	87.9 (13.9)	82.9 (12.3)
Apparent Clearance (L/day)#	0.062 (0.019)	0.074 (0.028)
Metabolism	Catabolic pathways; Same manner as endogenous IgG	
Excretion	Not likely to undergo renal excretion	

* Geomean (geometric %CV)
† Median (range)
‡ Observed geomean (geometric %CV) concentration 1 day after dosing
§ Observed geomean (geometric %CV) concentration 150 days after dosing
¶ Observed geomean (geometric %CV) concentration 210 days after dosing
# Arithmetic mean (SD)

For repeat dose pre-exposure prophylaxis, it is expected that 6-month repeat EVUSHELD dosing will result in steady-state serum tixagevimab and cilgavimab trough concentrations greater than or equal to Day 183 tixagevimab and cilgavimab serum concentrations following a single EVUSHELD dose. Predicted steady-state serum tixagevimab and cilgavimab trough concentrations after 6-month repeat EVUSHELD dosing are in the range of the observed mean Day 150 and mean Day 210 concentration in serum (Table 4) following a single EVUSHELD dose.

Specific Populations

The PK profile of tixagevimab and cilgavimab were not affected by sex, age, race or ethnicity. Body weight had no clinically relevant effect on the PK of tixagevimab and cilgavimab in adults over the range of 36 kg to 177 kg.

Pediatric Population

The PK of tixagevimab and cilgavimab in pediatric individuals have not been evaluated.

The dosing regimen is expected to result in comparable plasma exposures of tixagevimab and cilgavimab in pediatric individuals ages 12 years of age or older who weigh at least 40 kg as observed in adult individuals *[see Use in Specific Populations (8.4)]*.

Renal impairment
Tixagevimab and cilgavimab are not eliminated intact in the urine.

Renal impairment is not expected to impact the PK of tixagevimab and cilgavimab, since monoclonal antibodies with molecular weight >69 kDa are known not to undergo renal elimination. Similarly, dialysis is not expected to impact the PK of tixagevimab and cilgavimab.

There is no difference in the clearance of tixagevimab and cilgavimab in individuals with mild or moderate renal impairment compared to individuals with normal renal function. There were insufficient subjects with severe renal impairment to draw conclusions *[see Use in Specific Populations (8.6)]*.

Hepatic impairment
No specific studies have been conducted to examine the effects of hepatic impairment on the PK of tixagevimab and cilgavimab. The impact of hepatic impairment on the PK of tixagevimab and cilgavimab is unknown *[see Use in Specific Populations (8.7)]*.

Drug Interaction Studies
Drug-drug interaction studies have not been performed. Based on key elimination pathways, tixagevimab and cilgavimab interactions with concomitant medications that are renally excreted or that are substrates, inducers, or inhibitors of CYP enzymes are unlikely *[see Drug Interactions (7)]*.

12.4 Microbiology

Antiviral Activity
In a neutralization assay on Vero E6 cells, tixagevimab, cilgavimab, and their combination neutralized SARS-CoV-2 (USA-WA1/2020 isolate) with EC_{50} values of 60.7 pM (9 ng/mL), 211.5 pM (32 ng/mL), and 65.9 pM (10 ng/mL), respectively.

Tixagevimab, cilgavimab, and their combination showed reduced or no antibody-dependent cell-mediated cytotoxicity (ADCC), antibody-dependent cellular phagocytosis (ADCP), or antibody-dependent natural killer cell activation (ADNKA) in cell culture studies. Tixagevimab, cilgavimab, and their combination did not mediate antibody-dependent complement deposition (ADCD) activity with guinea pig complement proteins.

Antibody Dependent Enhancement (ADE) of Infection
The potential of tixagevimab and cilgavimab to mediate antibody-dependent viral entry was assessed in FcγRII-expressing Raji cells co-incubated with recombinant virus-like particles (VLPs) pseudotyped with SARS-CoV-2 spike protein, with antibody concentrations at a range of 6.6 nM (1 µg/mL) to 824 pM (125 ng/mL). Tixagevimab, cilgavimab, and their combination did not mediate entry of VLPs into these cells under the tested conditions.

The potential for ADE was also evaluated in a non-human primate model of SARS-CoV-2 using EVUSHELD. Intravascular administration prior to virus inoculation resulted in a dose-dependent improvement in all measured outcomes (total viral RNA in the lungs or nasal mucosae, infectious virus levels in the lungs based on $TCID_{50}$ measurements, or lung injury and pathology based on histology measurements). No evidence of enhancement of viral replication or disease was observed at any dose evaluated, including sub-neutralizing doses down to 0.04 mg/kg.

Antiviral Resistance

There is a potential risk of treatment failure due to the development of viral variants that are resistant to tixagevimab and cilgavimab. Prescribing healthcare providers should consider the prevalence of SARS-CoV-2 variants in their area, where data are available, when considering prophylactic treatment options.

Escape variants were identified following serial passage in cell culture of SARS-CoV-2 or replication competent recombinant vesicular stomatitis virus (VSV) expressing SARS-CoV-2 spike protein in the presence of tixagevimab or cilgavimab individually or in combination. Variants which showed reduced susceptibility to cilgavimab expressed spike protein amino acid substitutions R346I (>200-fold), K444E (>200-fold), and K444R (>200-fold). No escape variants to tixagevimab, or the tixagevimab and cilgavimab combination were selected.

In neutralization assays using recombinant VLPs pseudotyped with SARS-CoV-2 spike and harboring individual spike amino acid substitutions identified in circulating SARS-CoV-2, variants with reduced susceptibility to cilgavimab alone included those with R346I (>200-fold), K444E (>200-fold), K444Q (>200-fold), K444R (>200-fold), V445A (21- to 51-fold), G446V (4.2-fold), N450K (9.1-fold), or L452R (5.8-fold) substitutions. Variants with reduced susceptibility to tixagevimab alone included those with Q414R (4.6-fold), L455F (2.5- to 4.7-fold), G476S (3.3-fold), E484D (7.1-fold), E484K (6.2- to 12-fold), E484Q (3.0-fold), F486S (>600-fold), F486V (121- to 149-fold), Q493K (2.4- to 3.2-fold), Q493R (7.9-fold), E990A (6.1-fold), or T1009I (8.2-fold) substitutions. Variants harboring an E484K (2.4- to 5.4-fold), Q493R (3.4-fold), E990A (5.7-fold), or T1009I (4.5-fold) substitution exhibited low level reduced susceptibility to tixagevimab and cilgavimab in combination.

VLPs pseudotyped with the SARS-CoV-2 spike of variant strains with reduced susceptibility to cilgavimab included those with R346K:E484K:N501Y (Mu, 21-fold), and those with reduced susceptibility to tixagevimab included those harboring E484K (Alpha, 18.5-fold; Beta, 3.5- to 15-fold). Similar results were observed, where data was available, in neutralization assays using authentic SARS-CoV-2 variant strains.

Tixagevimab and cilgavimab in combination retained neutralization activity against pseudotyped VLPs and/or authentic SARS-CoV-2 variant strains harboring all spike substitutions identified in Alpha (B.1.1.7, 0.5- to 5.2-fold), Beta (B.1.351, 1.0- to 3.8-fold), Gamma (P.1, 0.4- to 2.0-fold) and Delta (B.1.617.2, 0.6- to 1.2-fold) variants of concern, and Eta (B.1.525, 3.1-fold), Iota (B.1.526, 0.3- to 3.4-fold), Kappa (B.1.617.1, 0.5- to 3.4-fold) Lambda (C.37, 0.7-fold), and Mu (B.1.621, 7.5-fold) variants of interest. Tixagevimab and cilgavimab in combination also retained neutralization activity against Epsilon (B.1.427 / B.1.429, 0.8- to 3.5-fold), R.1 (3.5-fold), B.1.1.519 (1.4-fold), C.36.3 (2.3-fold), B.1.214.2 (0.8-fold), and B.1.619.1 (3.3-fold) variant alerts for further monitoring and B.1.616 (0.5-fold), A.23.1 (0.4-fold), A.27 (0.8-fold), and AV.1 (5.9-fold) variants de-escalated from further monitoring (Table 5).

Table 5 Pseudotyped Virus-Like Particles and Authentic SARS-CoV-2 Neutralization Data for SARS-CoV-2 Variant Substitutions with EVUSHELD

Lineage with Spike Protein Substitution	Country First Identified	WHO Nomenclature	Key Substitutions Tested	Fold Reduction in Susceptibility* (Pseudotyped VLPs†)	Fold Reduction in Susceptibility* (Authentic virus‡)
B.1.1.7	UK	Alpha	N501Y	0.5- to 5.2-fold	No Change§
B.1.351	South Africa	Beta	K417N+E484K +N501Y	No Change§	No Change§
P.1	Brazil	Gamma	K417T+E484K +N501Y	No Change§	No Change§
B.1.617.2	India	Delta	L452R+T478K	No Change§	No Change§
AY.1/ AY.2	India	Delta [+K417N]	K417N+L452R +T478K	No Change§	No Change§
B.1.525	Multiple country origin	Eta	E484K	No Change§	ND
B.1.526	United States	Iota	E484K	No Change§	No Change§
B.1.617.1	India	Kappa	L452R+E484Q	No Change§	No Change§
C.37	Peru	Lambda	L452Q+F490S	No Change§	ND
B.1.621	Colombia	Mu	R346K+E484K +N501Y	7.5-fold	ND
B.1.427 / B.1.429	United States	Epsilon	L452R	No Change§	No Change§
R.1	Multiple country origin	-	E484K	No Change§	ND
B.1.1.519	Multiple country origin	-	T478K	No Change§	ND
B.1.616	France	-	V483A	No Change§	ND
A.23.1	UK	-	V367F	No Change§	ND
A.27	Multiple country origin	-	L452R+N501Y	No Change§	ND
AV.1	Multiple country origin	-	N439K+E484K	5.9-fold	ND

* Range of reduced potency across multiple variants of each lineage using research-grade pseudotyped VLP neutralization assays; mean fold change in half maximal inhibitory concentration (EC_{50}) of mAb required for a 50% reduction in infection compared to wild type reference strain

† Pseudotyped virus-like particles expressing the entire SARS-CoV-2 spike variant protein and individual characteristic spike substitutions except L452Q were tested including Alpha (+L455F, E484K, F490S, Q493R, and/or S494P), and Delta (+K417N) harboring additional indicated RBD substitutions that are no longer detected or detected at extremely low levels within these lineages

‡ Authentic SARS-CoV-2 expressing the entire variant spike protein were tested including Alpha (+E484K or S494P) harboring additional indicated RBD substitutions that are no longer detected or detected at extremely low levels within these lineages

§ No change: <5-fold reduction in susceptibility

ND, not determined; RBD, receptor binding domain

It is not known how pseudotyped VLPs or authentic SARS-CoV-2 neutralization susceptibility data correlate with clinical outcome.

In PROVENT, illness visit sequencing data were available for 21 of 33 subjects with SARS-CoV-2 infection (6 of 13 who received tixagevimab and cilgavimab and 15 of 20 placebo). At an allele

fraction ≥25%, 14 of 21 subjects were infected with variants of concern or variants of interest, including 8 subjects with Alpha (B.1.1.7) (8 who received placebo), 1 subject with Beta (B.1.351) (1 who received tixagevimab and cilgavimab), 3 subjects with Delta (B.1.617.2) (3 who received placebo), and 2 subjects with Epsilon (B.1.429) (2 who received tixagevimab and cilgavimab). Seven additional subjects were infected with B.1.375 (1 who received tixagevimab and cilgavimab) or the A_1 set of lineages containing a constellation of spike protein substitutions including D614G and P681H or Q677P (3 who received tixagevimab and cilgavimab and 3 placebo). Additional spike protein RBD substitutions detected at an allele fraction ≥3% included V503F in the tixagevimab and cilgavimab group.

In STORM CHASER, illness visit sequencing data was available for 19 subjects with SARS-CoV-2 infections (12 of 12 who received tixagevimab and cilgavimab and 7 of 7 placebo). At an allele fraction ≥25%, 12 of 19 subjects were infected with variants of concern or variants of interest, including 9 subjects with Alpha (B.1.1.7) (5 who received tixagevimab and cilgavimab and 4 placebo) and 3 subjects with Epsilon (B.1.427 / B.1.429) (2 who received tixagevimab and cilgavimab and 1 placebo). Seven additional subjects were infected with B.1.1.519 (1 who received tixagevimab and cilgavimab) or the A_1 set of lineages containing a constellation of spike protein substitutions including D614G and D138H, Q675H, Q677H, or V1176F (4 who received tixagevimab and cilgavimab and 2 placebo). Additional spike protein RBD substitutions detected at an allele fraction ≥3% included S325P, Del342, C361W, Del428, F429V, and F515C in the tixagevimab and cilgavimab group.

Evaluation of neutralization susceptibility of variants identified through global surveillance and in subjects who received tixagevimab and cilgavimab is ongoing.

It is possible that variants resistant to tixagevimab and cilgavimab could have cross-resistance to other monoclonal antibodies targeting the RBD of SARS-CoV-2. The combination of tixagevimab and cilgavimab retained activity against pseudotyped VLPs harboring individual SARS-CoV-2 spike substitutions (K417E/N, D420N, K444Q, V445A, Y453F, L455F, N460K/S/T, E484D/K/Q, F486V, F490S, Q493K/R, and S494P) identified in neutralization escape variants of other monoclonal antibodies targeting the RBD of SARS-CoV-2 spike protein.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity, genotoxicity, and reproductive toxicology studies have not been conducted with tixagevimab and cilgavimab.

13.2 Animal Toxicology and Pharmacology

In a toxicology study in cynomolgus monkeys, tixagevimab and cilgavimab had no adverse effects when administered via IM injection.

In tissue cross-reactivity studies with tixagevimab and cilgavimab using human adult and fetal tissues no binding of clinical concern was detected.

Tixagevimab and cilgavimab have been assessed in rhesus macaque and cynomolgus macaque models of SARS-CoV-2 infection. Prophylactic administration of tixagevimab and cilgavimab (N= 4

rhesus macaque; N= 3 cynomolgus macaque) three days prior to infection prevented SARS-CoV-2 infection of the upper and lower respiratory tracts in dose-dependent manner. Prophylactic administration of 4 mg/kg tixagevimab and cilgavimab resulted in a 7-$\log_{10}$ reduction in viral sub-genomic messenger RNA (sgmRNA) in nasopharyngeal swabs and 5 to 6-$\log_{10}$ reduction in sgmRNA or infectious virus titer in bronchoalveolar lavage samples at Day 2 post-challenge in all animals relative to placebo-treated animals.

Compared to placebo, prophylactic administration of tixagevimab and cilgavimab (N= 3 cynomolgus macaque) reduced lung injury associated with SARS-CoV-2 infection.

The applicability of these findings to a clinical setting is not known.

14 CLINICAL STUDIES

The data supporting this EUA are based on analyses from the Phase III trials PROVENT (NCT04625725) and STORM CHASER (NCT04625972). Both trials are evaluating the safety and efficacy of EVUSHELD (150 mg of tixagevimab and 150 mg of cilgavimab) for the prophylaxis SARS-CoV-2 symptomatic illness (COVID-19).

Efficacy Data from PROVENT

PROVENT is an ongoing Phase III, randomized (2:1), double-blind, placebo-controlled clinical trial studying EVUSHELD for the pre-exposure prophylaxis of COVID-19 in adults ≥18 years of age. All subjects were either ≥60 years of age, had a pre-specified co-morbidity (obesity, congestive heart failure, chronic obstructive pulmonary disease, chronic kidney disease, chronic liver disease, immunocompromised state, or previous history of severe or serious adverse event after receiving any approved vaccine), or were at increased risk of SARS-CoV-2 infection due to their living situation or occupation. Subjects could not have previously received a COVID-19 vaccine. Subjects received a single dose (administered as two IM injections) of EVUSHELD or placebo. The study excluded subjects with a history of laboratory-confirmed SARS-CoV-2 infection or SARS-CoV-2 antibody positivity at screening. Once COVID-19 vaccines were locally available, subjects were permitted on request to unblind to make an informed decision on vaccine timing and to receive COVID-19 vaccination.

The baseline demographics were balanced across the EVUSHELD and placebo arms. The median age was 57 years (with 43% of subjects aged 60 years or older), 46% of subjects were female, 73% were White, 3% were Asian 17% were Black/African American, and 15% were Hispanic/Latino. Of the 5,197 subjects, 78% had baseline co-morbidities or characteristics associated with an increased risk for severe COVID-19, including obesity (42%), diabetes (14%), cardiovascular disease (8%), cancer, including a history of cancer (7%), chronic obstructive pulmonary disease (5%), chronic kidney disease (5%), chronic liver disease (5%), immunosuppressive medications (3%) and immunosuppressive disease (<1%).

For the primary endpoint, a subject was defined as a COVID-19 case if their first case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurred after administration and prior to Day 183. The primary analysis included 5,172 subjects who were SARS-CoV-2 RT-PCR-negative at baseline, of which 3,441 received EVUSHELD and 1,731 received placebo. Only events that occurred prior to unblinding or vaccine receipt were included. EVUSHELD receipt resulted in a statistically significant (p-value <0.001) 77% reduction in incidence of SARS-CoV-2 RT-PCR-positive symptomatic illness

(COVID-19) when compared to placebo (Table 6). At the time of analysis the median follow-up time post-administration was 83 days (range 3 to 166 days).

Similar results were observed for EVUSHELD recipients compared to placebo recipients in the reduction in incidence of SARS-CoV-2 RT-PCR-positive symptomatic illness or death from any cause (12/3,441 versus 19/1,731, respectively) with relative risk reduction of 69% (95% CI: 36, 85; p-value= 0.002), and in the reduction in incidence of SARS-CoV-2 RT-PCR-positive symptomatic illness regardless of unblinding or vaccine receipt (10/3,441 versus 22/1,731, respectively) with relative risk reduction of 77% (95% CI: 52, 89 ; p-value <0.001).

Table 6 Incidence of Symptomatic COVID-19 in Adults (PROVENT)

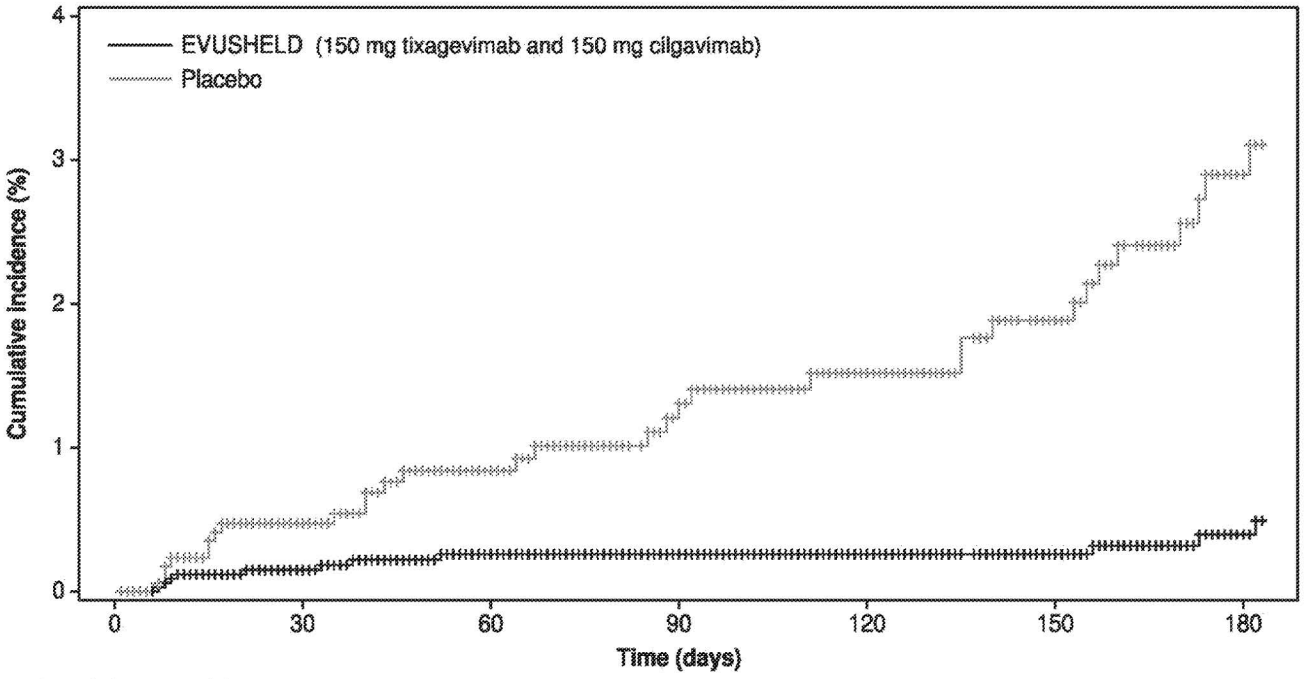
	N*	Number of events, n (%)	Relative Risk Reduction, % (95% CI)
EVUSHELD†	3,441	8 (0.2%)	77% (46, 90)
Placebo	1,731	17 (1.0%)	

N = number of subjects in analysis; CI = Confidence Interval
* subjects were censored after receiving the vaccine or being unblinded to consider the vaccine, whichever occurred earlier
† EVUSHELD dose (150 mg tixagevimab and 150 mg cilgavimab)

Among subjects who received EVUSHELD, there were no severe/critical COVID-19 events (defined as SARS-CoV-2 RT-PCR-positive symptomatic illness characterized by a minimum of either pneumonia [fever, cough, tachypnoea or dyspnea, and lung infiltrates] or hypoxemia [SpO_2 <90% in room air and/or severe respiratory distress] and a WHO Clinical Progression Scale score of 5 or higher) compared to one event (0.1%) among subjects who received placebo.

An additional data cut was conducted to provide post-hoc updated efficacy and safety analysis, the median follow-up was 6.5 months for subjects in both EVUSHELD and placebo arms. The relative risk reduction of SARS-CoV-2 RT-PCR-positive symptomatic illness was 83% (95% CI: 66, 91) with 11/3,441 (0.3%) events in the EVUSHELD arm and 31/1,731 (1.8%) events in the placebo arm, see Figure 1. These results are consistent with the duration of protection predicted by population PK modelling *[see Clinical Pharmacology (12.3)]*. Among subjects who received EVUSHELD there were no severe/critical COVID-19 events compared to five events among subjects who received placebo.

Figure 1 Kaplan Meier: Cumulative Incidence of Symptomatic COVID-19* (PROVENT)



Number of participants at risk

EVUSHELD	3441	2957	2393	2054	1815	1667	1044
Placebo	1731	1483	1177	991	856	774	472

* Subjects who do not experience a primary endpoint event (and had not discontinued) are censored at Day 183. Subjects who were unblinded/vaccinated prior to an event are also censored at the earlier time of unblinding/vaccination.

Efficacy Data from STORM CHASER

STORM CHASER is an ongoing Phase III randomized (2:1), double-blind, placebo-controlled clinical trial of EVUSHELD for the post-exposure prophylaxis of COVID-19 in adults ≥18 years of age. Subjects who had not previously received a COVID-19 vaccine were enrolled following potential exposure (within 8 days) to an identified individual with a laboratory-confirmed SARS-CoV-2 infection (symptomatic or asymptomatic). Subjects received a single dose (administered as two IM injections) of EVUSHELD or placebo. The study excluded subjects with a history of laboratory-confirmed SARS-CoV-2 infection or SARS-CoV-2 antibody positivity at screening. Once COVID-19 vaccines were locally available, subjects were permitted on request to unblind to make an informed decision on vaccine timing and to receive COVID-19 vaccination.

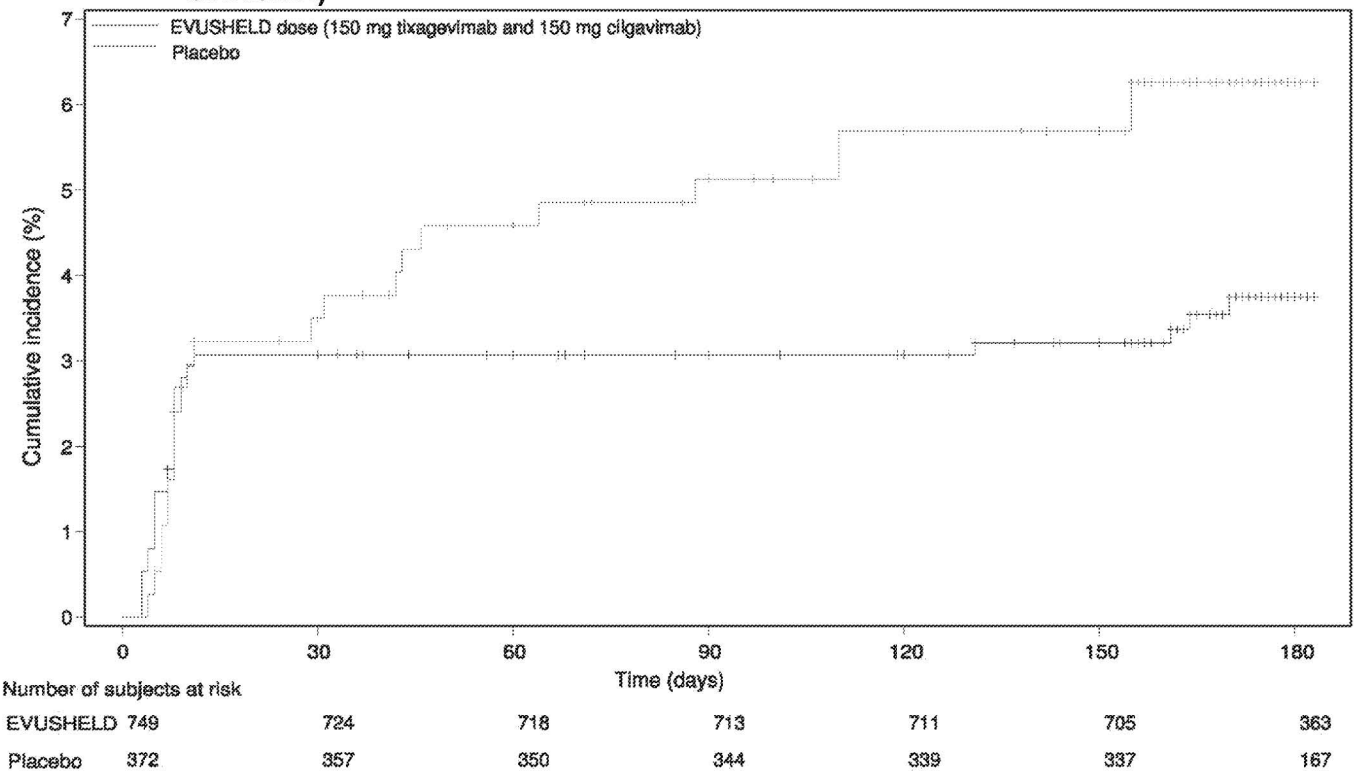
Of the 1,121 subjects who were randomized and received EVUSHELD (N= 749) or placebo (N= 372), 48 subjects were positive for SARS-CoV-2 (RT-PCR analysis of nasopharyngeal swabs) at baseline.

The primary efficacy analysis, comparison of the incidence of a subject's first case of SARS-CoV-2 RT-PCR-positive symptomatic illness occurring post-dose and before Day 183, did not demonstrate a statistically significant effect for EVUSHELD versus placebo with 23 cases of symptomatic COVID-19 in the EVUSHELD arm (3.1%) and 17 cases in the placebo arm (4.6%) (relative risk reduction of 33%, 95% CI: -26, 65). At the time of analysis the median follow-up time post-administration was 49 days (range 5 to 115 days).

The study did not demonstrate benefit for EVUSHELD in preventing symptomatic COVID-19 in the first 30 days after randomization, leading to the limitation of use for post-exposure prophylaxis *[see Emergency Use Authorization (1)]*. However, there was a higher proportion of symptomatic COVID-19

cases among placebo recipients after Day 29 (see Figure 2 below, data from the post-hoc updated efficacy analysis with a median follow-up time of 6.5 months). EVUSHELD is not authorized for post-exposure prophylaxis of COVID-19 in individuals who have been exposed to someone infected with SARS-CoV-2.

Figure 2 Kaplan Meier: Cumulative Incidence of Symptomatic COVID-19* (STORM CHASER)



* Subjects who do not experience a primary endpoint event (and had not discontinued) are censored at Day 183.

16 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Each EVUSHELD co-packaged carton contains two vials (Table 7):

- 1 single-dose vial of tixagevimab injection as a sterile, preservative-free, clear to opalescent and colorless to slightly yellow solution.
- 1 single-dose vial of cilgavimab injection as a sterile, preservative-free, clear to opalescent and colorless to slightly yellow solution.

Table 7 EVUSHELD co-packaged carton contents

Carton (2 vials per pack)	Components	
	1 vial of Tixagevimab 150 mg/1.5 mL (100 mg/mL) **(dark grey cap)**	**1 vial of Cilgavimab** 150 mg/1.5 mL (100 mg/mL) **(white cap)**
NDC 0310-7442-02	NDC 0310-8895-01	NDC 0310-1061-01

Storage and Handling

Store unopened vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light. Discard any unused portion.

DO NOT FREEZE. DO NOT SHAKE.

17 PATIENT COUNSELING INFORMATION

As a prescribing healthcare practitioner, you must communicate to the patient, parent and caregiver information consistent with the "FACT SHEET FOR PATIENTS, PARENTS OR CAREGIVERS" and provide them with a copy of this Fact Sheet prior to administration of EVUSHELD.

Cardiovascular Events
Inform individuals that a higher proportion of subjects who received EVUSHELD versus placebo reported cardiovascular serious adverse events (myocardial infarctions and heart failure). Advise individuals to seek immediate medical attention if they experience any signs or symptoms suggestive of a cardiovascular event *[see Warnings and Precautions (5.3)]*.

For additional information, please visit the website or call the telephone number provided below.

To access the most recent EVUSHELD Fact Sheets, please scan the QR code provided below.

Website	Telephone number
http://www.evusheld.com	1-800-236-9933

18 MANUFACTURER INFORMATION

Distributed by: AstraZeneca Pharmaceuticals LP, Wilmington, DE 19850

Manufactured by: Samsung Biologics, 300 Songdo bio-daero, Yeonsu-gu, Incheon 21987, Republic of Korea

From: b6
Sent: 5/31/2021 7:37:03 PM
To: Nath, Avindra (NIH/NINDS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b81ca051950b4d458d74037a6a86ead6-b6
Subject: Re: Severe Covid Vaccine Reaction from b6 in Pfizer Trial b6

I apologize, I forgot to include the doctor's name. It is b6 from b6 b6

Kind regards,

b6

From: b6
Sent: Monday, May 31, 2021 3:35 PM
To: Nath, Avindra (NIH/NINDS) [E] b6
Subject: Re: Severe Covid Vaccine Reaction from b6 in Pfizer Trial b6

Hi Dr. Nath,

I spoke to one of the doctors in Inpatient Rehabilitation that is in the new monthly rotation team coming in and he is going to call you tomorrow regarding b6 case. They are supposed to get me the medical release document to sign today.

She is still in inpatient rehabilitation waiting to be transferred to b6 for their b6 to address what they are saying is b6 This was our only option other than taking her home and figuring out where to get her treatment on our own. If that isn't the right treatment and doesn't work, they will refer her to somewhere else. She is b6 b6 b6 She is still walking with a walker, she hasn't b6 but we have been working with her on our own. She will start b6 if a bed isn't available and she is not transferred and then will b6 after she is discharged from b6

Thanks again for all your help, I hope you were able to have some time off today for Memorial Day!

Kind regards,

b6

From: Nath, Avindra (NIH/NINDS) [E] b6
Sent: Thursday, May 27, 2021 11:00 AM
To: b6
Cc: Safavi, Farinaz (NIH/NINDS) [E] b6 Wiebold,

Amanda (NIH/NINDS) [E] b6
Subject: Re: Severe Covid Vaccine Reaction from b6 in Pfizer Trial for b6

Sorry for what you are going through. Hope b6 gets better soon.
Best wishes.
Avi

From: b6
Date: Thursday, May 27, 2021 at 8:48 AM
To: Nath, Avindra (NIH/NINDS) [E]
Cc: Safavi, Farinaz (NIH/NINDS) [E] b6 b6
Wiebold, Amanda (NIH/NINDS) [E]
Subject: Re: Severe Covid Vaccine Reaction from b6 in Pfizer Trial for b6

Hi Dr. Nash,

Thank you for following up so quickly. I shared your information with her neurologist but I haven't heard back from him yet. We met with b6 Inpatient Rehabilitation doctors yesterday and they said they were not willing to call you and were standing firm on the b6 but we were welcome to get a second opinion. However in her MyChart notes it said b6 b6

Unfortunately, our only option now is to have her transferred to b6 for their b6 b6 to work on b6 so she doesn't have to rely on b6 b6 At least then they will be able to help monitor and possibly help resolve the problems she is having with b6

After b6 she is very close to being able to walk on her own and can walk with a walker. She suffered for b6 b6 while they dismissed her symptoms and deteriorating health.

My frustration is that b6 has the same symptoms and recovery as the diagnosis's other people who have had adverse reactions to the vaccine. They are unwilling to look any further into this because then they would have to admit the vaccine caused her reaction. This is happening over and over to other people to this day and healthy people (soon to include children) are having their lives ruined forever. Kids 12-15 have only had their first dose and soon will have their second dose, their immune responses are stronger than adults and if they have any autoimmune disorders many of them are not aware of it yet which could be one of the many things that they were unwilling to figure out with b6 who is in a trial at their hospital. They just want to slap a psychological sticker on her so they don't have any accountability to this and it is wrong.

Thank you from the bottom of my heart for being so willing to help out when you are inundated to begin with, I really appreciate it. I pray you are able to figure out why this is happening to so many people and the public is informed so they can be prepared if this happens to them and they don't have to go through what b6 went through.

Kind regards,

b6

Sent from my iPhone

On May 26, 2021, at 9:35 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Thanks for the additional information. Due to HIPPA b6 would need to give consent to her physicians to talk to me about her. Then the physicians would need to contact me. Sorry, I am not allowed to contact the physicians directly. OK to share my contact information below with them.
Avi

From: b6
Date: Wednesday, May 26, 2021 at 10:57 AM
To: Nath, Avindra (NIH/NINDS) [E]
Cc: Safavi, Farinaz (NIH/NINDS) [E] b6 b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Re: Severe Covid Vaccine Reaction from b6 in Pfizer Trial for b6 b6

Hi Dr. Nath,

Thank you for the quick response, I know you are very busy. Thank you for offering to talk to her neurologist. I am going to email him your contact information, his name is b6 b6 Right now she is inpatient rehabilitation for walking and her doctors are b6 and b6 b6

She was diagnosed with b6 shortly after she started having her symptoms. They have done b6 They have not done b6 b6 If she can't walk today without a walker b6 then they are discharging her). She still has b6 b6 b6 She also has numbness from her waist down but does have some feeling coming back.

I am sharing a summary of her test results, ER visits and hospitalizations. I also have a document hat gives more details of her symptoms as they progressed that is a work in progress. My concern is she was tagged with b6 early on and there has been an unconscious bias from that point forward by specialists she has seen and the ER doctors. Additionally all of the doctors are from the hospital that she participated in the Pfizer trial and from the beginning no one was even willing to talk about the vaccine as the trigger for this.

From what I have read, the peripheral immune response and psychiatric disease can produce the same type of Neurologic symptoms. My concern is they are treating her symptoms and not the underlying cause.

I am extremely concerned about her health and the discharge plan they have for her which is b6 b6 which she does not have. I am not fully confident they will reach out to you but my plan is to refuse to let her be discharged until they do.

I appreciate your help, we are desperate to get b6 better. She has developed b6 b6 due to her experience.

b6

b6

Kind regards,

b6

Sent from my iPhone

On May 25, 2021, at 10:27 PM, Nath, Avindra (NIH/NINDS) [E] b6 wrote:

Dear b6
Sorry to hear of b6 illness. Sounds like she has been through a lot and been investigated extensively. It is hard to make a diagnosis over emails, but if it would help we would be glad to talk to her physicians or the neurologist who took care of her. We have certainly heard of a lot of cases of neurological complications form the vaccine and will be glad to share our experience with them. You are welcome to share my contact information.
Best wishes.
Avi
Avindra Nath MD
Chief, Section of Infections of the Nervous System
Clinical Director,
National Institute of Neurological Disorders and Stroke
National Institutes of Health, Bethesda, MD

b6

From: b6
Date: Monday, May 24, 2021 at 12:36 AM
To: Safavi, Farinaz (NIH/NINDS) [E] b6 Nath, Avindra (NIH/NINDS) [E] b6
Cc: b6 Wiebold, Amanda (NIH/NINDS) [E] b6
Subject: Severe Covid Vaccine Reaction from b6 in Pfizer Trial for b6

b6

Hello Dr. Nath and Dr. Safavi,

b6 shared your contact information and recommended reaching out to you for help b6 was a

healthy b6 with no major medical issues, the only things on her medical chart b6 She participated in the Pfizer vaccine trial for b6 at b6 and was confirmed that she got the vaccine on Monday by b6 b6 She received her first dose in the trial on b6 The next day she had a fever of 101, felt tired, and had swelling at the injection site but all of these resolved within a couple of days. She received her second dose on b6 She had immediate pain at the injection site which didn't happen with the first dose. About 18 hours after receiving the vaccine, she developed the following: severe muscle/nerve pain, painful electrical shocks down her neck and spine which caused her to walk hunched over, severe chest pain that felt like her heart was being pulled out, numbness, and swelling in her vaccine arm (left), her fingers and toes turned white and were ice cold to the touch, the pain in her toes was so bad she walked on her heels, severe abdominal pain (especially on the lower right side) and a fever of 101.4. We were instructed to take her to the ER at b6 where they did b6

b6

Over the next b6 her severe abdominal pain along with the muscle and nerve pain persisted plus she new symptoms including fatigue, nausea, vomiting, abdominal distension, regurgitation of food, and eventually the inability to swallow food or liquids, itchy rash on her arms, peeling skin on her feet, unexplained painful cysts on her vagina and then her head, tinnitus, vision problems, headaches, dizziness, erratic blood pressure, and heart rate, memory loss, brain fog, verbal and motor tics, fainting/seizures (10+ a day), loss of feeling from the waist down then paralysis of her legs, inability to walk, muscle weakness, abnormal gait, gastroparesis, urinary retention, anxiety, and medical PTSD. Additionally, she b6 menstrual cycle on b6 which continued off and on for over a month with clumps of blood and then off and on spotting until b6 and nothing since then. Between b6 we had to take her to the ER nine (9) times and she was admitted to the hospital 3 times. In between hospital visits she has seen multiple specialists at b6 and had b6 b6 instead she continued to decline.

After several desperate calls to multiple doctors expressing our concern for her declining health and more ER trips we finally got help from our new Care Coordinator to have neurology guarantee, she would be admitted if we went to the ER on b6 When she got to the ER on b6 she could not walk, was unable to feel or move below her waist, had tachycardia and her blood sugar was b6 Once she was stable they admitted her to neurology and then transferred her to Inpatient

Rehabilitation on b6 As of today b6 she is finally close to being able to walk without a walker but she still has an abnormal gait. She also still has b6 and continued problems with urination and gastroparesis, not to mention the PTSD from this experience with doctors, especially in the ER and Pfizer Vaccine Trial, doubting her and treating her like a mental patient. Right now every Wednesday and Friday, she has to b6

b6

b6 NOTE: the words in italics are directly from her medical chart.

b6 has gone from being a typical healthy b6 who worried about doing well in school and loved hanging out with friends to being so ill she had to b6 She has been in the hospital for b6 where she b6 b6 She is the strongest person I know and I am so proud of her for pushing through this nightmare and never giving up. There is no doubt in my mind that the vaccine caused this. All of these medical problems started less than 24 hours after the second dose of the Pfizer covid vaccine and did not just go away within 72 hours like they say. She was not forced to do the vaccine trial, she asked to do it b6 b6 so she could help get our world back to normal. The only diagnosis we have been given is b6

b6

b6 no explanation as to why the vaccine triggered it They have dismissed her having b6

b6

Once she was given the b6 diagnosis they stopped any further testing that could and should have been done. We have had issues with doctors avoiding vaccine conversations and the immunologist/allergist who saw her for 15 minutes is the doctor who "told" b6 her symptoms were likely not due to the vaccine. She is not even close to being functional and that is with b6

b6

b6

b6 And no one can explain or improve her urinary and GI issues. We have a family meeting today to discuss her discharge on b6 b6 We are desperate to get her treatment that will help her get back to the healthy b6 she was before she got the Pfizer vaccine. I was told her case was included in Pfizer's final report on the trial b6 but they did not share the end diagnosis and all of her symptoms. They summed it up as b6 b6 it was MUCH more than that! We do not want this to happen to more innocent people, especially children!

Kind regards,

b6

b6

From: Togias, Alkis (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C8B85408814D496194BED8D69D6143EB-b6]
Sent: 2/24/2021 11:12:08 PM
To: b6
Subject: Re: Bad Shock Reaction to my first Moderna shot

Dear b6
Thank you for your note and I am sorry you experienced such a reaction. From your description it is hard for me to give you an opinion whether it was an allergic reaction or not. Both the Moderna and the Pfizer vaccines have induced allergic reactions. I would recommend that you see an allergist in your area to discuss it in more depth and potentially undergo some evaluation (although there are no tests that would definitely confirm or rule-out a diagnosis of an allergic reaction). The most important decision is, of course, whether you should receive your second dose or not.
I would also recommend that you report your reaction to the VAERS system, which alerts the CDC and the FDA. These Agencies have the responsibility of recording reactions that patients and physicians report. This gives them the ability to identify common features that may indicate a particular problem for which research needs to be done or some specific measures need to be taken.
With kind regards,
Alkis Togias

Alkis Togias, M.D.
Branch Chief, Allergy, Asthma and Airway Biology
DAIT/NIAID/NIH

5601 Fishers Lane, Room 6B40
Bethesda, MD 20892-9827
email: b6
tel: b6

For Courier Mail please use the following ZIP code: Rockville, MD 20852

On 2/24/21, 5:13 PM, b6 wrote:

Hi Doctor Togias:

I'm a b6 and got my first Moderna shot b6.

But – I had a pretty scary reaction within one hour of getting it.

I received it on b6 at the b6 in b6 b6, and was in very high spirits.
I'm a big fan of vaccines, everyone was nice, I didn't even feel the needle, and I sat down for the requisite 15 minutes feeling great.

But about 6 minutes after the shot, I got a feeling that I was losing consciousness, I started breathing harder, and my salivary glands actuated. This wave passed within a minute and then I felt fine again (and I didn't say anything to the clinic).

However, about twenty minutes after that, while driving (alone) home on the freeway, it hit me again for five or six minutes, and I wasn't sure if I was going to pass out or not. I kind of fought it, breathing in deeply and trying to ignore my salivary glands, and it slowly went away. By the time I got home it was a little over an hour after the shot, and I was feeling almost normal.

This was a frightening occurrence, and I suspect it was a mild anaphylactic shock.

I'm not an allergic person – as far as I know b6 b6 – and in 2020 I got b6 b6 – and never felt anything like this.

I'm letting you know this because if I had this reaction, I'm sure many other people have and will also. Maybe there is something wrong with the Moderna vaccine, or at least with the batch I got. Were

my symptoms similar to the ones experienced by some of the vaccine recipients in San Diego or the eight people who received the Pfizer vaccine ?

And do you have any advice on whether I should get the second shot in a month, or a fraction of it ? Or maybe wait for a different vaccine?

thanks very much,

b6

From: b6
Sent: 7/10/2022 9:26:40 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-b6
Subject: [EXTERNAL] Fwd: Third mRNA Vaccine following a bout of Mild vaccine-related Myocarditis

Cc: b6

Dear Dr Fauci,

Our otherwise healthy, b6 experienced a bout of mild post-Pfizer Vaccine myocarditis, 5 days after his 2nd dose. He is now 5 months from the event and the question is whether he can safely receive the 3rd dose?

I am writing to learn if you have any knowledge regarding the relative risk to his getting the 3rd dose before b6

Thank you,

b6

From: b6
Sent: 10/20/2021 8:44:27 PM
To: Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94b6]
CC: NIAID Ocpostoffice (NIH/NIAID) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e0decb7e93a4a3e924a827af8ff676e-niaidocpost]; NHLBI FOIA REQUEST (NIH/NHLBI) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae4bf55a555d4329b49e2f57fc19277a-nhlbifoiare]
Subject: Significant Problems with CICP
Attachments: McGovern submission issue CICP.pdf; Gmail - Update for Case #b6 pdf

Good afternoon

I am hoping this information can find its way to Dr. Fauci.

Dr. Fauci seems like a person that truly cares - and I thank him for all his hard work, intelligence, dedication, and sacrifice during this COVID pandemic we find ourselves in.

In short:

* I received myocarditis from the Pfizer vaccine b6 and spent 3 days in the hospital. It wasn't fun. It was a wretched experience. I now have bills to pay, to pay off damages I incurred. Thank goodness - the government has a program to assist people in my situation: the CICP. However, the CICP currently has 8 people reviewing these claims. To me, that is simply unacceptable. They should have 50 people reviewing these claims, at least.

I've contacted the CICP, news organizations, and my local Senators and Congressman. Haven't heard much of anything yet.

To me - there are very simple, ZERO COST, solutions to this problem - that could be enacted TOMORROW. It just takes someone with authority, caring, and the will to do it.

See attached more documentation on this issue. I use foul language in it - but it's to convey my frustration. I hope you are as frustrated as I am. I for one, think the Federal Government could do better here. I hope you think so too.

I would love to hear from Dr Fauci or anyone at NIH with a response.

I realize the CICP is probably not within your direct chain of authority. But it's all one Federal Government, and we're all one nation - after all. So hopefully you all in the know, and with access to powerful people, can do something about this - or at least let me know that someone is aware of this problem and is working on it.

I'm standing by for a response. I'd love to chat - with anyone - at NIH about this.

Thanks

b6

Office of James McGovern

Digital Privacy Release Form

Complete the form below to request help with a Federal Agency. When complete, click Submit to send to our office for assistance.

Fields marked with * are required

Please Provide Applicable Identifying Information

Agency Involved

Department of Health and Human Services

Prefix	First Name	MI	Last Name
	b6		

Social Security Number	DOB	Email Address	Phone Number
		b6	

Street Address Line 1	Street Address Line 2	City	State	Zip Code
		b6		

Agency Case Number	Mortgage Loan Number	Rank	Military Rank
	b6		

Have you contacted any other elected official regarding this case?

Yes

If Yes, Officials Name?

Senator Markey, Senator

Please explain the problem and the resolution/outcome you are seeking:

I also contacted the Washington Post, Fox News, NPR, and The NY Times. Here's the deal: As far as I know, COVID-19 is the most serious viral infection in this country (and the world I suppose too), since the 1918 flu pandemic. The COVID-19 vaccine is also the first time we have used mRNA vaccines in literally hundreds of millions of people in this country. Hmmm... new virus... new vaccine... injected into hundreds of millions of people in this country.... What did we think was going to happen next? Don't get me wrong... I am grateful for the vaccine and its benefit to fighting this horrible disease COVID-19. However, like any medicine - some small segment of the population will have an adverse effect, like what happened to me - I ended up in the hospital for 3 days and they almost performed open heart surgery on me. These are facts, not exaggerations. So... hundreds of millions of new vaccine recipients... some small percentage of which will have adverse effects. And, thank goodness!, the government has a program to compensate folks that fall into this situation: the CICP. But wow... you'd think someone, in all their infinite wisdom, would realize: wow, we better put more resources into that CICP program!, because there is probably going to be a huge influx of claims! New virus, new vaccine, injected into hundreds of millions of people in this country! And... guess what! Apparently the CICP has been given NO surge in resources, to handle the HUGE increase in claims they have received, like mine for example! What does this mean? Instead of waiting weeks for a determination - how long will we have to wait? Months? A year? Wow, that's a really shitty program for the American people! I sure would like to think we could handle the crisis in a smart way! My status: I was hurt by the pfizer vaccine[b6](myocarditis - ended up at[b6]for three days, they almost performed open heart surgery on me.) Three months later, I submitted my claim to the CICP. They sent me a response back saying they needed more documentation. Ok, I gave them all the medical documentation they need. They've had this documentation for one month now. I want an answer. I don't want to wait any longer. I incurred expenses NOW, and I want to be reimbursed NOW. Getting reimbursed a year from now - is a pretty shitty program! I called the CICP. The people there are friendly, knowledgeable, and seem to be hard working. I spoke with Amber Johnson there and a Captain Dale Mishler. I asked both of these people details about when my claim would be decided on. Of course, as government workers, they told me "they do not know". I understand they can't commit to anything. What they did say is that the cases are reviewed on a first come, first serve basis, and there are about 1,500 cases ahead of me. I asked how long it takes them on average to review one case. One person one day? Captain Mishler said he couldn't really say, it varied. I asked how many people they have reviewing these cases. I was hoping they would say somewhere around 50. Captain Mishler said they have 8 people reviewing cases and are looking to on board 3 more. 8 people reviewing cases 11 months into a nation wide novel vaccination effort... IS UNACCEPTABLE. Here are some places that have more than 8 people that work there: * the McDonald's down the street from my house * the Dunkin Donuts down the street from my house * the local pesticide company that applies insecticide to my lawn * the bus drivers for my son's elementary school .... you get my point. THE ANSWER HERE, IS SIMPLE, IF SOMEBODY (CONGRESS?) CARES AT ALL TO DO A GODDAMN THING ABOUT IT: LET THE CICP HIRE A TEMPORARY (1 YEAR, EXTENDED MORE IF NEEDED) TO DEAL WITH THE GODDAMN OBVIOUS SURGE OF VACCINE CLAIMS THAT THERE ARE GOING TO BE, SINCE WE ARE TRYING TO VACCINATE THE ENTIRE GODDAMN COUNTRY WITH A NEW VACCINE (mRNA) FOR A NEW VIRUS!! Really, if we were fore-thinking, this surge would already be in place. IT IS UNACCEPTABLE FOR CASES LIKE MINE TO LINGER FOR MONTHS BECAUSE THIS AGENCY IS NOT ADEQUATELY STAFF TO HANDLE THIS SURGE THERE ARE I AM SURE A WHOLE LOT OF DELIVERABLE SOLUTIONS! HERE'S JUST A FEW OFF THE TOP OF MY HEAD: * ACTIVATE THOSE IN THE MILITARY WITH MEDICAL TRAINING (NATIONAL GUARD, ARMY, NAVY, USCG, MARINES, ETC, ETC,) - AND SEND THEM TO THE CICP TO QUICKLY CUT THROUGH THE SURGE OF CLAIMS!! DONE! THERE ARE NURSES, DOCTORS, ETC ETC THAT WORK IN THE MILITARY. PUT THEM TO GOOD WORK, LET'S GO! * Pass special funding - like an amendment in the current infrastructure bill - to give the CICP emergency funding to temporarily hire more qualified people (contractors, or civil servants - whatever is faster!), to cut through these cases The CICP needs an influx of more people to review these cases, so they aren't left sitting on desks for months at a time. It can definitely be a temporary influx (1 year, then extended as needed, or cancelled hopefully at that point!), until the case load drops down. But having these cases sit around for months - is unacceptable. We can do better in this country!!!!!!!!!! CONGRESSMAN MCGOVERN - I KNOW YOU THINK SO TOO!! Thank you for your assistance. Please contact me anytime about this. I'd love to chat to find quick, easy solutions to this critical problem for the American taxpayer! I have attached the email trail between the CICP and I. The CICP has all my medical documents. I am just waiting on them to make a decision on my claim. I want to wait weeks, not months - not years. It's been 4 weeks already. I deserve an answer, now. I have incurred large medical expense damages, and this program was setup to compensate people like me. It's a pretty shitty program, if it takes a long time to do so, rather than in a timely manner. I'd like to think we can at least do as good as Massachusett's RMV. The RMV takes weeks for stuff, not months, not years. The CICP is capable of processing these claims in weeks - Congress just needs to give them the resources to get more people to do it. Thanks![b6]

Constituent Authorization

To be able to assist you, we must have a signed privacy release form that clearly outlines your problem and the remedy you are seeking. By checking the box below you are giving our office permission to look into the matter on your behalf. Please make sure to attach below any relevant identifying information and supporting documents which relate to your

inquiry.

☒ I hereby request the assistance of the Office of Representative James McGovern to resolve the matter described below. I authorize James McGovern to receive any information that they might need to provide this assistance. The information I have provided to Rep. James McGovern is true and accurate to the best of my knowledge and belief. The assistance I have requested from Rep. James McGovern is in no way an attempt to evade or violate any federal, state, or local law.

Date/Time

10/7/2021 5:22:26 PM

*** Signature**

b6

Gmail b6

Update for Case # b6

b6 Wed, Oct 6, 2021 at 12:59 PM

To: b6

Dale

Thank you sincerely for speaking with me a moment ago.

I understand you have 8 staff members reviewing these cases, and are looking to on board 3 more.

Let's step back for a moment and think about this:

As far as I know, COVID-19 is the most serious viral infection in this country (and the world I suppose too), since the 1918 flu pandemic.

The COVID-19 vaccine is also the first time we have used mRNA vaccines in literally hundreds of millions of people in this country.

Hmmm... new virus... new vaccine... injected into hundreds of millions of people in this country.... What did we think was going to happen next?

Don't get me wrong... I am grateful for the vaccine and its benefit to fighting this horrible disease COVID-19.

However, like any medicine - some small segment of the population will have an adverse effect, like what happened to me - I ended up in the hospital for 3 days and they almost performed open heart surgery on me. These are facts, not exaggerations.

So... hundreds of millions of new vaccine recipients... some small percentage of which will have adverse effects. And, thank goodness!, the government has a program to compensate folks that fall into this situation: the CICP.

But wow... you'd think someone, in all their infinite wisdom, would realize: wow, we better put more resources into that CICP program!, because there is probably going to be a huge influx of claims! New virus, new vaccine, injected into hundreds of millions of people in this country!

And... Congress has apparently given you 8 people to review these cases. There are more people that work at the local coffee shop down the street from my house. **8 people is unacceptable**. You need an influx of more people to review these cases, so they aren't left sitting on desks for months at a time. It could even be a temporary influx, until the case load drops down. But having these cases sit around for months - is unacceptable. **We can do better in this country - I know you think so too!**

I will let Congress know that. (Also news outlets if I have to.)

Thank you for your assistance, and thank you for your service to our Nation.

b6

On Wed, Oct 6, 2021 at 12:14 PM b6 wrote:

> Good day
>
> I received an out of office message from Captain Mishler, which directed me to contact Tamara Overby, so here I am.
>
> I look forward to speaking with Ms. Overby, so I can gain an understanding of why it's taking so long for my case to be reviewed.
>
> Thanks!
>
> b6

b6

On Wed, Oct 6, 2021 at 11:34 AM b6 wrote:

Amber

Thanks for the call.

I found what appears to be Captain Mishler's email online, and I've included him on this email.

I look forward to speaking with Captain Mishler.

Thank you for your help

b6

On Tue, Oct 5, 2021 at 5:33 PM b6 wrote:

To my friends at CICP:

You have now had my medical records for almost one month!

I'm done waiting! Your time is up!

Here's the deal:

If my package does not move into the compensation negotiation phase by this **Friday, October 8th** - I am going to start engaging with my Congressman Jim McGovern, and Senators Warren and Markey on a daily basis - and **I'm sure they'll be able to figure out what the hold up is**.

I have a sincere question for you:

Does 1 + 1 = 2?

YES! Yes it does!

How long did it take you to answer that question? Hopefully, not that long!

Here's another question for you:

Did the pfizer COVID-19 vaccine cause me to get myocarditis?

YES! Yes it did!!

You have AMPLE medical records that show that, too!

I AM DONE WAITING FOR YOU. I WANT THE MONEY THAT IS OWED TO ME THROUGH THIS PROGRAM. YOU HAVE UNTIL FRIDAY TO MOVE ME INTO THE NEXT PHASE OF THIS PROCESS - AND IF NOT - THEN I START CONTACTING LAWMAKERS, WHOM I KNOW CAN GET TO THE BOTTOM OF WHY IT'S TAKING YOU SO LONG!!

Thanks for your help!

Call me anytime! I'd love to chat!

b6

On Tue, Sep 28, 2021 at 2:11 PM HRSA HSB CICP <CICP@hrsa.gov> wrote:

> Thank you for your email to the Countermeasures Injury Compensation Program (CICP). There is no new update for your claim.

From: b6
Sent: Monday, September 27, 2021 9:55 AM
To: HRSA HSB CICP <CICP@hrsa.gov>
Subject: Re: Update for Case # b6

Good morning

Do you have an update on my case? **Another week has gone by.** The CDC has already established a link between an mRNA COVID-19 vaccine and myocarditis. See here:

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

This is what happened to me. It's so obvious in the comprehensive medical documentation I provided to you.

Please confirm my eligibility promptly so we can move into the compensation phase.

Thank you!

b6

On Tue, Sep 21, 2021 at 11:38 AM b6 wrote:

> Ok, thank you
>
> I am asking kindly that you expedite the approval of my eligibility, so we can move into the compensation phase
>
> I received myocarditis from my Pfizer COVID vaccine. This is an indisputable fact. It's all there in the documentation you have.
>
> I pay my taxes on time every year. I meet deadlines imposed on me by the IRS. I hope the government can now act swiftly on my behalf
>
> I am asking for your swift approval of my eligibility, so that we can proceed promptly to the compensation phase
>
> Thank you
>
> b6
>
> Sent from my iPhone

On Sep 20, 2021, at 4:16 PM, HRSA HSB CICP <CICP@hrsa.gov> wrote:

Thank you for your email to the Countermeasures Injury Compensation Program (CICP). The CICP has received your claim and the additional documentation you submitted. If additional information is required you will be notified by mail. The CICP cannot estimate when a decision may be made in you claim.

Below is a summary of the CICP process that we hope will be helpful.

1. A Request for Benefits package is submitted to the CICP. The Request Package consists of the Request for Benefits form and relevant medical records, although they do not have to be submitted at the same time.
2. The Package is reviewed by CICP medical staff to determine whether the requester is eligible for program benefits, including whether a covered injury was sustained.
3. If the requester is determined to be eligible for program benefits, the requester is asked to submit additional documentation to determine the type and amount of compensation the requester may be entitled to receive. The requester is notified in writing of the eligibility and benefits determinations.
4. If the requester is found ineligible for program benefits, the requester is informed in writing of the disapproval.
5. The requester may ask HRSA to reconsider the program's eligibility or benefits determination. When a request for reconsideration is received, a qualified panel, independent of the program, is convened to review the program's determination of ineligibility.
6. The panel makes its recommendation to HRSA who makes a final determination with regard to the specific issue(s) identified in the reconsideration request. Requesters may not seek review of the reconsideration decision.

From: b6
Sent: Friday, September 17, 2021 8:25 AM
To: HRSA HSB CICP <CICP@hrsa.gov>
Subject: Update for Case # b6

Good day

I am requesting a status update for Case # b6

It is for me, b6

I recently mailed you a full set of pertinent medical records. My UPS tracking shows that it was received by CICP on September 7th.

You have now had a full 7 business days to review my package.

Can you respond answering the following questions I have:

* Please confirm you have received all of my medical records.

* Please confirm that you do not need anything else from me to review my case at this time

* When do you estimate you will determine if I am eligible for benefits or not? Please advise - as I have incurred significant damages, and would like to be compensated sooner rather than later.

Thank you

b6