<[redacted]@hms.harvard.edu>, [redacted]
<[redacted]@niaid.nih.gov>, [redacted]@cdc.gov, [redacted]@cdc.gov, [redacted]
[redacted] <[redacted]@stanford.edu>

Hi Dr Marks,
I have been told multiple times that someone will contact me from the FDA, CDC and Pfizer, but I have never been contacted. I hope your colleague will actually contact me. Multiple people have reached out to me now from as far away as France who have also suffered severe neurological reactions to the vaccine. The common thread is paresthesias and an internal tremor/ vibration. Many have motor weakness as well. Like me, these people have been unable to find medical care as doctors in the community and universities have not heard about these reactions. Most of these patients are being referred to psychiatrists.
On top of being severely injured from the vaccines, it is a disgrace that our illnesses are not being validated and we cannot find doctors to help us, as the medical community has been kept in the dark. It is time that these reactions be made public and the medical community be educated. When will this happen?
I research the internet daily and all that I come up with is that there are no significant serious reactions to the vaccines and that any such reports cannot be clearly linked to the vaccines. This is absolutely not true!
How unfair this is to patients like me and the many others out there suffering.

Sincerely,
Danice Hertz MD [redacted]

On Mar 6, 2021, at 12:58 PM, [redacted]
<[redacted]@fda.hhs.gov> wrote: Dear Dr. Hertz,
This message is in response to your inquiry submitted to Dr. Peter Marks, director of FDA's Center for Biologics Evaluation and Research.

I hope that this message finds you doing well, and that your health is improving.
In your email you mention that you have reported the potential adverse events that you experienced to the manufacturer. If you haven't already done so, you should consider the submission of a report through the Vaccine Adverse Event Reporting System (VAERS). If you are not familiar, VAERS is a national vaccine safety surveillance program co-sponsored by the FDA and the Centers for Disease Control and Prevention (CDC).
The purpose of VAERS is to detect possible signals of adverse events (possible side effects) associated with vaccines. VAERS collects and analyzes information from reports of adverse events that occur after the administration of licensed vaccines - or those authorized for use. VAERS encourages the reporting of any significant adverse event occurring after the administration of any vaccine licensed or authorized for use in the U.S. An adverse event can be reported even if it is uncertain or unlikely that the vaccine caused it.
General background related to VAERS is available at: https:// www.fda.gov/vaccines-blood-biologics/vaccine-adverse-events/ va ers-overview https://www.fda.gov/vaccines-blood-biologics/ vaccine-adverse-events/va ccine-adverse-event-reporting-system-vaers-questions-and-answers
There are several options for reporting. You can submit a VAERS report online at: https://vaers.hhs.gov/esub/index.jsp. It is important to point out that sessions time out

after 20 minutes of inactivity and no information is saved if you do not complete the online report within that timeframe.
Information about how to complete a VAERS form can be found at: https:// www.fda.gov/media/76517/download Note: There is a copy of the form included within this link that you can print, fill out manually, and mail in if online reporting is not an option for

you.

In closing, providing COVID-19 resources to consumers and healthcare professionals is a responsibility that FDA takes very seriously.
Each of the three companies that have COVID-19 vaccines authorized for use in the U.S. have submitted pharmacovigilance plans to FDA to monitor the safety of the vaccine that they manufacturer. The pharmacovigilance plans include a plan to complete longer-term safety follow-up for participants enrolled in ongoing clinical trials. The pharmacovigilance plans also include other activities aimed at monitoring the safety profile of the vaccine that they manufacturer - and ensuring that any safety concerns are identified and evaluated in a timely manner.

Responsibility for additional post-authorization vaccine safety monitoring will be shared primarily by FDA and the CDC, along with other agencies involved in healthcare delivery. Post-authorization safety monitoring during the COVID-19 pandemic vaccination program will aim to continuously monitor the safety of COVID-19 vaccines to rapidly detect safety problems if they exist. There will be multiple, complementary systems in place with validated analytic methods that can rapidly detect signals for possible vaccine safety problems. The U.S. government has a well-established post- authorization/post-approval vaccine safety monitoring infrastructure that will be scaled up to meet the needs of a large-scale COVID-19 vaccination program. The U.S. government – in partnership with health systems, academic centers, and private sector partners – will use multiple existing vaccine safety monitoring systems to monitor COVID-19 vaccines in the post-authorization/approval period. Some of these systems are VAERS, the Vaccine Safety Datalink (VSD), the Biologics Effectiveness and Safety (BEST) Initiative, and Medicare claims data.

I have reached out to colleagues familiar with FDA’s efforts in this

area to determine if they are aware of signals similar to the events that you have described in your email. Please feel free to reach out to me directly with any questions that you may have. Kind regards,

[redacted], Consumer Affairs Branch
Center for Biologics Evaluation and Research Office of Communication,
Outreach and Development U.S. Food and Drug Administration
Tel: [redacted]
[redacted]@fda.hhs.gov
This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.

3-6-21 my response my email to [redacted] email dated 3-6-21

Re: Adverse neurological reactions to COVID mRNA vaccines
To: "[redacted]" <[redacted]@fda.hhs.gov> Cc: Peter.Marks@fda.hhs.gov Hello,
Yes I have filed 6 reports to VAERS as well as multiple reports to Pfizer, the FDA and CDC. In addition to written reports. I have filed verbal reports to all of these agencies. There has been absolutely no response. I wonder if any of my reports are registered or acknowledged. I have been very ill for 10 weeks starting 30 minutes after receiving the Pfizer Covid vaccine. Initially, I thought I would not survive. I have consulted with Dr. [redacted] and his associates at the NIH who believe I have a sensory polyneuropathy in response to the vaccine. He believes it is the same syndrome that covid longhaulers develop. His group has many other patients like me. I am relieved to have found doctors who know what is going on and can help me. I have gathered a

group of people with similar reactions who have also reported their reactions many times with no response. They too have been unable to find doctors aware of these reactions to help them. Several of them are physicians. It has been a very difficult experience for all of us.
I understand the importance of getting the population vaccinated, but being so injured and not being able to get validation and medical care has made this experience very difficult. Transparency is essential.

Thank you for your recommendation to contact VAERS. Unfortunately this is not helpful as it has already been done. Hopefully, you will become aware of the injuries some people are experiencing from the vaccines and educate the medical community so that medical care will be available for people like me.

Thank you,
Danice Hertz MD [redacted] [redacted]

Sent from my iPhone
3-8-21 email from [redacted] from FDA in response to my email of 3-6-21

On Mar 8, 2021, at 6:29 AM, [redacted]
<[redacted]@fda.hhs.gov> wrote: Dear Dr. Hertz,
I am sorry to hear about your experience.

Did you provide your contact information when you submitted your VAERS report? To the best of my knowledge, you will receive a confirmation number electronically - or a VAERS identification number by mail - depending on your method of reporting. This serves as confirmation that your report was received.

It is my understanding that you are contacted by VAERS when/if follow-up information is needed.

VAERS data and individual reports (without personally identifying information) are available to the public on the VAERS and CDC WONDER websites at:

https://vaers.hhs.gov/data.html

https://wonder.cdc.gov/vaers.html

Also, VAERS report forms can be obtained under the Freedom of Information (FOI) Act, with patient and reporter identifying information redacted.

You can request information about adverse events reported to VAERS by faxing requests to (301) 443-1726, or by sending requests to:

Food and Drug Administration Freedom of Information Staff
(HFI-35) 5600 Fishers Lane
Rockville, MD 20857

Additionally, If you have your VAERS identification number, you can access a copy of your report at the CDC VAERS WONDER website. For help getting your report, contact VAERS at (800) 822-7967 or info@vaers.org. If you want information beyond what's available on CDC WONDER, it is possible that this is available through a FOIA request.

To the best of my knowledge, healthcare professionals can request a clinical consultation for particularly complex individual patient cases by contacting the CDC's Clinical Immunization Safety Assessment (CISA) Project. To request a COVID-19 CISA clinical consultation, visit:

https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/cisa/index.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccinesafety%2Factivities%2F CISA.html

Best regards,

[redacted], Consumer Affairs Branch

Center for Biologics Evaluation and Research
Office of Communication, Outreach and Development U.S. Food and Drug Administration
Tel: [redacted]
[redacted]@fda.hhs.gov

This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not

[redacted]

necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.

Sent from my iPhone

3-8-21 my email to [redacted] from FDA in response to his email of 3-8-21 **From:** Danice Hertz <[redacted]>
Date: March 8, 2021 at 1:14:59 PM PST
To: "[redacted]" <[redacted]@fda.hhs.gov>

Cc: Peter.Marks@fda.hhs.gov, [redacted]@cdc.gov
Subject: Re: [EXTERNAL] Re: Adverse neurological reactions to COVID mRNA vaccines

Yes, of course I provided my contact information and have all of the report confirmations, copies of my reports and VAERS ID numbers for the 6 reports I filed. I am fully aware of the many 100's of reports of similar reactions in the VAERS database. The same is true for the 11 people in my group with similar severe reactions. We and our physicians have requested CDC CISA

consults which have been completely unhelpful. I would think the FDA and CDC would want to know about these reactions. We have all been seriously ill. It is truly shocking that our reports have not been taken seriously and that the FDA is not asking for follow up from us. There is apparently no concern about people being injured by the vaccines.
The suggestions you make in both of your emails to me are nonsensical. I am a physician, not a moron. You skirt the issue that there are many of us that have been injured by the vaccines and are being ignored. Your emails are insulting and demeaning. You are completely missing my point. I guess that is just representative of how seriously you are taking the fact that there are many people being severely injured by the Covid vaccines and are struggling to get validation and medical care because these reactions are being hidden from the medical community. This is truly shocking. Having practiced medicine for 33 years, I always had faith in our regulatory agencies. Now, having been seriously injured by this vaccine and struggling to be taken seriously and get medical assistance, I no longer have faith.

Danice Hertz M.D.

[redacted]

[redacted]
Sent from my iPhone

3-17-21 email to Peter Marks MD at FDA, [redacted] at FDA, [redacted] at CDC, [redacted] at PFizer, [redacted] MD at NIH and other important doctors. **From:** Danice Hertz <[redacted]>
Sent: Wednesday, March 17, 2021 6:14:53 PM

To: [redacted] <[redacted]@stanford.edu>; [redacted] Md <[redacted]@hms.harvard.edu>; [redacted] (NIH/