From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Date: On Sep 16, 2021, at 2:01 PM,
To: Bri Dressen [redacted]
Cc: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, "Richards, Paul" <Paul.Richards@fda.hhs.gov>, "McNeill, Lorrie" <Lorrie.McNeill@fda.hhs.gov>, "Frantz-Bohn, Susan" <Susan.Frantzbohn@fda.hhs.gov>

Dear Ms. Dressen,

Thank you for reaching out again. As you know, I was unable to join your meeting with FDA on August 23, 2021 because of urgent matters related to the ongoing pandemic. Lorrie McNeill, a senior leader at CBER, who met with you carefully listened to the information on individual experiences after vaccination with the COVID-19 vaccine and shared that information with me and our other subject matter experts who are involved in our vaccine safety surveillance activities. I am so sorry to hear of the serious medical issues you are experiencing and the tremendous impact this has had on your life.

We have met with our colleagues at NIH, and they may be better positioned to conduct the type of clinical research and to offer recommendations for treatment that you and others who have experienced these events seek. FDA is not able to provide medical advice or guidance and does not have a role in active clinical research about treatment of adverse events.

The Vaccine Adverse Event Reporting System (VAERS) has not identified any potential safety signal for the adverse experiences you provided both in your letter and at the meeting. At this point in time, FDA physicians have found that the adverse events reported following COVID-19 vaccination have been consistent with what was found during the clinical trials and is stated in the Fact Sheets for Vaccine Recipients and Health Care Providers.

FDA diligently and carefully reviews reports submitted to VAERS to identify potential signals that would indicate the need for further study. Extremely rare adverse events have been identified using VAERS and FDA has communicated that information to the public and health care providers. One example is from April 2021, when FDA and CDC physicians initially identified six serious adverse event reports (including 3 deaths) of thrombosis with thrombocytopenia syndrome (TTS) out of 6.8 million individuals that had been vaccinated with the Janssen COVID-19 vaccine.

I understand that this may not be the response you'd hoped for. Please know that we take our vaccine safety surveillance responsibilities very seriously. We

will continue to carefully evaluate all serious reports of adverse events following COVID-19 vaccination and are committed to transparency about any findings.

My sincerest hope that things improve for you,

Peter Marks

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-----Original Message-----
From: Bri Dressen [redacted]
Date: September 16, 2021 at 8:08:59 PM MDT
To: "Marks, Peter" <Peter.Marks@fda.hhs.gov>
Cc: "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, "Richards, Paul" <Paul.Richards@fda.hhs.gov>, "McNeill, Lorrie" <Lorrie.McNeill@fda.hhs.gov>, "Frantz-Bohn, Susan" <Susan.Frantzbohn@fda.hhs.gov>
Subject: Re: [EXTERNAL] Follow-Up

Dr Marks,

I am unsure I am understanding your message correctly. Just so I have a better understanding, before I go to the NIH, would you mind giving me a call?

We have gone above and beyond to provide insight where the safety signals may be failing to show this this reaction. We are looking for some sort of literal lifeline…that lifeline really should not be people being quietly ushered into the NIH for help, months into their suffering. The NIH has also told me and others that they are not taking in any more cases. There are way too many of us, and only a small team there.
Unless there is some arrangement or setup that the agencies are working on that I am unaware of…we are totally on our own.

But more importantly, those who are in the acute phase should be met with appropriate medical care locally, when early intervention has been indicated as key.

I am perplexed by the example of an extremely rare adverse event being recognized by 6 cases (3 fatal), as we met with your team as 6 cases with serious adverse reactions representing thousands, including fatalities (I myself have over 5000 Americans in my group, there is one other with another 3000..just in my small sphere).

Obviously my energy is extremely limited, and I have no idea how to navigate this complicated system.

I cannot stress to you how dire the situation is for these people. There is a reason for these emails, we are not being helped. I keep trying to tell myself there are good people who will be willing to examine this, who will believe that our lives matter. However as time goes by I am repeatedly met with the dark reality that awaits those like us, who are being failed by a system that was designed specific for those of us who experience AEs. Instead of a safety net, we are met with a big gaping hole.

When can we discuss?
-Brianne
[redacted]

[redacted]