



-----Original Message-----

From: Brianne Dessen [REDACTED]
Date: January 9, 2022 at 9:58:05 PM MST

To: "Marks, Peter" <Peter.Marks@fda.hhs.gov>

Cc: Lorrie McNeill <lorrie.mcneill@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, "Richards, Paul" <Paul.Richards@fda.hhs.gov>, Joel Wallskog [REDACTED]

Subject: Followup Jan 4th Meeting

Dr Marks,

I appreciate you taking the time to meet with us last week. Below, find the contact for a few researchers examining the persistent symptoms following the Covid vaccines. Along with a brief description of the area of focus.

1) Dysautonomia -

As we mentioned in the call last week, there likely are issues with identifying this syndrome if only looking through VAERS or similarly reported databases.

1- even in typical circumstances dysautonomia is grossly under diagnosed

2- Dysautonomia is not diagnosed in ERs or ICUs, this is found through autonomic specialty labs. Hospital settings are far more likely to file VAERS reports than an autonomic specialist, which take months to get into, and dx many months after the onset of the vaccination injury.

So, it would be reasonable to approach autonomic specialists / long covid specialists about their observations.

S*** - Autonomic Neurology Lab**

Dr. ****

S***** says this is a conversation for their entire department to discuss with you. They have one MD who is working on getting a vax trial setup now.

The vax injured connection with S***** is a woman named Jarfa Wabbs. S***** is also a patient of theirs.

2) Neuropathy -

****Please review with your data team:** Historically, neuropathy presents in the predominantly male population aged 59+. However as discussed previous, neuropathy in our case is predominantly female, aged 29-40. I am curious if the reporting databases would bring up this signal if it isn't queried by straight population numbers, but rather gender or age.

Neuropathy is likely to be inadequately reported through the VAERS and BEST systems because of the circumstances previously mentioned for dysautonomia.

W*****

Small Fiber Neuropathy Case Report: ****

He is expanding this for a review of 100 participants with neuropathy, post covid vaccine. His initial findings lead him to realize the strong potential tie.

Injured connection is Janean Rundo and me, Brianne Dressen.

3) Tinnitus -

Our findings are that this is not just J&J... not by a long shot. This symptom is more proportionate to the general neuro symptoms by brand as previously reported in our patient led survey of 500 participants. This is more likely to be reported appropriately. However, many suffering neuro problems will not list this as a symptom (e.g., in my case yes, I have tinnitus now and it was a freight train in my head for the first four months. I didn't report because it was not high on my list of complaints, I had way too many other problems going on that were concerning for my quality of life.)

B*****

He has been conducting research for most of last year on tinnitus after the covid vaccines. I suspect it may be in peer review process now.

Injured connection is Shaun Barcovage, NP.

Mayo Clinic

Vaccine researcher and vaccine reaction sufferer

Co-Authored a case series with *****

Injured connections, Shaun Barcovage and Brianne Dressen.

4) Immunology

Dr *****

Like the researchers above, this long-hauler researcher found these post-vax symptoms mirror Covid PASC. So much so that their same testing and methods to identify abnormalities in the immune cells of long-haulers, has also worked for us as well. Not only are the post vax injured group coming back with the same issues in our immune cells as the long haulers (spike protein in the monocytes, the control group has none), but it is in much higher levels than long-haulers.

(With the high level of resources, focus and funds allotted to long-haulers research and collaboration, and the many similarities between PASC and post Covid vaccine injury, it would make sense to encourage exploration of these similarities. It would lead to clues and eventual healing for both groups.)

They also have potentially identified that the proper inflammatory response that should engage when vaccinated, does not engage in the typical fashion in those suffering problems after the vaccines. In some cases, the pro-inflammatory markers don't increase at all.

The long-hauler portion of their study has been accepted by "Frontiers in Immunology". Their subsequent paper using the same methods with the post vaccine injured cohort is going through peer review now, data is collected and analyzed.

<https://www.frontiersin.org/articles/10.3389/fimmu.2021.746021/full>

Dr *****

Running several studies on long-haulers and the post vax groups. Identifying issues with MCAS in both groups. MCAS has turned out to be another common issue with the post-vaccine group.

Other Topics to Note:

MIS-A, MIS-C, MIS-V

This is quickly emerging as a concerning issue for our injured MDs and scientists tracking these reports. Please refer to the attached document. I know our injured MDs alerted this issue to Dr Woodcock earlier this month.

5) Myocarditis and Clots

Side note on myocarditis and clotting currently acknowledged by the FDA and CDC. Every person in our groups that have one of these two conditions, also have similar neuro issues as those of us who are not currently acknowledged by the FDA and CDC. Namely POTS, brain fog/memory loss, and inflammation (MCAS). Even the perfectly healthy very fit young males with the lasting myocarditis are struggling with the POTS and inflammation/brain fog/memory loss. Makes me suspect that somehow these all are a result of the same mechanism of action.

6) Parasthesias

Added to the package insert for Pfizer in the EU. We request the US follow suit. (but with all brands) doctors are much more receptive to recognize this side effect if it is communicated through the proper channels.

7) Correlation vs Causation

While we understand that correlation does not equal causation, we also find a strong correlation with the change in our blood that mirrors long-haul, and symptomology that mirrors long-haul.

Because of this, I have to ask what is the process by which Covid PASC symptoms have been so readily tied back to Covid, whereas the same symptoms due to the Covid vaccines have not?

Also, while it may be coincidental to have one or maybe two strange symptoms pop up, is it reasonable to dismiss 10, 15, 20, new symptoms that occur in a single person post vaccine. Then for this same pattern to ensue in tens of thousands of others?

Correlation may not immediately tie to causation, but correlation must lead to investigation. Single event is correlation, multiples become much more than that.

In conclusion, I appreciate your time and look forward to hearing from you soon.

Attached, find our latest collection of peer-reviewed case reports/research articles about Covid vaccine reactions. This collection has about 850 reports, which provides many more potential contacts for you with those who are/have looked into these issues.

Regards,
Brianne Dressen

[REDACTED]

-----Original Message-----

From: "Marks, Peter" <Peter.Marks@fda.hhs.gov>

Date: January 10, 2022 at 5:52:00 AM MST

To: Brianne Dressen [REDACTED]

Cc: "McNeill, Lorrie" <Lorrie.McNeill@fda.hhs.gov>, "Woodcock, Janet" <Janet.Woodcock@fda.hhs.gov>, "Richards, Paul" <Paul.Richards@fda.hhs.gov>, Joel Wallskog [REDACTED]

Subject: RE: [EXTERNAL] Followup Jan 4th Meeting

Dear Ms. Dressen,

Thanks so much for all of this information. We really appreciate this and will start working through the papers and contacting investigators to better understand things.

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
240-402-8116 voice
301-595-1310 fax
Peter.Marks@fda.hhs.gov

[REDACTED]