

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

From: **Bri Dessen** [REDACTED]
Date: Mon, Feb 7, 2022 at 8:37 AM
Subject: Re: [EXTERNAL] Followup Jan 4th Meeting
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Richards, Paul <Paul.Richards@fda.hhs.gov>

Good morning Dr Marks.
I hope you are staying safe and healthy through this surge.

We had discussed a month ago just meeting with me and your team, to make the best use of the limited time and to allow us to just get down to business...go through some of these questions to see where we can help fill in the gaps. We have some new research that would be relevant for this topic of neurological complications as well.

We really just want to see these people get on the path to healing.

Can we get a time scheduled on your and your team's calendar?

Best,
Brienne Dessen

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

From: **Marks, Peter** <Peter.Marks@fda.hhs.gov>
Date: Thu, Feb 10, 2022 at 12:40 PM
Subject: RE: [EXTERNAL] Followup Jan 4th Meeting
To: Bri Dessen [REDACTED]
Cc: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>, Richards, Paul <Paul.Richards@fda.hhs.gov>

Dear Ms. Dessen,

Thanks for your message. We have been continuing to work through the concerns that you and others have brought to our attention, and are happy to update you. The next few weeks are very challenging on the calendar, but I will ask Lorrie to help us find time for a follow up meeting at the end of February or in early March.

Best Regards,
Peter

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

On Mon, Feb 14, 2022 at 9:01 AM McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov> wrote:
Good morning, Ms. Dressen –

I will look for some potential dates/times and be back in touch.

Best regards –

Lorrie

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

From: Brianne Dressen [REDACTED]
Sent: Tuesday, February 15, 2022 2:25 PM
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>;
Richards, Paul <Paul.Richards@fda.hhs.gov>
Subject: Re: [EXTERNAL] Followup Jan 4th Meeting

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Thank you Lorrie.

Dr Marks and Dr Woodcock,

While we wait for a meeting to be scheduled, please note the published report/analysis below RE: MIS (also a proposed agenda item from the email below). This is a time-sensitive issue as it is related to teens and children, which warrants review by your team before our scheduled meeting time.

A recent early online release in the archives of pathology and laboratory medicine, <https://meridian.allenpress.com/aplm/article/doi/10.5858/arpa.2021-0435-SA/477788/Autopsy-Histopathologic-Cardiac-Findings-in-Two> details the postmortem pathology results from two adolescents who died shortly after Pfizer COVID vaccination due to myocarditis. The authors describe very specific differences in the vaccine caused myocardial cases versus traditional myocarditis. They note that the post vaccine reaction may be mediated by the same immune mechanisms behind COVID MIS-C.

As you know, MIS causes tissue damage and often death or morbidity.

MIS-A presentation includes fever, hypotension, cardiac dysfunction, shortness of breath, abdominal pain, neurological symptoms and diarrhea.

Very similar symptoms are often seen in the neurological vaccine injuries we have been discussing, however the lack of guidance for appropriate medical eval and workup is leaving these individuals without proper diagnosis and worse, direction for treatment.

Early detection and treatment greatly improves outcomes with MIS (A, C, V) which is a critical step to save lives and prevent permanent damage.

Several case reports have described MIS-V or MIS following vaccination, as we have passed along previously, and will list here:

Multisystem inflammatory syndrome in an adult following Pfizer (MIS-V): <https://pubmed.ncbi.nlm.nih.gov/34326117/>

Multisystem inflammatory syndrome in a 12yo male following Pfizer: <https://pubmed.ncbi.nlm.nih.gov/34978781/>

Multisystem inflammatory Syndrome in a 12 year old boy after Pfizer: <https://pubmed.ncbi.nlm.nih.gov/34955518/>

MIS in a 12yoM following Pfizer: <https://pubmed.ncbi.nlm.nih.gov/35062704/>

MIS-C in a 17yoM after his second dose of Pfizer: <https://pubmed.ncbi.nlm.nih.gov/34617315/>

Multisystem Inflammation in a 20yoM following Pfizer: <https://pubmed.ncbi.nlm.nih.gov/34765984/>

MIS-A in a 21yoF following Moderna vaccination which was given 27 days after COVID infection: <https://pubmed.ncbi.nlm.nih.gov/34954311/>

Fatal Multisystem inflammatory syndrome after 2nd dose of Pfizer in a 30yo: <https://pubmed.ncbi.nlm.nih.gov/34586059/>

MIS-A in a 37yoF 10 days post 2nd Moderna COVID vaccine and 1 month from COVID infection: <https://pubmed.ncbi.nlm.nih.gov/34868588/>

Multisystem inflammatory syndrome in children by covid-19 vaccination of adolescents in France: <https://pubmed.ncbi.nlm.nih.gov/34928295/>

Multisystem inflammatory syndrome in a COVID-19 vaccinated adolescent female with sickle cell disease: <https://pubmed.ncbi.nlm.nih.gov/34955521/>

3 cases of Multisystem Inflammatory Syndrome after Pfizer: <https://pubmed.ncbi.nlm.nih.gov/34034858/>
CDC Review of MIS: <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab936/6445178?searchresult=1>

Orthopedic surgeon dies of MIS-A after vaccination: <https://www.wjhl.com/news/regional/tennessee/memphis-surgeon-dies-of-covid-related-illness-weeks-after-receiving-second-covid-vaccine/>

Multisystem inflammatory syndrome in an adult following AstraZeneca: <https://pubmed.ncbi.nlm.nih.gov/34811978/>

Postvaccination MIS in an adult with no evidence of prior COVID-19 infection following AstraZeneca: <https://pubmed.ncbi.nlm.nih.gov/34852213/>

MIS-A in an adult woman 18 days following AstraZeneca vaccination: <https://pubmed.ncbi.nlm.nih.gov/34511054/>

Autoantibody release in children after COVID mRNA vaccination: A risk factor of multisystem inflammatory syndrome? <https://pubmed.ncbi.nlm.nih.gov/34835284/>

Multisystem inflammatory syndrome following COVID-19 vaccination: ignored and underdiagnosed: <https://pubmed.ncbi.nlm.nih.gov/34940858/>

We just had two more kids pop up with this yesterday, and another 6 year old hospitalized since dec 10th with medical teams refusing to look into the peer-reviewed published literature and conduct necessary testing/evaluation. These kids did their part, and are long overdue for those in trusted authoritative positions like the FDA to do their part on behalf of these kids. It is a truly helpless situation they are enduring, but it doesn't need to be that way.

I am happy to discuss at your earliest convenience with you or your team.
-Brianne

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

From: **Woodcock, Janet** <Janet.Woodcock@fda.hhs.gov>
Date: Tue, Feb 15, 2022 at 1:38 PM
Subject: RE: [EXTERNAL] Followup Jan 4th Meeting
To: Brianne Dressen <briandressen@gmail.com>

Thank you for sharing this pre-print. Janet Woodcock

