Aaron Siri

From: Aaron Siri
Sent: Monday, November 1, 2021 12:11 PM
To: sean.mccluskie@hhs.gov; aux7@cdc.gov; ayv6@cdc.gov; janet.woodcock@fda.hhs.gov; peter.marks@fda.hhs.gov
Cc: Elizabeth Brehm; Gabrielle Palmer; McNeill, Lorrie
Subject: RE: [EXTERNAL] Physician Accounts of Severe Covid-19 Vaccine Injuries & Request for Assistance

Good afternoon Mr. Becerra, Dr. Walensky, Dr. Woodcock, Dr. Marks, and Dr. Shimabukuro,

We are in receipt of Ms. McNeill's email below regarding the physicians whose serious injuries from Covid-19 vaccines have not been addressed by your agencies. Your response continues to make clear you have no intention of taking their concerns seriously. They detail in their sworn declarations that they *have* submitted the serious injuries they and their patients have suffered to VAERS but have received no adequate response. Yet, Ms. McNeill's advice to these injured physicians, many of whom can no longer work because of your Covid-19 vaccine, is to submit (apparently again) the serious harms they suffered to VAERS?!

You may find it uncomfortable and irritating to deal with Americans, including physicians, who are complaining that the product you are promoting has injured them, but where else are they to turn? You have closed off all other avenues of redress and placed the entire responsibility for vaccine safety on your own shoulders.

In the normal course, these harms would be addressed by suing the companies that produce these products – but you have removed all liability for these companies for any injuries from these products. (https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx.) You have even removed the right of Americans to sue these companies for willful misconduct unless you first agree to bring such a claim. (42 U.S.C. § 247d-6d(c)(5).) If that were not bad enough, you have even eliminated the right to informed consent by propelling coercive measures that will result in Americans being excluded from work, school, military, and civil society unless they submit to receiving your Covid-19 vaccine products. Coercion is the antithesis of consent.

Meaning, Americans cannot sue for harms, they cannot say no to receiving the product, and when they are injured, their only recourse is to turn to you, but yet you are not interested in hearing their complaints. These physicians are making a reasonable request. They are not on the whole seeking to end your vaccination program, remove liability on the manufacturers, nor even end your coercive mandates – they are simply asking that treatments be developed to address the serious injuries from the products that you have promoted and for which you have made yourselves solely responsible. The first step in developing treatment is acknowledging these injuries. Instead, your tone deaf and incredible response is for them to (apparently again) submit VAERS reports.

We will forward Ms. McNeill's response below to these physicians, which will only add insult to their injury. Your response and conduct here, with little doubt, will do multi-fold more to fuel vaccine hesitancy than all of the combined false claims about your products currently floating around the internet.

As a postscript, for reasons already addressed many times, VAERS and VSD are being utilized to confirm your biases about the products you promote. You repeatedly state that VAERS *cannot* confirm a *safety issue* yet simultaneously and incredibly claim it *can* confirm *safety*. The VSD's data, which you will not permit the public to access despite it being deidentified, are used to support the policies you have already implemented – a simple review of VSD studies makes that plain – and what bias could that introduce? If you were truly confident in the safety of these products and the data evidencing same, you would make the data within the VSD available to the public forthwith.

Best regards,

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Monday, November 1, 2021 5:44 AM
To: Aaron Siri <aaron@sirillp.com>
Subject: RE: [EXTERNAL] Physician Accounts of Severe Covid-19 Vaccine Injuries & Request for Assistance

Dear Mr. Siri,

This is in follow up to your recent correspondence with Dr. Janet Woodcock, Acting Commissioner of Food and Drugs, and Dr. Peter Marks, Director of FDA's Center for Biologics Evaluation and Research (CBER), as well as other HHS officials. You have sent many emails and communications to Drs. Woodcock and Marks concerning the safety of COVID-19 vaccines and other topics related to COVID-19 and vaccination.

FDA is committed to ensuring the safety of the products we regulate. FDA has been considering data on the safety and efficacy of vaccines that could potentially be authorized for children ages 5-11. In addition, our agency has been conducting and will continue to conduct rigorous active and passive safety surveillance on the FDA-authorized COVID-19 vaccines to ensure that we detect any safety signals of concern, and if we confirm any safety issues, please be assured that we will share the information with the public as rapidly as possible. We also have comprehensive postmarketing surveillance and risk assessment programs for other products we regulate. The purpose of these programs is to identify adverse events that did not appear during the approval or review process. FDA actively monitors reports of adverse events and may use this information to update labeling, and, if appropriate, to reevaluate the approval or marketing decision.

We also note that we are evaluating your requests, but our agency experts have significant demands on their time due to the public health emergency. In addition, in the future if you are aware of vaccine injuries we recommend you report them to VAERS.

We would appreciate it if you would direct future correspondence to my office at ocod@fda.hhs.gov. Please note that any correspondence directed to Dr. Woodcock and Dr. Marks will also be forwarded to this account. While you may not receive replies from Dr. Woodcock, Dr. Marks or other HHS officials to your emails, others in FDA will review any information you wish to provide to the agency and evaluate as appropriate. We have limited resources to respond to the many varied inquiries we receive each day, but our surveillance programs are robust and we take seriously any and all information regarding the safety of COVID-19 vaccines and other products that we regulate.

Best regards,

Lorrie

Lorrie H. McNeill
Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov

From: Aaron Siri <aaron@sirillp.com>
Sent: Wednesday, October 27, 2021 7:03 PM
To: Mccluskie, Sean E (OS) <Sean.Mccluskie@hhs.gov>; Walensky, Rochelle P (CDC) <aux7@cdc.gov>; Shimabukuro, Tom (CDC) <ayv6@cdc.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] Physician Accounts of Severe Covid-19 Vaccine Injuries & Request for Assistance

Dear Mr. Becerra, Dr. Walensky, Dr. Woodcock, Dr. Marks, and Dr. Shimabukuro,

Please find attached a letter which demands your immediate attention.

Best regards,
Aaron

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