# Siri | Glimstad

NEW YORK | LOS ANGELES | MIAMI PHOENIX | DETROIT | DENVER | AUSTIN

200 Park Avenue, 17th Floor, New York, NY 10166 sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

### SENT VIA EMAIL

Mr. Xavier Becerra Secretary U.S. Department of Health & Human Services 200 Independence Ave., S.W. Washington, D.C. 20201 c/o Sean McCluskie sean.mccluskie@hhs.gov Dr. Rochelle P. Walensky Director Dr. Tom Shimabukuro, Deputy Director COVID-19 Vaccine Task Force, Centers for Disease Control & Prevention 1600 Clifton Road Atlanta, GA 30329 aux7@cdc.gov ayv6@cdc.gov October 27, 2021

Dr. Janet Woodcock Interim Commissioner Dr. Peter Marks Director, Center for Biologics Evaluation and Research Food & Drug Administration 10903 New Hampshire Ave. Silver Spring, MD 20993 janet.woodcock@fda.hhs.gov peter.marks@fda.hhs.gov

Re: Physician Whistleblower Accounts of Severe Covid-19 Vaccine Injuries

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

We write with the utmost urgency on behalf of physicians from across this country -- see the 11 declarations attached -- whose firsthand reports of serious and fatal injuries from COVID-19 vaccines to your public health agencies have not been taken seriously and remain unaddressed.

#### A. Injuries from Covid-19 Vaccines

The harms they have been reporting are not redness at the injection site. The harms are all serious. As detailed in the appended declarations signed by these physicians, they include serious cases of:

small fiber neuropathy; loss of temperature sensation in extremities; constant shakiness to muscles; lesion on spinal cord; paresthesias; tachycardia; fatigue; heat intolerance; gastric paresis; joint pain; subjective fevers; paresthesias; brain fog; tremors; twitching; internal vibrations; tinnitus; blurred vision; dizziness and imbalance; headaches; balance difficulties; burning sensations; menstrual cycle irregularities; hair loss; bladder incontinence; cognitive impairment; persistent numbness and tingling in hands; constipation; irritability; weakness

Each of these harms has been confirmed, based on the clinical judgment of the patient's treating physician, as being caused by a Covid-19 vaccine.

These physicians and their patients all supported the Covid-19 vaccine. Almost all of them are fully vaccinated. It is understandable that you would not want to admit that a product you have authorized, approved, and widely promoted caused harm, but we implore you to have the moral fortitude to rise above your personal interests.

These physicians stand to lose an incredible amount coming forward – their income, jobs, careers, privacy, etc. But they do so to put the interest of the public and of their patients ahead of their own. We ask you to do the same.

To avoid future harms from this vaccine and to heal the doctors' patients, and in some cases to heal themselves, research is critically needed to understand how the Covid-19 vaccine is causing these harms. Understanding same is the first step in developing effective treatments for these harms, many of which are novel and otherwise unresponsive to conventional treatments. Physicians in this group have been pleading with your agencies for months to conduct this research. Instead, their concerns have been treated as a public relations issue, not a health issue.

You tell the public to trust their doctors. If individuals have concerns about the vaccine, you tell them: "speak with your doctor." These very doctors are telling you there is a serious problem. They have been telling you that for months in myriad correspondences with your agencies. It should not be that you only listen to doctors if they parrot your preferred messaging regarding Covid-19 vaccines. To the contrary, they should *especially* be listened to when their clinical experience directly opposes that messaging.

These doctors, like most doctors, are the last individuals that want to admit that a Covid-19 vaccine caused their patient's or their own injuries. And they are the last to want to publicly make such an admission. Truly. But reality does not afford them these luxuries. The injuries they report are all too real.

These devastating injuries are detailed in the attached and, as noted, each has been confirmed, based on the clinical judgment of the patient's treating physician, as being caused by a Covid-19 vaccine. It is statistically improbable that any one physician should see numerous serious Covid-19 vaccine injuries if the safety claims regarding this vaccine were true. Yet, in just the appended declarations, there are 4 physicians that have collectively treated more than 18 patients with a serious Covid-19 vaccine injury.

It also should not be that a physician should have to "risk it all" to advocate for themselves or their patients. These physicians rightly fear retaliation by your agencies and the medical establishment by coming forward. This toxic environment is the result of your zealous promotion, including through the press and social media, of these vaccines and denigration of those – and especially any health care professional – who question your conclusions or guidance regarding these products. Because of this fear of retaliation, a number of the physicians requested to keep their identities confidential. We have verified each of their identities by directly communicating with each over videoconference, verifying their medical license numbers and their national provider identifiers, and cross-referencing the foregoing with publicly available sources.

#### **B.** Dire Need for Your Agencies to Address These Injuries

It is time to stop ignoring these physicians who are but the brave few willing to step forward. These physicians, when reaching out to your agencies for the last 10 months, seeking to address these harms physician-to-physician, genuinely believed your agencies would want to learn about their harms, address them immediately, and to seek to develop treatments for their and their patients' debilitating conditions. They have sadly come to realize their assumptions were false.

Even worse, your agencies have dismissed concerns raised by many of these physicians by stating that the harms they are reporting are not being detected in VAERS. But dismissing these harms based on VAERS is entirely inappropriate.

As you are aware, an AHRQ-funded study by Harvard Medical School of 715,000 patients tracked reporting to VAERS over a three-year period at Harvard Pilgrim Health Care. It concluded that "fewer than 1% of vaccine adverse events are reported."<sup>1</sup>

This disturbingly low rate is confirmed by the rate at which anaphylaxis after COVID-19 vaccine is reported to VAERS. The CDC Director claims that "Anaphylaxis after COVID-19 vaccination is **rare** and occurred in approximately **2 to 5 people per million** vaccinated in the United States based on events reported to VAERS."<sup>2</sup> That claim is contradicted by a recent study at Mass General Brigham that assessed anaphylaxis in a clinical setting after the administration of COVID-19 vaccines and found "severe reactions consistent with anaphylaxis occurred at a rate of **2.47 per 10,000 vaccinations**."<sup>3</sup> This is equivalent to 50 to 120 times more cases than what VAERS and the CDC are reporting.

The underreporting of anaphylaxis by the CDC and VAERS is particularly troubling because it is mandatory for medical providers to report anaphylaxis after any COVID-19 vaccine to VAERS,<sup>4</sup> most of these reactions occur within 30 minutes of vaccination,<sup>5</sup> and there has been an intense campaign by health authorities to inform medical providers that they need to report anaphylaxis after COVID-19 vaccination to VAERS. Nonetheless, the rate of reporting still appears to be only around 0.8 to 2 percent of all cases of anaphylaxis.

This raises serious concerns regarding the underreporting of adverse events following COVID-19 vaccination to VAERS, especially for adverse events that do not occur immediately after vaccination and where health care providers have not been specifically directed to report such adverse events to VAERS. Yet you dismiss all of the injuries complained of by the doctors in the appended declarations because you have not seen a signal for same in VAERS.

<sup>&</sup>lt;sup>1</sup> <u>https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf</u>. *See also* a U.S. House Report similarly stated: "Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events." <u>https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf</u>.

<sup>&</sup>lt;sup>2</sup> <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html</u>

<sup>&</sup>lt;sup>3</sup> <u>https://jamanetwork.com/journals/jama/fullarticle/2777417</u>

<sup>&</sup>lt;sup>4</sup> See, e.g., <u>https://www.fda.gov/media/144413/download</u>.

<sup>&</sup>lt;sup>5</sup> See <u>https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html;</u> see also <u>https://jamanetwork.com/journals/jama/fullarticle/2777417</u> (mean time to reaction is 17 minutes post-vaccination).

## C. Steps Needed to Address These Injuries

Given your conduct to date and the passage of over 10 months without addressing their harms in any concrete manner, we hereby write on their behalf to demand the following:

1. Confirm that, for purposes of addressing the harms detailed by these physicians, you will presume these injures have been factually and accurately represented in the appended letter unless you have documentary evidence to the contrary.

2. Agree to meet with the physicians described herein within 14 days with a multidisciplinary team of experts from NIH and FDA with the purpose of discussing and devising the research needed to uncover the mechanism of injury for these harms and the steps necessary to discover effective treatments. The disciplinary team should include, at the least, leading experts in the fields of internal medicine, neurology, allergy/immunology, immunotoxicology, neurobiology, vaccinology, rheumatology, epidemiology, biostatistics, hematology, dermatology, gastroenterology, nephrology, ophthalmology, otolaryngology, gynecology, and cardiology.

3. Agree to allocate 1% of all funding that HHS and its agencies have with regard to Covid-19 toward identifying the mechanisms of injury from Covid-19 vaccines and preventing and treating such injuries. This results in 99% of Covid-19 funding being allocated toward preventing and addressing harms from Covid-19 disease and 1% of funding being allocated toward preventing and addressing harm from Covid-19 vaccines. This allocation is more than reasonable given the intent and drive by HHS to vaccinate every individual in the United States, and that those injured by Covid-19 vaccination are at least as worthy of protection and help as those injured by Covid-19 disease.

Please confirm that you will fulfill your duties as public servants and meet these exceedingly reasonable requests. If we do not receive such confirmation in writing on or before noon on November 1, 2021 to the foregoing, we intend to take all available legal action including pursuant to, *inter alia*, 5 U.S.C. § 553; 5 U.S.C. § 706, 21 C.F.R. § 10.30 and, more importantly, an appeal to the American people to force political change on this issue.

Very truly yours,

- 1

Aaron Siri, Esq. Elizabeth A. Brehm, Esq.