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May 19, 2021

VIA EMAIL AND FEDEX

Dr. Rochelle P. Walensky
Director, Centers for Disease Control and Prevention
Royal Bldg. 21, Rm 12000
1600 Clifton Road
Atlanta, GA 30333
Aux7@cdc.gov

Dear Doctor Walensky:

We previously wrote on behalf of Informed Consent Action Network ("ICAN") on March 17, 2021 with a serious concern regarding anaphylaxis, specifically, and underreporting to VAERS, generally.[1] Sandra Cashman, MS Executive Secretary responded on your behalf on March 22, 2021 stating: "Thank you for your letter on behalf of the Informed Consent Action Network and your interest in anaphylaxis associated with COVID-19 vaccine administration. Please see the latest information on the COVID-19 response at https://www.cdc.gov/COVID-19/." This response does not address the issue raised.

If the CDC does not address the concern and explain how its current estimates regarding anaphylaxis are accurate,[2] it will be in breach of its obligations under the National Childhood Vaccine Injury Act of 1986 Act and the Information Quality Act, both of which provide the CDC with the obligation to provide accurate information. If the agency does not provide a substantive response, we will be filing a formal petition.

Very truly yours,

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

Cc: Marion.Gruber@fda.hhs.gov

[1] ICAN's letter of March 17, 2021 is appended hereto.

[2] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html ("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.").

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March 17, 2021

VIA EMAIL AND FEDEX

Dr. Rochelle P. Walensky
Director, Centers for Disease Control and Prevention
Royal Bldg. 21, Rm 12000
1600 Clifton Road
Atlanta, GA 30333
Aux7@cdc.gov

Dear Doctor Walensky:

We previously wrote on behalf of Informed Consent Action Network ("ICAN") with regard to deficiencies in the VAERS system. We write again on ICAN's behalf regarding another alarming report which brings into focus ICAN's previously expressed concerns.

According to the CDC, "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." https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html. This is in stark contrast to 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." https://jamanetwork.com/journals/jama/fullarticle/2777417. This is equivalent to 50 times 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. *See, e.g.*, https://www.fda.gov/media/144413/download. In addition, the CDC reports that most of these reactions occur within 30 minutes of vaccination. *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html *see also* https://jamanetwork.com/journals/jama/fullarticle/2777417 (mean time to reaction is 17 minutes post-vaccination). Vaccine administrators, then, should be aware of a majority, if not all, of these cases as recipients are being observed for 15 to 30-minute periods at vaccination sites. Additionally, with regard to COVID-19 vaccines, there has actually been a push by health authorities to inform medical providers that they need to report anaphylaxis 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 (i) under-reporting of other serious adverse events following COVID-19 vaccination, and (2) adverse events following other vaccines for which there

has not been the same push to report adverse events. The anaphylaxis study highlights the urgency of the ongoing, well-known problem with adverse event reporting post-vaccination.

Unless and until this is addressed, underreporting to a passive signal detection system will continue to blind health agencies, medical professionals, and patients from what is really occurring in the clinic and will render true informed consent impossible.

Kind Regards,

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

Cc: Marion.Gruber@fda.hhs.gov