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VIA EMAIL AND FEDEX

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HHS Office of the Secretary
Secretary, Health & Human Services
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Washington, D.C. 20201
c/o Sean McCluskie
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Rochelle P. Walensky
Director, Centers for Disease Control and Prevention
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Janet Woodcock, M.D. Interim Commissioner,
Food and Drug Administration
10903 New Hampshire Avenue
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Re: *Underreporting to VAERS*

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

We have previously written to you on our client's behalf about underreporting to VAERS. We have been asked to write again due to additional concerning information.

We previously pointed out how an AHRQ-funded study by Harvard Medical School tracked reporting to VAERS over a three-year period at Harvard Pilgrim Health Care involving 715,000 patients and found that "fewer than 1% of vaccine adverse events are reported."[1] 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."[2]

We further reported to you about anaphylaxis cases and reporting of same after COVID-19 vaccine which is seriously concerning. As previously explained, 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."[3] 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

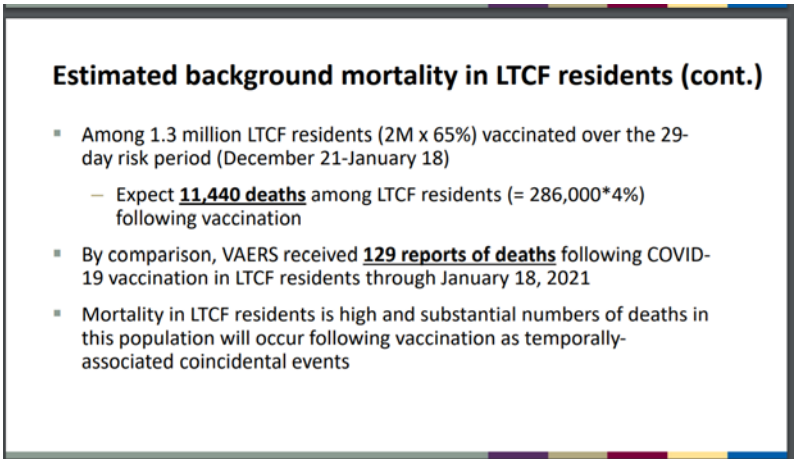
[1] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.

[2] https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.

anaphylaxis occurred at a rate of 2.47 per 10,000 vaccinations."[4] This is equivalent to 50 times to 120 times more cases than what VAERS and the CDC are reporting for a condition that occurs almost immediately after vaccination and which vaccine providers are repeatedly advised to report.

An ACIP meeting again brought into clear focus this incredible level of under reporting for even cases of death. During the January 27, 2021 meeting, Tom Shimabukuro of the CDC's COVID-19 Vaccine Safety Task Force, Vaccine Safety Team, explained that it was expected that 11,440 deaths from long term care facilities ("**LTCF**") would be reported to VAERS given the number of deaths that would naturally occur during the period directly after COVID-19 vaccination in these facilities:[5]



Instead, VAERS only received 129 reports of deaths following COVID-19 vaccination in LTCF (or 1.1%). This again reflects the serious under reporting to VAERS, even for deaths, and is consistent with the study cited above. This is especially troubling since the need to report to VAERS for deaths after COVID-19 has been repeatedly reiterated to vaccination providers and is required by law.[6]

If anaphylaxis and death are being underreported, consider the level of underreporting for serious adverse events that do not occur immediately after vaccination or are not easily identified. This should seriously concern HHS, CDC, and FDA but, given the response to our previous letters addressing this topic, it does not appear there is any concern. There are serious safety signals that are likely being missed and for the ones that are identified, such as anaphylaxis or CVST in conjunction with thrombocytopenia, the actual rate seen in VAERS may be only the

[4] https://jamanetwork.com/journals/jama/fullarticle/2777417.

[5] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf.

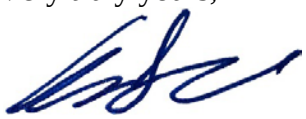
[6] *See the* Fact Sheet for Healthcare Providers Administering Vaccine for each of the three authorized vaccines available at https://www.fda.gov/media/144413/download; https://www.fda.gov/media/144637/download; and https://www.fda.gov/media/146304/download ("The vaccination provider is responsible for mandatory reporting of the following to the Vaccine Adverse Event Reporting System (VAERS): … • serious adverse events* (irrespective of attribution to vaccination)… • cases of COVID-19 that result in hospitalization or death.").

tip of the iceberg. Ignoring and casting aside these issues in the drive to vaccinate and promote vaccine confidence may eventually be the undoing of the very confidence you seek to instill.

As explained before, unless and until underreporting to VAERS 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. With the drive to vaccinate every single American with COVID-19 vaccines, the safety of all Americans, literally, depends on this broken system. Fix it.

The first step to fix it is, at the least, to automate hospital and clinical medical records to automatically send VAERS reports for all clinically significant events occurring within a window of time after vaccination. This already exists for other purposes. It can be done for vaccines as well, which is clear from the CDC's own publications on this topic and pages 31 to 34 of our client's letter exchange with HHS on this issue available here: https://icandecide.org/hhs/vaccines-safety-12-31-18.pdf.

Very truly yours,



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