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VIA EMAIL AND FEDEX

Mr. Alex Azar
Secretary, HHS
U.S. Department of Health & Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201
Alex.Azar@hhs.gov

Re: *Mandated Reportable Events for COVID-19 Vaccines Authorized or Licensed in the United States Pursuant to 42 U.S.C. § 300aa-25*

Dear Secretary Azar:

We write on behalf of our client, Informed Consent Action Network ("**ICAN**"), to make an important request regarding safety surveillance of any COVID-19 vaccine which is, or will be, authorized or licensed for use in the United States.

Pursuant to 42 U.S.C. § 300aa-25, as Secretary of Health and Human Services, you have the authority to require health care providers and vaccine manufacturers to report adverse reactions, events, and contraindications following the receipt of a vaccine to the Vaccine Adverse Events Reporting System ("**VAERS**") – a system co-administered by the Centers for Disease Control & Prevention ("**CDC**") and the Food and Drug Administration ("**FDA**").[1]

ICAN therefore requests that you immediately make it mandatory that *all adverse events* following a COVID-19 vaccination, with the exception of mild events, be reported by vaccine manufacturers and all health care providers to VAERS.

Currently, only a very limited number of adverse events must be reported pursuant to 42 U.S.C. § 300aa-25, namely shoulder injuries or fainting within seven days of receiving the vaccine or any serious issue resulting from such shoulder injury or fainting.[2] The Pfizer emergency use authorization does require that health care providers report a limited list of serious adverse events, however this list is not exhaustive and would not capture all adverse events including, for example,

[1] *See* 42 U.S.C. § 300aa-25(b).

[2] *See* 42 U.S.C. § 300aa-25(b) and https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf.

Bell's Palsy, nor is there any indication the requirement to report such events will apply once licensure is granted for this vaccine.[3]

Both the CDC and the FDA have acknowledged the need for comprehensive safety surveillance as the nation implements the widespread administration of COVID-19 vaccinations. Tom Shimabukuro (Captain, U.S. Public Health Service Vaccine Safety, Team Lead of COVID-19 Response for the Centers for Disease Control and Prevention) recently presented at the Clinician Outreach and Communication Activity Webinar, held on December 14, 2020, about the importance of safety surveillance: "Clinical trials used to authorize or license vaccines for use - may not detect all types of adverse events, especially ones that are rare or take longer to occur (delayed onset) and - don't always look at special populations (e.g., pregnant women and people with certain pre-existing medical conditions)."[4]

The FDA has also acknowledged that "[f]ollowing authorization of the vaccine, use in large numbers of individuals may reveal additional, potentially less frequent and/or more serious adverse events not detected in the trial safety population of approximately 30,000 participants over the period of follow-up at this time."[5] The FDA has stated, then, that "[a]ctive and passive safety surveillance will continue during the post-authorization period to detect new safety signals."[6] Safety surveillance must therefore be undertaken as thoroughly as possible.

The need for long-term safety tracking of all adverse events (other than mild local or systemic reactions) is also critical. The Moderna vaccine trial protocol calls for monitoring of certain adverse events through the duration of the study (759 days) and the Pfizer vaccine trial protocol calls for monitoring for only 6 months post-second dose. Neither of these is an appropriate time-period to capture potential serious long-term adverse events including cancer or any neurological, cardiovascular, or autoimmune diseases. Additionally, the unblinding and/or cross-over (either blinded or open label) which both Pfizer and Moderna are currently planning obviate the comparator placebo group, creating yet another concern.

Compounding this problem is the well and long-known fact that VAERS suffers from significant inadequacies. This passive system collects a drastically low percentage of actual adverse events that occur, with one study funded by the Federal government finding that only 1% of vaccine adverse events are reported to VAERS.[7] Many health care professionals do not report to VAERS because they are not mandated to do so, they do not know what adverse events to look for or to connect to a vaccination, or because there is no routine follow-up with doctor or patient after an adverse event is reported. Until these very serious issues are corrected, reporting of any and all adverse events (with the exception of mild local and systemic reactions) must be required in an attempt to identify any signals or causal relationships missed in the limited clinical trials for COVID-19 vaccines.

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[3] https://www.fda.gov/media/144413/download.

[4] https://emergency.cdc.gov/coca/calls/2020/callinfo_121420.asp.

[5] https://www.fda.gov/media/144434/download at 50.

[6] *Id*.

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

In the absence of any liability on the part of the manufacturers and vaccine administrators, the American public must be confident that safety surveillance is the highest priority with these vaccines. For this and the other reasons above, detailed and thorough mandates regarding adverse event reporting must be put into place.

Requiring that health care providers and vaccine manufacturers report *all* adverse events, other than mild reactions, following receipt of a COVID-19 vaccine is critical to assuring that any safety issues with these products are captured and addressed. This minimal level of safety surveillance of these innovative and novel vaccines is critical to increase confidence with the American public that decisions pertaining to any coronavirus vaccine are made with a sound, independent scientific basis, with people's safety at the forefront. We ask that you respond to ICAN's request and address the serious issue identified above forthwith in order to avoid erosion of confidence in the HHS, Operation Warp Speed, and vaccine programs generally.

Very truly yours,

Aaron Siri, Esq.
Elizabeth Brehm, Esq.