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VIA EMAIL AND FEDEX

February 17, 2021

Norris Cochran
Acting Secretary, Health and Human Services
200 Independence Avenue S.W.
Room 503H-3
Washington, D.C., 20201
Norris.Cochran@hhs.gov

Dr. Rochelle P. Walensky
Director, Centers for Disease Control and
Prevention
1600 Clifton Road, Building 21, Rm12000
Atlanta, GA 30333
Aux7@cdc.gov

Re: *COVID-19 Vaccine Safety Tracking – V-SAFE and VAERS*

Dear Mr. Cochran and Dr. Walensky:

Congratulations to each of you on your recent roles and appointments to HHS and CDC, respectively. We write on behalf of Informed Consent Action Network (“ICAN”) with regards to the V-safe program currently being utilized in the rollout of the COVID-19 vaccines.

As you know, the existing reporting system created pursuant to 42 U.S.C. §300aa-25 is the Vaccine Adverse Events Reporting System (“VAERS”). ICAN seeks confirmation that any adverse events reported to V-safe by vaccine recipients are being automatically included in the VAERS database so that VAERS may be as robust and effective as possible. If that is not occurring, ICAN requests that this change be made immediately as this lack of submission of data will render VAERS, which already suffers numerous shortfalls, even less effective by spreading data across two separate systems.

We understand from a September 22, 2020 ACIP presentation that V-safe users may receive a follow-up telephone call if a “clinically important” adverse event is reported. Then, following that call, the event may be submitted to VAERS “if appropriate.” This is inadequate. We respectfully submit that, because VAERS is a signal detection system, *all* adverse events submitted via V-safe be submitted to VAERS. In order to detect a signal, VAERS needs as much data regarding adverse events as possible, otherwise, a signal or signals could potentially be missed. As these vaccines are novel vaccine platforms and are being administered on a large scale,

the need for broad and complete data is crucial in order to increase transparency and elevate vaccine confidence. We hope you both agree.

Very truly yours,

A handwritten signature in blue ink, appearing to read 'ASiri', written in a cursive style.

Aaron Siri, Esq.

Elizabeth A. Brehm, Esq.