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VIA FEDEX AND EMAIL
June 6, 2023

Robert M. Califf, MD
Commissioner, Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Commissioner@fda.hhs.gov

Re: Removal of Reports from the Vaccine Adverse Events Reporting System

Dear Commissioner Califf,

We write on behalf of Informed Consent Action Network ("**ICAN**") regarding the recent removal of 1,102 reports from the Vaccine Adverse Event Reporting System ("**VAERS**"). Included in the removed VAERS reports were **225 reported deaths, 16 life-threatening events, 51 additional ER visits, and 108 hospitalizations**.[1] ICAN respectfully requests an explanation as to why these records were removed.

A majority of these records, **784 out of the 1,102 reports**, involved Janssen's COVID-19 vaccine, which recently had its Emergency Use Authorization revoked by the FDA.[2] To be clear, post-marketing safety monitoring should not end when a vaccine's emergency authorization is revoked. Removing a product from the market does not remove the harm that product caused while authorized. This is particularly concerning when it comes to vaccines that have never received full FDA approval, hence, whose full data the public does not have access to, and while thousands of Americans continue to suffer from debilitating injuries following the receipt of these products.

VAERS is one of the only systems available to assess the safety of vaccines, especially those still under emergency use authorization. The removal of reports degrades the integrity of the system and its data and only deepens the American people's distrust of their health agencies. Accordingly, please restore the missing reports to VAERS and explain the removal.

Sincerely,

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

[1] *See* Attachments.

[2] *See* https://www.fda.gov/vaccines-blood-biologics/coronavirus-covid-19-cber-regulated-biologics/janssen-covid-19-vaccine.