

January 11, 2023

## VIA EMAIL AND FEDERAL EXPRESS

Robert M. Califf, MD  
Commissioner, Food and Drug Administration  
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Silver Spring, MD 20993-0002  
[commissioner@fda.hhs.gov](mailto:commissioner@fda.hhs.gov)

Rochelle P. Walensky, MD, MPH  
Director, Centers for Disease Control and  
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Roybal Bldg. 21, Rm 12000  
1600 Clifton Road  
Atlanta, GA 30333  
[Aux7@cdc.gov](mailto:Aux7@cdc.gov)

Re: *Explanations Sought Regarding Omission and Deletion of Certain Vaccine Adverse Event Reporting System Data*

Dear Commissioner Califf and Dr. Walensky:

On behalf of the Informed Consent Action Network (“ICAN”), we write regarding the omission and deletion of certain Vaccine Adverse Event Reporting System (“VAERS”) data. Prompt agency action, as detailed below, to address this issue is urgently needed.

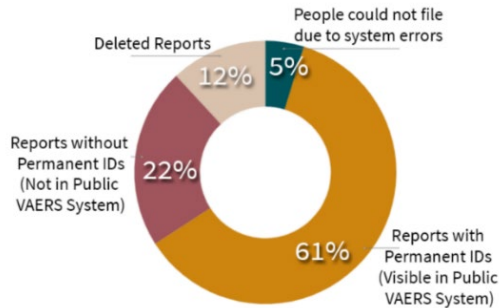
### **I. INDEPENDENT ANALYSIS REVEALS FREQUENT OMISSION AND DELETION OF VAERS REPORTS**

React19, a patient advocacy organization representing more than 20,000 COVID vaccine-injured individuals, reviewed a randomly gathered sampling of 126 VAERS report numbers filed by 103 unique COVID vaccine-injured individuals. React19’s audit was prompted by concerns raised by its members that they: (a) never received permanent VAERS report identification numbers; (b) could not locate their VAERS reports post-submission on the website; and/or (c) their VAERS reports were altered, merged with previous reports, or otherwise deleted entirely.<sup>1</sup>

Of the 126 total VAERS reports analyzed, 22% were not in the public VAERS system, 12% were deleted, and 5% featured technical difficulties, rendering the individuals unable to file his or her respective report. These findings are represented in the following graph:

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<sup>1</sup> React19, VAERS Audit (Dec. 3, 2022), <https://react19.org/vaers-audit/>.



Notably, of the 15 deleted reports, 53% were reports of permanent disability and 27% were hospitalizations/emergency room visits. Of the 79 publicly visible reports, only 23% were reports of permanent disability.

React19 also analyzed cases of death reports not actually listed as death reports on the public facing records; in one case, when an individual sought to have the system updated to reflect a death, this individual was advised that amended data are not publicly facing.

All in all, the audit concluded that “1 in 3 reports are either not processed through the system for the public to review due to lack of assignment of a permanent ID and/or deletion after original publication.”<sup>2</sup>

This is problematic for many reasons as highlighted in the audit. In particular, the missing data highlights a lack of transparency on the part of the FDA and CDC. VAERS is the primary post-marketing surveillance system utilized to assess vaccine safety, and the public and the vaccine injured alike deserve to have access to this information.

## II. ACTION REQUEST

We respectfully request a response to the following and that corrective action be taken to correct these concerns forthwith:

1. Explain why these reports of serious injury are withheld from the public VAERS database.
2. Make public what percent of reports submitted to VAERS are not public facing and why are they not public facing.
3. Explain why amended/updated reports are not published in the public facing database.

Very truly yours,

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

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<sup>2</sup> *Id.*