

May 22, 2024

VIA EMAIL AND FEDEX

Members, Vaccines and Related Biological
Products Advisory Committee
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 71
Silver Spring, MD 20993-0002
VRBPAC@fda.hhs.gov
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Re: June 5, 2024, VRBPAC Committee Meeting – Discussion of and Recommendations for the Selection of Strain(s) to be Included in the 2024-2025 Formula for COVID-19 Vaccines

Dear VRBPAC Members:

We write on behalf of our client, Informed Consent Action Network (“ICAN”), regarding VRBPAC’s continued futile efforts to respond to the rapidly changing COVID-19 viral mutations with vaccines that are (among other issues) antiquated before they are even released. ICAN asks that VRBPAC address the following serious issues with COVID-19 vaccines at the June 2024 meeting before even considering the selection of a 2024-2025 strain selection.

The SARS-CoV-2 virus continues to mutate at an extraordinary rate. The Omicron KP.2 variant, which was reported to comprise approximately 1% of the SARS-CoV-2 spectrum as of March 16, 2024, had increased to 25% by April 27, 2024—in less than six weeks’ time. Conversely, the Omicron JN.1 variant declined from 67.1% dominance over that same period, to just 22%.¹

This dramatic shift in variants underscores the futility of attempting to create variant-matched COVID-19 vaccines, which inevitably results in a never-ending parade of vaccines that are (among other issues) obsolete by the time they are administered to the public. Compounding this is the indisputable fact that, for the vast majority of the population, COVID-19 is now indistinguishable from the common cold.

The aggressive push to vaccinate all Americans over the age of 6 months with a product that has proven to have substantial risks is especially concerning due to the increasing revelations of harms.² An objective review of all available evidence reflects that FDA and CDC cannot claim the benefits of these products outweigh the risks.

¹ See CDC Nowcast variant tracker, available at <https://covid.cdc.gov/covid-data-tracker/#variant-proportions>.

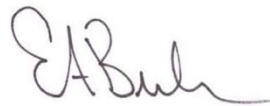
² See [COVID-19 vaccines and adverse events of special interest: A multinational Global Vaccine Data Network \(GVDN\) cohort study of 99 million vaccinated individuals - ScienceDirect](#).

Nowhere is this more clear than within the V-safe data that ICAN obtained from CDC and made public. Once revealed, the risk of the vaccines became patently obvious, as per the following:

- V-safe's original data release ³ showed that of 10,108,273 users, 3,353,110 (~32%) either needed to seek medical care, could not attend work or school, or could not perform daily activities following vaccination. Approximately 7.7% (782,913) of users reported having to seek medical care after receipt of a COVID-19 vaccine at least once. Within that 7.7%, more than 70% sought outpatient/urgent clinical care, emergency room care, and/or were hospitalized.
- While 782,913 users reported having to receive medical care at least once, there were 2,108,022 total reports of receiving medical care, which means that on average each person seeking medical care did so at least two to three times following COVID-19 vaccination. Another **25%** reported being unable to perform normal activities and/or missing school or work.
- A large portion of V-safe data includes free-text entries which contain information input by users that did not fit into any of the "check-the-box" categories. That data has only started to be released and already contains thousands of reports of chest pains, heart palpitations, and/or shortness of breath (the three top symptoms of myocarditis), more than 1,000 reports of ear ringing or tinnitus, hundreds of reports of menstrual disturbances, approximately 54 reports of miscarriage following vaccination, and much more. ⁴ Furthermore, the above represents only a fraction (approx. 390,000 out of 7.8 million) of the free-text entries in CDC's possession.

If VRBPAC does not consider, address, and debate the above points at its June meeting, before it even considers a vote on strain selection for a 2024-2025 formula for COVID-19 vaccines, it will further erode its already highly diminished level of public trust and perceived credibility. Indeed, one need look no further than the current uptake of the most recent COVID-19 vaccine despite the FDA and CDC's multi-billion-dollar campaign to promote same.

Very truly yours,



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³ See *V-safe Dashboard* <https://icandecide.org/v-safe-data/>.

⁴ See *V-safe Free-text Data* <https://icandecide.org/v-safe-data/>.