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VIA EMAIL AND FEDEX

Amanda Cohn, M.D.
Centers for Disease Control and Prevention
1600 Clifton Rd NE MS A-19
Atlanta, GA 30329-4018
Email: acohn@cdc.gov

Re: Janssen COVID-19 Vaccine

Dear Dr. Cohn:

We write on behalf of the Informed Consent Action Network ("**ICAN**") to bring to your attention critical and timely additional information regarding CVST and other concerns regarding the Janssen COVID-19 vaccine

I. CVST

There may be additional cases of Cerebral Venous Sinus Thrombosis ("**CVST**"), some of which have also been accompanied by thrombocytopenia, that have not been reported to Janssen Pharmaceuticals or to the Vaccine Adverse Events Reporting System ("**VAERS**"). The reporting of anaphylaxis after receipt of the COVID-19 vaccine is instructive.

According to the CDC, "Anaphylaxis after COVID-19 vaccination is **rare** and occurred in approximately 2 to 5 people per million vaccinated in the United States based on events reported to VAERS."[1] In contrast, a recent study at Mass General Brigham assessed anaphylaxis after COVID-19 vaccines in a clinical setting and found "severe reactions consistent with anaphylaxis occurred at a rate of 2.47 per 10,000 vaccinations."[2] This is equivalent to 50 times to 120 times more cases of anaphylaxis than what VAERS and the CDC are reporting.

The underreporting of anaphylaxis by the CDC and VAERS is particularly troubling because: (i) it is *mandatory* for medical providers to report anaphylaxis after any COVID-19

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html.

[2] https://jamanetwork.com/journals/jama/fullarticle/2777417.

vaccine to VAERS[3] and health authorities have done extensive outreach to advise health providers of this requirement; and (ii) vaccine administrators are supposed to observe recipients for 15 to 30-minutes after vaccination and anaphylaxis typically occurs within 30 minutes of vaccination.[4] Nonetheless, it appears only around 0.8 to 2 percent of all cases of anaphylaxis are reported.[5]

This raises serious concerns regarding under-reporting of CVST, other clotting issues, and thrombocytopenia following receipt of the Janssen COVID-19 vaccine.

II. Other Serious Events Following Janssen's Vaccine

We understand that the combination of CVST and thrombocytopenia is extraordinarily difficult to ignore because it virtually does not happen – an outstanding observation that left virtually no doubt that it was caused by the vaccine. On the other hand, cardiac, immune-mediated, and neurological events, among others, that may occur from the Janssen vaccine are signals that may be easily missed or dismissed because they get buried with existing cases from other causes.

In that regard, Janssen's COVID-19 vaccine has a multi-fold higher rate of reported adverse events than the two other authorized COVID-19 vaccines. Since distribution of the Janssen vaccine began on March 1, VAERS has received a total of **6,615 reports** of adverse events for this vaccine as compared to **440 reports** for Moderna's and **323 reports** for Pfizer's.[6]

This raises the serious concern that Janssen's vaccine is less safe than the other COVID-19 vaccines for reasons beyond reports of CVST.[7]

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As you are well aware, vaccine hesitancy has been increasing in this country. The number of individuals who distrust the guidance from our public health authorities, including your

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

[4] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html *see also* https://jamanetwork.com/journals/jama/fullarticle/2777417 (mean time to reaction is 17 minutes post-vaccination).

[5] That VAERS may only capture a tiny fraction of adverse events is consistent with a Harvard Pilgrim Study, funded by AHRQ, which stated that VAERS captures "fewer than 1% of vaccine adverse events." https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf.

[6] https://wonder.cdc.gov/vaers.html.

[7] It is also worth noting that while the CDC asserts that "genetic material delivered by the viral vector does not integrate into a person's DNA" (https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/viralvector.html), researchers at the Department of Microbiology, Immunology & Molecular Genetics, UCLA School of Medicine explain that "studies have shown that replication-incompetent adenoviral vectors randomly integrate into host chromosomes at frequencies of 0.001-1% of infected cells." (https://pubmed.ncbi.nlm.nih.gov/12109211/). ICAN has twice asked Dr. Rochelle P. Walensky to explain this discrepancy and has twice received responses that fail to refute these studies.

committee, is growing. A vote that does anything other than withdraw the recommendation for this vaccine will no doubt increase vaccine hesitancy and exacerbate the mistrust that already exists.

A vote to permit the continued use of a vaccine that has killed at least one individual when there are two other vaccines available – neither of which this committee or the FDA have asserted present this same risk – will be viewed as a decision made for interests other than what is best for the public and will raise serious ethical and legal concerns.

These concerns are compounded by the fact that a voting member of your committee with whom you have deliberated, regularly interacted, and are influenced by, consciously and unconsciously, is the principal investigator paid by Janssen to conduct the clinical trial for its COVID-19 vaccine at St. Louis University.

ICAN remains dedicated to ensuring safety and transparency for the American public regarding COVID-19 vaccines. Each of the above concerns, individually and together, warrants your immediate and careful consideration and attention. If ICAN can provide any additional information or assist the committee in any other manner, please let us know.

Very truly yours,

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