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VIA ELECTRONIC FILING

March 3, 2021

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Commissioner Stephen M. Hahn, M.D.
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: *Citizen Petition and Petition for Administrative Stay of Action (Docket Number: FDA-2020-P-1770)*

Dear Commissioner Hahn,

Attached is a reply to the FDA's December 11, 2020 response to ICAN's Citizen Petition and petition for administrative stay of action regarding the clinical trial of BNT162b, a vaccine to prevent the novel coronavirus SARS-CoV-2 (COVID-19).

This demands your careful attention and ICAN looks forward to receiving a timely response. ICAN is available to answer questions and provide any relevant additional information.

Very truly yours,

/s/ Aaron Siri
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Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Commissioner Stephen M. Hahn, M.D.
5630 Fishers Lane
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Rockville, MD 20852

Dear Commissioner Hahn,

We write on behalf of our client Informed Consent Action Network ("ICAN"), in reply to your December 11, 2020 response to ICAN's Amended Citizen Petition and Petitions for Administrative Stay of Action (Docket Number FDA-2020-P-1770) regarding Pfizer's COVID-19 vaccine.

Any and all adverse events and reactions documented for entire duration of the trial

The Petitioner requested that any and all adverse events and reactions to the Pfizer vaccine be documented for the entire duration of the clinical trial. The FDA responded that the collection of certain information "would not necessarily be of value in assessing the safety" of the vaccine and "may actually have negative consequences for the clinical development of the vaccine." Additionally, the FDA categorized some adverse events as "those for which there is little reason to believe that a vaccine caused the event."

Respectfully, with a novel vaccine platform that has never been authorized for use in humans, it is unclear which events may or may not be caused by the vaccine. Petitioner reiterates its request that all adverse events, other than minor, are tracked and documented for the entire duration of the trial. These adverse events should include any and all neurological, cardiovascular, and immunological events, among others. It is unclear from the trial protocol that these would all be considered "serious" adverse events and therefore, they would not be captured for the entirety of the trial and possibly not more than 6 months. Permitting the sponsor conducting the clinical trial to artificially carve out adverse events should be unacceptable to the FDA.

Documentation of adverse events and reactions shall last at least twenty-four months for adults, thirty-six months for children, and sixty months for infants and toddlers

The Petitioner further requested that adverse events be tracked for a duration of at least 24 months for adults, 36 months for children, and 60 months for toddlers. First, the FDA's response only addresses its issuance of an emergency use authorization and does not address requirements for full licensure of the Pfizer vaccine. For full licensure, these time periods for safety review are critical. Second, the response does not address the specific concerns related to toddlers and children: how can it be determined whether the vaccines cause any adverse events years down the road if these populations are not tracked for years?

Similarly, with regard to adults, how will any long-term issues be identified with a novel vaccine platform if they are not tracked for longer than 6 months? The answer is they will not be.

The agency's 2-month median follow-up period "is based on extensive historical experience with vaccines." However, it is clear that this vaccine is a novel vaccine never before used in humans. The mechanism by which this vaccine is meant to prevent or lessen disease is one never before used. Therefore, it is not scientifically appropriate to extrapolate the results of other vaccines' trials or post-marketing experience to these vaccines. There is little to no assurance that what has been seen before with other vaccines is what will be seen with this vaccine. Petitioner reiterates the request for long-term safety tracking in both pediatric and adult populations.

Adequate sample size, appropriately powered

First, Petitioner appreciates the acknowledgement that "all vaccines are associated with some risk." Petitioner is optimistic that the FDA would agree that the clinical trial was not properly powered to pick up one of those risks – anaphylaxis – as a potential serious adverse event. Additionally, the agency's response did not directly address the critical issue with children. It is unclear how pediatric trials will be designed and powered, however it is inadequate to approve studies that are only powered to find, at best, issues that are 1 in 1000, especially for children. Children are not affected by COVID-19 at a far lesser rate than 1 in 1,000, nor are young adults. It is therefore important to understand whether or not they will face a higher risk with the vaccine than with the disease.

* * *

In conclusion, Petitioner reiterates its reasonable requests: all new medical issues that arise should be tracked for sufficient time periods in pediatric and adult populations. All studies, and specifically pediatric studies, must be adequately powered to detect adverse events that happen at

rates less than 1 in 1,000 in an environment where the goal is to vaccinate every one of the millions of individuals in this country.

Very truly yours,

/s/ Aaron Siri
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