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SENT VIA EMAIL

March 12, 2021

Dr. Peter Marks
Director, Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
W071-3128
Silver Spring, MD 20993-0002
Email: Peter.Marks@fda.hhs.gov

Re: *Lipid Nanoparticles in COVID-19 Vaccines*

Dear Dr. Marks:

Thank you for your February 19, 2021 response to our letter of January 5, 2020 sent on behalf of ICAN.

While appreciated, your two-page response fails to address the only question posed in our initial letter: “If LNPs from the vaccine, which contain the mRNA, are entering brain tissue and an immune reaction is occurring during the second dose to these LNPs, does this pose a safety concern to vaccine recipients?”

As you know, the precautionary principle in medicine means that we do not assume that a new treatment/its components are safe until proven safe. The burden is on the FDA to evaluate evidence for safety with regard to the function of every system and organ, not just general toxicity.

In addition to the studies cited in our opening letter, we have been asked to also share a Moderna conducted mouse study that used the intramuscular injection of a different mRNA vaccine prototype with the exact same LNP formulation. See <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5475249/>. This study showed that the brain was not spared from mRNA delivery. Although the amount of the mRNA vaccine in the brain was much lower than in the tissues that were more proximal to the site of injection, the brain is a delicate organ and we do not know that the potential expression of the spike protein on the surface of either neurons or microglia (even if transiently and in lower amounts than in the periphery), would not disrupt some important process or set off a long-term pathological condition in some fraction of the recipients.

Splitting headaches have been reported after the COVID-19 vaccine as well as severe neurological symptoms. We were asked to share the following link with stories of these reactions: <https://prezi.com/i/byzl22mqwfaa/experiences-following-cvv/>. These reactions are different in-kind than from other vaccines. These types of stories have not been posted following influenza

vaccines, for example. New vaccine formulations, including those utilizing LNPs, certainly require more careful attention and hence our client respectfully requests a specific answer to the question posed above.

Very truly yours,

/s/ Aaron Siri

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