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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-1601)*

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 Phase 2 and 3 trials of vaccines 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
Aaron Siri
Elizabeth Brehm
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Division of Dockets Management
Department of Health and Human Services
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Commissioner Stephen M. Hahn, M.D.
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Dear Commissioner Hahn,

We write on behalf of our clients, Del Bigtree and the Informed Consent Action Network ("ICAN"), in reply to your December 11, 2020 response to ICAN's Citizen Petitions and Petitions for Administrative Stay of Action (Docket Number FDA-2020-P-1601).

ICAN finds FDA's response to this petition (and related documents) curious considering that 13 days after ICAN's initial petition was filed demanding placebo-controlled trials, the FDA released a guidance document on June 30, 2020 providing that these trials should include a placebo-controlled arm. ICAN appreciates the FDA's position that a placebo is the appropriate control.

It also hereby requested that the FDA confirm the placebo arm will be maintained through the conclusion of the trial in order to maintain the integrity of the trial and the validity of the safety data produced by the trial.

ICAN will address its requests for adequately powered trials and sufficient tracking of adverse events in its reply to the FDA regarding other Citizen Petitions filed by ICAN.

Very truly yours,

/s/ Aaron Siri
Aaron Siri
Elizabeth Brehm
Jessica Wallace
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