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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
Rm. 1061
Rockville, MD 20852

Dear Commissioner Hahn,

Enclosed is an Amended Petition for Administrative Stay of Action filed by Del Bigtree and the Informed Consent Action Network ("ICAN") regarding clinical trials of vaccines for SARS-CoV-2 which raise exigent concerns that demand your immediate attention.

ICAN looks forward to receiving a timely decision and we, as counsel to the petitioners, remain available to answer questions and provide any relevant additional information.

Very truly yours,

/s/ Aaron Siri
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UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND THE FOOD AND DRUG ADMINISTRATION

AMENDED PETITION FOR STAY OF ACTION TO REQUIRE, *INTER ALIA*, PLACEBO CONTROL GROUP IN CLINICAL TRIALS OF COVID-19 VACCINES	**:**	**Docket No. FDA-2020-P-1601**

ADMINISTRATIVE STAY OF ACTION

The undersigned submits this amended petition under 21 CFR § 10.35 and related and relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request the Commissioner of Food and Drugs (the "**Commissioner**") require that all Phase II and III trials vaccines against the novel coronavirus, SARS-CoV-2 ("**COVID-19**") include, *inter alia*, a placebo (saline injection) control group (i.e., a comparator group).

A. Decision Involved

1. Approval of the Investigational New Drug ("**IND**") Application(s) or any other approval by the FDA which approved a Phase II and/or Phase III trial for ChAdOx1 nCoV-19 with a control group that will receive MenACWY instead of a saline placebo, as well as the approval of any other Phase II or Phase III trial for any COVID-19 vaccine that does not comport with the conditions in Section B below.

B. Action Requested

2. A stay of the approval of the application for any Phase II and III trials of vaccines against COVID-19, including for ChAdOx1 nCoV-19, that do not include a placebo control group (i.e., a placebo comparator group) until:

a. the study design for the trial is amended to include a placebo control group (i.e., a placebo comparator group);

b. the placebo is specified as a saline injection and, if visually distinguishable from the vaccine, both should be packaged in opaque vials;

c. the placebo control group is of at least equivalent size to the experimental group; and

d. all systemic adverse reactions, adverse events, serious adverse events, medically-attended adverse events, new onset medical conditions, and any other health issue arising or exacerbated post-vaccination are to be documented for each subject post-vaccination for a period of at least twelve months for adults, thirty-six months for children and teenagers, and sixty months for infants and toddlers.

C. Statement of Grounds

3. The undersigned hereby incorporates by reference as if fully set forth herein the Statement of Grounds from its Citizen's Petition submitted simultaneously with this request. These incorporated allegations support that: (i) without the requested stay above, the petitioner will suffer irreparable harm, (ii) the requested stay is not frivolous and is being pursued in good faith, (iii) the request demonstrates sound public policy, and (iv) the public interest favors granting a stay.

4. Petitioner will suffer irreparable harm because once the FDA licenses a COVID-19 vaccine, states are expected to make this product mandatory, and hence without the FDA assuring proper safety trials of the vaccine *now*, the petitioner will not have the opportunity to object to receiving the vaccine based on deficient clinical trials *later*. (*Citizen's Petition* ¶¶ 2-8.) Furthermore, if the vaccine is licensed without a placebo control group now, ethical considerations may prevent such a placebo-controlled study post-licensure, thereby preventing any such study from ever occurring. (*Citizen's Petition* ¶ 5.) The request for a stay is not frivolous and is being pursued in good faith as it seeks to increase the scientific integrity and reliability of the trials of any potential COVID vaccine. (*Citizen's Petition* ¶¶ 2-12.) Requiring a placebo control group for the trials of a vaccine where no vaccine exists for the target infection is well supported by the sound public policy detailed in the FDA's own guidance documents. (*Citizen's Petition* ¶¶ 2-7.) Finally, the public interest weighs strongly in favor of the requested relief because using a placebo control (i) will comport with the best scientific practices, (ii) increase public confidence in the safety and efficacy of a product expected to be mandated, and (iii) using a non-inert substance as a control will have the opposite result in that it will create uncertainties regarding the safety of the COVID vaccine. (*Citizen's Petition* 2-12.)

5. The undersigned therefore respectfully urges that the actions requested above be adopted forthwith.

D. Certification

6. I certify that, to the best of my knowledge and belief: (a) this petition includes all information and views upon which the petition relies; (b) this petition includes representative data and/or information known to the petitioner which are unfavorable to the petition; and (c) I have taken reasonable steps to ensure that any representative data and/or information which are unfavorable to the petition were disclosed to me. I further certify that the information upon which I have based the action requested herein first became known to the party on whose behalf this petition is submitted on or about the following date: May 28, 2020. I have not received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Informed Consent Action Network
Del Bigtree, President
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