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VIA ELECTRONIC FILING

July 20, 2020

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 Citizen Petition 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

PETITION FOR ADMINISTRATIVE ACTION TO REQUIRE, *INTER ALIA*, PLACEBO CONTROL GROUP IN CLINICAL TRIALS OF COVID-19 VACCINES	**:**	**Docket No. 2013-S-0610**

AMENDED CITIZEN PETITION

The original petition in this matter was submitted on June 17, 2020. In that petition, the undersigned requested that the Food and Drug Administration (the "**FDA**") require, among other things, that all clinical trials of a COVID-19 vaccine include a control group that receives a placebo. This request was submitted because, among other things, on May 22, 2020, the FDA approved a clinical trial of a COVID-19 vaccine in which the control group would receive a MenACWY vaccine instead of a placebo.[1]

In light of the guidance issued by the FDA on June 30, 2020, titled *Development and Licensure of Vaccines to Prevent COVID-19: Guidance for Industry* (the "**FDA COVID-19 Guidance**"), which provided, *inter alia*, that the control group receive a placebo in all clinical trials for COVID-19 vaccines, the undersigned submits this amended petition.

This amended petition is being submitted pursuant to 21 C.F.R. § 10.30 and related relevant provisions of the Federal Food, Drug, and Cosmetic Act and Public Health Service Act, the Public Health and Welfare at, *inter alia*, 42 U.S.C. § 262(a)(2)(A)-(C) and 42 U.S.C. § 262(j), and 42 U.S.C. § 300aa-10 *et seq.*, to request that the Commissioner of Food and Drugs (the "**Commissioner**") require, *inter alia*, that all Phase II and III trials of vaccines against the novel coronavirus, SARS-CoV-2 ("**COVID-19**") track all adverse events for an adequate period of time.

A. Action Requested

1. For Phase II and Phase III trials of COVID-19 vaccines, it is hereby requested that the Commissioner require any and all adverse events and reactions (including, but not limited to, systemic adverse reactions, adverse events, non-serious adverse event, serious adverse events, medically-attended adverse events, new onset medical conditions, and any other health issue of any degree or type arising or exacerbated post-vaccination, whether suspected, unexpected, expected or otherwise, and whether or not considered related to the vaccine) be documented for the entire duration of the clinical trial.

[1] https://www.clinicaltrials.gov/ct2/history/NCT04400838?V_1=View#StudyPageTop (last visited July 10, 2020).

2. For Phase II and III trials of COVID-19 vaccines, it is hereby requested that the Commissioner require all adverse events and reactions for each subject be tracked post-vaccination for a minimum period of twelve months for adults, thirty-six months for children, and sixty months for infants and toddlers.

3. For Phase III trials of COVID-19 vaccines, it is hereby requested that more specific and appropriate guidance on the number of subjects receiving the vaccine and placebo be provided in the FDA COVID-19 Guidance, and that the updated guidance require at least 20,000 subjects receive the COVID-19 vaccine with a 1:1 randomization between vaccine and placebo groups.

4. In the FDA COVID-19 Guidance, the FDA provided that, "Later phase trials, including efficacy trials, should be randomized, double-blinded, and placebo controlled … with 1:1 randomization between vaccine and placebo groups." The foregoing guidance, which comports with our June 17, 2020 requests, is appreciated but it is hereby requested that the FDA formally adopt this industry guidance, with the necessary flexibility, as formal regulatory requirements.

B. Statement of Grounds

5. The need for adequate clinical trials of any potential COVID-19 vaccine is acute for many reasons, including because: (i) according to the most recent CDC estimates, COVID-19 rarely injures children and younger healthy adults; (ii) overall, 99.74% of those infected with COVID-19 recover;[2] (iii) even without social distancing, it appears that only a minority of those in contact with an infected individual become infected; and (iv) the vaccine will likely be administered to at least hundreds of millions of individuals. If the vaccine, for example, causes .3% of children to develop a chronic health condition a year after injection, that could cause lifelong health issues for millions of children. This is why international scientists have declared that "inadequately powered studies should themselves be considered a breach of ethical standards."[3] Without a clinical trial of sufficient size that reviews all potential adverse events for a sufficient duration, this potentially catastrophic result will not be identified prior to licensure.

6. Moreover, states are expected to mandate the vaccine for all their residents. For example, the New York State Bar Association recently issued a report on COVID-19 recommending that "[w]hen the efficacy of a COVID-19 vaccine has been confirmed, enact legislation requiring vaccination of each person unless the person's physician deems vaccination for his or her patient to be clinically inappropriate."[4] Mandating administration of the vaccine, thereby eliminating the right to informed consent, only makes more acute the need to assure that the safety and efficacy of any COVID-19 vaccine is robustly studied in an adequate clinical trial monitoring for any potential adverse events.

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[2] https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html#box (last visited June 2, 2020).

[3] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504487/ (last visited July 12, 2020).

[4] https://nysba.org/app/uploads/2020/05/HealthLawSectionTaskForceCOVID-19Report_5.13.20-1.pdf (last visited June 2, 2020).

7. Further heightening this need is the fact that the Secretary of the United States Department of Health & Human Services ("**HHS**") has already granted those developing and selling any COVID-19 product broad immunity from liability for injuries.[5]

8. Reflecting the importance of a robust clinical trial, on May 24, 2020, a member of the FDA's Vaccines and Related Biological Products Advisory Committee ("**VRBPAC**"), Dr. Paul Offit, told CNN News that, in order to determine whether a COVID-19 vaccine is safe and effective, "we are waiting for the big trial… the large prospective placebo controlled trial, we have 20,000 people who get a vaccine, 10,000 people who get a placebo, then and only then will you know whether a vaccine is safe and effective."[6]

a. Tracking All Adverse Events During the Clinical Trial

9. To increase assurance that potential adverse events from the candidate COVID-19 vaccines are captured, all adverse events and reactions (including but not limited to: systemic adverse reactions, adverse events, non-serious adverse event, serious adverse events, medically-attended adverse events, new onset medical conditions, and any other health issue of any degree or type arising or exacerbated post-vaccination, whether suspected, unexpected, expected or otherwise, and whether or not considered related to the vaccine) should be documented for each subject post-vaccination, whether or not they are considered vaccine-related by the investigator or sponsor, for the duration of the clinical trial.[7]

10. The adverse events captured beyond a short duration should not be limited to "serious adverse events," since there are many autoimmune, neurological and chronic health disorders which have a major impact on the quality of life, yet are categorized by the FDA as "adverse reactions" and not categorized as "serious adverse reactions."[8] To wit, there are a myriad of post-licensure adverse reactions reported by consumers and physicians and also listed in the package inserts for one or more vaccines, that any individual living with would categorize as "serious"; yet the FDA, under its current guidelines, may not. These include, but are not limited to: alopecia, autoimmune disease, lupus erythematosus, vasculitis, Bell's Palsy, hypotonia, migraine, myelitis, neuropathy, seizures, mental disorders, rhinitis, and vertigo.[9]

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[5] https://www.phe.gov/Preparedness/legal/prepact/Pages/default.aspx (last visited June 2, 2020).

[6] https://www.cnn.com/videos/health/2020/05/24/coronavirus-covid-19-vaccine-trials-vaccinologist-concern-ip-vpx.cnn (emphasis added) (last visited June 2, 2020).

[7] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.32 (last visited July 10, 2020) (defining "Adverse event" as "any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related"); https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event (last visited July 10, 2020).

[8] The FDA defines an adverse event to be "serious" if it results in one of the following specific outcomes: "death, a life threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect." FDA Guidance for Industry and Investigators, https://www.fda.gov/media/79394/download (last visited June 30, 2020).

[9] *See* https://www.fda.gov/biologicsbloodvaccines/vaccines/approvedproducts/ucm093833.htm (last visited June 30, 2020). Also, the determination of whether an adverse reaction is a "serious adverse event"

11. The current FDA COVID-19 Guidance provides that these adverse events should be captured for only 28 days after vaccination while "serious adverse events" should continue to be captured for at least 6 months. As the Principal Deputy Commissioner of the FDA, along with her colleagues at the FDA, wrote with regard to monitoring safety during a clinical trial: "sponsors are expected to monitor all adverse events, including nonserious ones, during drug development."[10]

12. Given that "serious adverse events" are already being captured for 6 months, it appears foolhardy to not also capture all adverse events. If a COVID-19 vaccine causes a systemic autoimmune issue to arise two months after vaccination, it would be irresponsible and unethical not to capture that reaction because it falls into the artificial zone of being an "adverse event" or "non-serious adverse event" rather than a "serious adverse event."

13. The undersigned therefore respectfully urges that the action requested in paragraph 1 above be adopted forthwith.

b. Minimum Period to Track Adverse Events

14. At a minimum, all adverse events and reactions should be documented for each subject post-vaccination for at least: (i) twelve months for adults, (ii) thirty-six months for children, and (iii) sixty months for infants and toddlers. These minimal timeframes provide an opportunity to capture adverse and non-specific health issues that the COVID-19 vaccine may cause.

15. The importance of capturing all potential health issues for a material duration is reflected in the clinical trials of, for example, the drugs Enbrel[11], Lipitor[12], and Botox,[13] which had safety review periods of 6.6 years, 4.8 years and 51 weeks respectively, with a placebo control group. As another example, the weight loss drug Belviq, indicated only for adult use, was safety tested in a placebo-controlled trial for two years before being licensed by the FDA in 2012.[14] In February 2020 the drug was voluntarily removed from the US market at the request of the FDA

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is typically left to the discretion of the sponsor of the clinical trial or the clinical investigators, who are paid by the sponsor, and therefore subject to bias. *See* 21 C.F.R. § 312.32, explaining that an adverse event may be categorized as "serious" if "in the view of either the investigator or sponsor, it results in any of the" listed outcomes.

[10] https://www.nejm.org/doi/pdf/10.1056/NEJMp1103464 (last visited July 12, 2020).

[11] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf (last visited June 2, 2020).

[12] https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf (last visited June 2, 2020).

[13] https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf (last visited June 2, 2020).

[14] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022529lbl.pdf (last visited July 10, 2020).

due to emerging data showing that people who had taken the drug as part of a large clinical trial had an increased occurrence of cancer five years later.[15]

16. The FDA states that the length of study for phase III clinical trials is typically "1 to 4 years"[16] and that the duration of a clinical trial should "reflect the product and target condition."[17] In accord with this guidance, and the fact that a COVID-19 vaccine will be an entirely novel product, the safety review period for adults should be at least 1 year. The need for this minimum safety review period following injection is further supported by the indications that the immunity conferred by a COVID-19 vaccine is expected to last approximately one year or maybe a few years, requiring repeated injections of the product during a person's life.

17. Moreover, taking into account the FDA's guidance that clinical trials should "reflect the product and target condition,"[18] the time frame for the safety review should be longer for minors, and in particular for babies and toddlers, since autoimmune, neurological, and developmental disorders will often not be diagnosed until after babies are at least a few years old.[19] Indeed, a 2019 review, authored by researchers at the FDA and Duke University, reviewed 306 pediatric clinical trials and found that short-term

> pediatric studies may not provide complete safety data across all critical periods of growth and development. This observation may be important because multiple periods of critical pediatric growth and development exist… Although the first 3 years of life are often considered more critical than older ages for brain development, biochemical studies of brain metabolism suggest that high brain metabolic rates characteristic of early childhood may not decline to adult levels until ages 16 to 18 years, suggesting that the school-age and adolescent periods are equally critical periods of brain development. Given this information, even the longest trial duration

[15] https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-withdrawal-weight-loss-drug-belviq-belviq-xr-lorcaserin-market (last visited July 10, 2020); https://www.health.harvard.edu/blog/weight-loss-drug-belviq-recalled-2020040919439 (last visited July 10, 2020).

[16] https://www.fda.gov/patients/drug-development-process/step-3-clinical-research (last visited July 12, 2020).

[17] https://www.fda.gov/media/102332/download (last visited July 12, 2020).

[18] https://www.fda.gov/media/102332/download (last visited July 12, 2020).

[19] For example, according to the CDC, even for a common neurological disorder such as ADHD, "5 years of age was the average age of diagnosis for children reported as having severe ADHD." https://www.cdc.gov/ncbddd/adhd/features/key-findings-adhd72013.html (last visited June 2, 2020). As another example, learning disabilities, a group of common developmental issues, are often "identified once a child is in school." https://www.nichd.nih.gov/health/topics/learning/conditioninfo/diagnosed (last visited June 2, 2020). Even for asthma, a very common autoimmune condition, whose symptoms are obvious, diagnosis can be difficult for children under 5 years of age because lung function tests aren't accurate before 5 years of age and "[s]ometimes a diagnosis can't be made until later, after months or even years of observing symptoms." https://www.mayoclinic.org/diseases-conditions/childhood-asthma/diagnosis-treatment/drc-20351513 (last visited June 2, 2020).

> identified in our study (364 weeks/7 years) does not completely evaluate potential critical stages of all pediatric growth and development periods.[20]

The FDA and Duke authors explained that, compared to licensing a drug for adults, "data on drug efficacy and safety in children may require an additional 6 years."[21] Since children have not been seriously affected by this virus, the risk of any vaccine must be fully understood in order to weigh it against any potential benefit.

18. The undersigned therefore respectfully urges that the action requested in paragraph 2 above be adopted forthwith.

c. Number of Subjects

19. The FDA COVID-19 Guidance provides as follows with regard to the number of subjects needed to assess safety:

> The pre-licensure safety database for preventive vaccines for infectious diseases typically consists of at least 3,000 study participants vaccinated with the dosing regimen intended for licensure. FDA anticipates that adequately powered efficacy trials for COVID-19 vaccines will be of sufficient size to provide an acceptable safety database for each of younger adult and elderly populations, provided that no significant safety concerns arise during clinical development that would warrant further pre-licensure evaluation.

20. A Phase III trial of a COVID-19 vaccine with 3,000 subjects cannot produce an adequate safety profile for a COVID-19 vaccine. SARS-CoV-2 poses a statistically insignificant risk of harm to children and young healthy adults. For this enormous cohort of the American population, the threshold for establishing that the COVID-19 vaccine is safer than the infection is exceedingly high and will require highly powered trials. Even within so-called higher risk groups, the percent of individuals suffering serious health issues from SARS-CoV-2 is statistically small on a population level, which again demands a well-powered trial to assess the safety of the vaccine versus natural infection.

21. Reflecting the foregoing, even Dr. Paul Offit, a member of VRBPAC and a staunch advocate for removing hurdles to the licensure of vaccines, has said that to determine whether a COVID-19 vaccine is safe and effective, "we are waiting for the big trial … the large prospective placebo controlled trial, we have **20,000 people who get a vaccine**, **10,000 people who get a placebo**, **then and only then will you know whether a vaccine is safe and effective**."[22]

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[20] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6526087/ (last visited July 12, 2020).

[21] *Id*.

[22] https://www.cnn.com/videos/health/2020/05/24/coronavirus-covid-19-vaccine-trials-vaccinologist-concern-ip-vpx.cnn (emphasis added) (last visited June 2, 2020).

22. The undersigned therefore respectfully urges that the action requested in paragraph 3 above be adopted forthwith.

d. Converting Guidance to Binding Regulations

23. In the FDA COVID-19 Guidance, the FDA provided that, "[l]ater phase trials, including efficacy trials, should be randomized, double-blinded, and placebo controlled … with 1:1 randomization between vaccine and placebo groups." The foregoing guidance, which comports with the undersigned's June 17, 2020 requests, are appreciated but it is hereby requested that the FDA formally adopt this industry guidance, with the necessary flexibility, as formal regulatory requirements.

24. According to the FDA and the Center for Disease Control and Prevention ("**CDC**"), randomized placebo-controlled trials are the standard for determining the safety and efficacy of a new drug or biological product, including new vaccines. A "placebo" is defined as "[a] substance or treatment that has no effect on human beings."[23] Clinical trials for new pharmaceutical products typically do not use a non-inert substance as a control because, due to its pharmacological effects, a non-inert substance makes it impossible to isolate the effects of just the experimental product being studied.

25. COVID-19 primarily impacts the elderly. The National Institute of Aging, an institute within the National Institutes of Health, explains as follows regarding designing clinical trials:

> In undertaking a clinical trial, researchers don't want to leave anything to chance. They want to be as certain as possible that the results of the testing show whether or not a treatment is safe and effective. The "gold standard" for testing interventions in people is the "randomized, placebo-controlled" clinical trial. ... A placebo is an inactive substance.[24]

26. Where an effective vaccine already exists for an infection, ethical considerations may require using the existing vaccine, rather than a placebo, as the control (an "**active control**"). The FDA's industry guidance explains that an "active control must be a drug whose effect is well defined," which means "historical placebo-controlled trials are available to define the active control effect."[25] The importance of only using an active control that has already been licensed based on a placebo-controlled trial is explained by the FDA as follows:

> The placebo-controlled trial measures the total pharmacologically mediated effect of treatment. In contrast, an active control trial …

[23] https://www.cdc.gov/vaccines/terms/glossary.html (last visited June 2, 2020); *see also* https://www.fda.gov/media/71349/download (last visited July 10, 2020).

[24] https://www.nia.nih.gov/health/why-are-placebos-important (last visited June 2, 2020).

[25] https://www.fda.gov/media/78504/download (last visited June 2, 2020).

> measures the effect relative to another treatment. The placebo-controlled trial also allows a distinction between adverse events due to the drug and those due to the underlying disease or background noise.[26]

Because there is no licensed COVID-19 vaccine, an active control is not appropriate for trials of COVID-19 vaccines, and hence clinical trials of potential COVID-19 vaccines should include a placebo control group.[27]

27. Without a placebo-controlled trial, cause and effect between a potential adverse effect and the vaccine being studied is very difficult and often impossible to establish.[28] Hence, once licensed, studying claims of injury occurring post-licensure becomes exceedingly difficult. This is because after licensure, it will be considered unethical to conduct a placebo-controlled clinical trial of a licensed COVID-19 vaccine. Having a scientifically valid and robust clinical trial prior to licensure will avoid this quagmire.

28. Fortunately, most of the FDA-approved Phase II and III study designs for potential COVID-19 candidate vaccines appear to include a saline placebo control group. For example, the leading candidate COVID-19 vaccine in the United States, developed with the National Institute of Allergy and Infectious Disease ("**NIAID**") lists "Placebo: Saline" as the control for its Phase

[26] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e10-choice-control-group-and-related-issues-clinical-trials (last visited June 2, 2020).

[27] Moreover, even after a COVID-19 vaccine has been licensed, there are still many considerations that must be taken into account before using a COVID-19 vaccine as a control, rather than a placebo, for any new potential COVID-19 vaccine. *See* https://www.fda.gov/RegulatoryInformation/Guidances/ucm126501.htm ("There are three principal difficulties in interpreting active-control trials. … One problem is that there are numerous ways of conducting a study that can obscure differences between treatments, such as poor diagnostic criteria, poor methods of measurement, poor compliance, medication errors, or poor training of observers. As a general statement, carelessness of all kinds will tend to obscure differences between treatments. Where the objective of a study is to show a difference, investigators have powerful stimuli toward assuring study excellence. *Active-control studies, however, which are intended to show no significant difference between treatments, do not provide the same incentives toward study excellence, and it is difficult to detect or assess the kinds of poor study quality that can arise.* The other problem is that a finding of no difference between a test article and an effective treatment may not be meaningful.") (emphasis added) (last visited June 2, 2020).

[28] https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.html ("establishing evidence for cause and effect on the basis of case reports and case series alone is usually not possible," rather, researchers need "to compare the incidence of the event among vaccinees with the incidence among unvaccinated persons") (last visited June 2, 2020); https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3505292/ (The entire advantage of a randomized placebo-controlled trial "is the ability to demonstrate causality" i.e., cause-effect relationship.) (last visited June 2, 2020); https://www.cdc.gov/vaccines/pubs/surv-manual/chpt21-surv-adverse-events.html (The Vaccine Adverse Events Reporting System (VAERS) is unable "to determine causation" because "there is a lack of an unvaccinated group for comparison in VAERS.") (last visited June 2, 2020).

II clinical trial.[29] As another example, the leading COVID-19 vaccines being developed in China both list a placebo control group in their Phase II study designs approved by the FDA.[30]

29. Unfortunately, this does not yet appear to be true for all of the COVID-19 vaccine trials approved by the FDA. For example, the Phase I/II clinical trial of the COVID-19 vaccine ChAdOx1 nCoV-19, currently under development by AstraZeneca, initially provided that the control group would receive a "Saline Placebo."[31] After approving this study design, the FDA inexplicably approved changing the control from a "Placebo Control" to "MenACWY," which is another vaccine for a bacterial infection unrelated to COVID-19. It is ethically and scientifically indefensible to use MenACWY vaccine as a control for a COVID-19 vaccine trial, including because the safety of MenACWY has never been established in a placebo-controlled clinical trial.[32]

30. Permitting clinical trials of a potential COVID-19 vaccine without a placebo control group is inappropriate, scientifically and ethically, especially given the above. The use of a non-inert substance as a control creates significant uncertainty in confirming, among other things, the safety of a COVID-19 vaccine. There is no reason to create such uncertainty or to compromise the scientific validity and robustness of the clinical trial for any candidate COVID-19 vaccine by having a control that is anything other than a saline placebo.

31. With regard to the relative number of subjects between the vaccine and placebo groups, we are pleased that the FDA COVID-19 Guidance provides for "1:1 randomization between vaccine and placebo groups" which comports with the request in the undersigned's original petition that, to assure sufficient power to properly compare the safety profile between the COVID-19 vaccine group and the saline placebo group, the saline placebo group should be at least the size of the group receiving the COVID-19 vaccine.[33]

32. The undersigned therefore respectfully urges that the action requested in paragraph 4 above be adopted forthwith.

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[29] https://www.clinicaltrials.gov/ct2/show/NCT04405076 (last visited June 2, 2020).

[30] https://www.clinicaltrials.gov/ct2/show/NCT04341389; (last visited June 2, 2020); https://www.clinicaltrials.gov/ct2/show/NCT04383574 (last visited June 2, 2020).

[31] https://clinicaltrials.gov/ct2/history/NCT04324606 (last visited June 2, 2020).

[32] *Ibid*. The trade name for MenACWY vaccine in the United States is Menveo. This product was licensed for adults based on a clinical trial in which the control group of 1,966 participants received either Menomune (209 participants) or Menactra (1,757 participants). https://www.fda.gov/media/78514/download (last visited June 2, 2020). Menactra was licensed based on a clinical trial in which Menomune was the active comparator. https://www.fda.gov/media/75619/download (last visited June 2, 2020). Quizzically, the clinical trials section of the package insert for Menomune only lists the clinical trial in which it was used as a comparator against Menactra. https://www.fda.gov/media/83562/download (last visited June 2, 2020). Meaning, the same clinical trial in which Menactra was studied with Menomune as its active control is apparently relied upon by the FDA to support the safety of both of these products. Using any of these products as an active control for a COVID-19 vaccine is unscientific and unacceptable. The control should be a saline placebo.

[33] https://www.fda.gov/media/87621/download (last visited June 2, 2020); https://www.fda.gov/media/139638/download at p.12 (last visited July 7, 2020).

C. Environmental Impact

33. The undersigned hereby states that the relief requested in this petition will have no environmental impact and therefore an environmental assessment is not required under 21 C.F.R. Sections 25.30 and 25.31.

D. Economic Impact

34. Economic impact information will be submitted upon request of the commissioner.

E. Certification

35. 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 and June 30, 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
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