DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

June 22, 2020

Del Bigtree, President
Informed Consent Action Network
2025 Guadalupe Street
Austin, TX, 78705

Sent via email to: aaron@sirillp.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA:

a) Require all Phase II and III trials of vaccines against COVID-19 include a placebocontrol group (i.e., a placebo comparator group);

b) The placebo shall be a saline injection without anything added. If the vaccine andsaline are visually distinguishable, opaque vials should be used.

c) The placebo control group shall be of at least equivalent size to the experimental group.

d) All systemic adverse reactions, adverse events, serious adverse events, medically-attended adverse events, new onset medical conditions, and any other health issuearising or exacerbated post-vaccination shall be documented for each subject post-vaccination for a period of at least twelve months for adults, thirty-six months forchildren and teenagers, and sixty months for infants and toddlers.

Your petition was received by this office on 06/18/2020 and it was assigned docket number FDA-2020-P-1601. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.06.22 15:14:42 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of Operations (OO)