DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

May 17, 2021

Meryl Nass, Scientific Advisory Board Member
& Robert F. Kennedy, Jr., Board Chair and Chief Litigation Counsel
Children's Health Defense
1227 North Peachtree Parkway, Suite 202
Peachtree City, GA 30269

Dear Petitioner:

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

1. FDA should revoke all Emergency Use Authorizations (EUA) and refrain from approving any future EUA, New Drug Application (NDA), or Biologics License Application (BLA) for any COVID vaccine for all demographic groups because the currents risks of serious adverse events or deaths outweigh the benefits, and because existing, approved drugs provide highly effective prophylaxis treatment against COVID, mooting the EUAs.

2. Given the extremely low risk of sever COVID illness in children, FDA should immediately refrain from allowing minors to participate in COVID vaccine trials, refrain from amending EUAs to include children, and immediately revoke all EUAs that permit vaccination of children under 16 for the Pfizer vaccine and under 18 for other COVID vaccines.

3. FDA should immediately revoke tacit approval that pregnant women may receive any EUA or licensed COVID vaccines and immediately issue public guidance to that effect.

4. FDA should immediately amend its existing guidance for the use of the chloroquine drugs, ivermectin, and any other drugs demonstrated to be safe and effective against COVID, to comport with current scientific evidence of safety and efficacy at currently used doses and immediately issue notifications to all stakeholders of this change.

5. FDA should issue guidance to the Secretary of the Defense and the President not to grant an unprecendented Presidential waiver of prior consent regarding COVID vaccines for Servicemembers under 10 U.S.C. § 1107(f) or 10 U.S.C. § 1107a.

6. FDA should issue guidance to all stakeholders in digital and written formats to affirm that all citizens have the option to accept or refuse administration of investigational COVID vaccines without adverse work, educational or other non-health related consequences, under 21 U.S.C. § 360bbb-3(e)(1)(a)(ii)(III) and the informed consent requirements of the Nuremberg Code.

7. Pending revocation of COVID vaccine EUAs, FDA should issue guidance that all marketing and promotion of COVID vaccines must refrain from labeling them "safe and effective," such as statements violate 21 U.S.C. § 360bbb-3.

This petition was received and processed under CFR 10.30 by this office on 05/16/2021.

It was assigned docket number FDA-2021-P-0460. 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 and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Dynna Gorham-Bigby

Digitally signed by Dynna Gorham-Bigby
Date: 2021.05.17 17:07:43 -04'00'

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

cc: mary.holland@childrenshealthdefense.org