



May 16, 2021

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Acting Commissioner Janet Woodcock, M.D.
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Acting Commissioner Woodcock:

Enclosed is a Citizen Petition filed on behalf of Children's Health Defense by Meryl Nass, M.D., Scientific Advisory Board member, and Robert F. Kennedy, Jr., Board Chair and Chief Litigation Counsel, requesting that the FDA revoke Emergency Use Authorizations for existing COVID vaccines and refrain from approving and licensing them.

Dr. Nass and Mr. Kennedy look forward to your timely review of this petition. They are available to answer questions and to provide any additional relevant information.

Sincerely yours,

A handwritten signature in blue ink that reads "Mary S. Holland".

Mary Holland
President and General Counsel
(845) 445-7807
mary.holland@childrenshealthdefense.org

VIA ELECTRONIC FILING

May 16, 2021

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND THE FOOD AND DRUG ADMINISTRATION**

**PETITION FOR ADMINISTRATIVE
ACTION REGARDING COVID-19
VACCINES**

Docket No. _____

CITIZEN PETITION

On behalf of Children’s Health Defense, the undersigned submit this petition under 21 C.F.R. § 10.20, § 10.30, § 50.23, § 600 – 680, § 601.2; 10 U.S.C. § 1107(f), § 1107a; 21 U.S.C. § 355(i)(4), § 360bbb-3; 42 U.S. Code § 247d; § 564 of the Federal Food, Drug, and Cosmetic Act (FDCA); the Public Readiness and Emergency Preparedness Act; the Public Health Service Act, and § 553(e) of the Administrative Procedures Act.

We request the Acting Commissioner of the Food and Drugs Administration (FDA) to issue, amend, revoke, or refrain from taking the administrative actions listed below regarding emergency use authorizations (EUAs), current and future new drug applications (NDAs), and biologics license applications (BLAs) for all COVID vaccines.

I. ACTIONS REQUESTED

1. FDA should revoke all EUAs and refrain from approving any future EUA, NDA or BLA for any COVID vaccine for all demographic groups because the current risks of serious adverse events or deaths outweigh the benefits, and because existing, approved drugs provide highly effective prophylaxis and treatment against COVID, mooted the EUAs.

2. Given the extremely low risk of severe 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. The FDA should issue guidance to the Secretary of the Defense and the President not to grant an unprecedented Presidential waiver of prior consent regarding COVID vaccines for Servicemembers under 10 U.S.C. § 1107(f) or 10 U.S.C. § 1107a.

6. The 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) ¹ and the informed consent requirements of the Nuremberg Code.²

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,” as such statements violate 21 U.S.C. § 360bbb-3.

II. STATEMENT OF GROUNDS

A. Safety

8. Vaccine Adverse Event Reporting System (VAERS) data reveal unprecedented levels of deaths and other adverse events since the FDA issued Emergency Use Authorizations (EUAs) for three COVID vaccines. As of May 10, 2021, VAERS reported 4,434 deaths of people who received at least one COVID vaccination.³

9. FDA and CDC have not responded to these data by issuing any warnings or restricting the use of these vaccines. Furthermore, the VAERS database is the only safety database to which the public has access. The government withholds extensive safety information from the public despite having at least ten additional data sources and expert consultants to analyze these data, according to Nancy Messonnier, MD, the Director of the National Center for Immunization and Respiratory Diseases.⁴ Examples include databases from the Centers for Medicare and

¹ 21 U.S.C. § 360bbb-3, Authorization for medical products for use in emergencies, <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21-chap9-subchapV-partE-sec360bbb-3.pdf>.

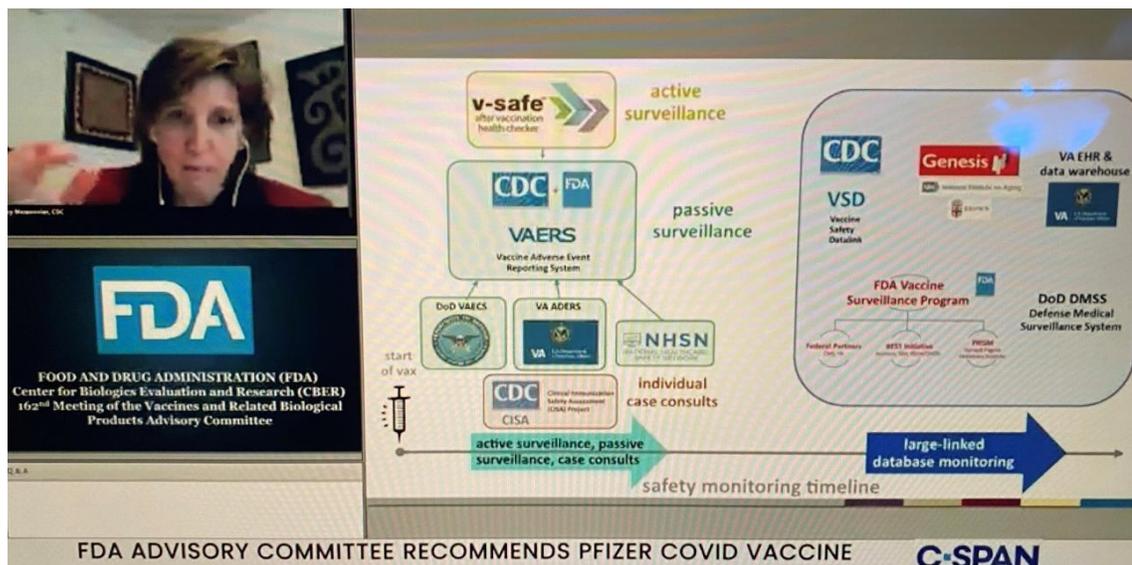
² Nuremberg Code, BRITISH MEDICAL JOURNAL, No. 7070, Volume 313, p. 1448 (Dec. 7, 1996), https://media.tghn.org/medialibrary/2011/04/BMJ_No_7070_Volume_313_The_Nuremberg_Code.pdf.

³ VAERS Vaccine Adverse Event Reporting System data, available at <https://vaers.hhs.gov/>.

⁴ FDA meeting on COVID 19 and Emergency Use Authorization, Part 1 (Video), Dec. 10, 2020, available at <https://www.c-span.org/video/?507053-1/fda-meeting-covid-19-vaccine-emergency-authorization-part-1>.

Medicaid, the Veterans Administration, the Defense Department (DMSS), the Vaccine Safety Datalink and the “Genesis” database, which is operated in cooperation with the National Institutes of Health and Brown University and includes 250 long-term care facilities and 35,000 residents.

10. Dr. Messonier told the FDA and its Vaccines and Related Biological Products Advisory Committee (VRBPAC) on December 10, 2020 that it had 11 systems that would evaluate COVID vaccine safety. Five systems would be active at the start of the vaccine program, and an additional six systems would become active over ensuing weeks. She said that the VAERS system was being enhanced for long-term care facilities, and added, “Hopefully you’ll understand how robust these systems are.” Below is the graphic she presented to the VRBPAC and the public on December 10, 2020.



11. The CDC website, updated on May 11, 2021 states, "These vaccines have undergone and will continue to undergo the most intensive safety monitoring in U.S. history. This monitoring includes using both established and new safety monitoring systems to make sure that COVID-19 vaccines are safe."⁵

12. The CDC website states that “CDC and FDA physicians review each case report of death as soon as notified and CDC requests medical records to further assess reports.”⁶ By contrast, a CDC official told a reporter for *The Daily Beast* that it lacks a "good way to track deaths that occur after vaccination in real time.” Furthermore, CDC told the reporter, "there are no current plans to include vaccination data in the current CDC Covid-19 mortality analysis.”⁷

⁵ CDC, *Safety of COVID-19 Vaccines* (updated May 11, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html>.

⁶ CDC, *Selected Adverse Events Reported after COVID-19 Vaccination* (updated May 11, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>.

⁷ Erin Banco, *White House asks CDC to study how many have died after COVID vaccine shots*,

13. Children's Health Defense asked CDC for information on post-vaccination deaths and injuries in early March 2021 and has yet to receive a response.⁸

14. Normally, licensed biologics manufacturers review adverse event reports pursuant to 21 C.F.R. § 600.80, while to date the CDC and the manufacturers appear to dispute most causal links to COVID vaccines. Any COVID vaccine license applicant “assumes responsibility for compliance with the applicable product and establishment standards” according to 21 C.F.R. § 600.3.⁹ CDC asserts that a “review of available clinical information, including death certificates, autopsy, and medical records has not established a causal link to COVID-19 vaccines,” yet recent assessments acknowledge “a plausible causal relationship between the J&J/Janssen COVID-19 vaccine and a rare and serious adverse event—blood clots with low platelets—which has caused deaths.”¹⁰ Denmark, among other nations, has banned the EUA J&J/Janssen COVID vaccine, stating, “the benefits of using the COVID-19 vaccine from J&J do not outweigh the risk of causing possible adverse effect in those who receive the vaccine.”¹¹

15. CDC calculated rates of adverse effects for anaphylaxis post-vaccination improperly, using VAERS reports as the numerator, even though CDC officials have acknowledged “it is not possible to use VAERS data to calculate how often an adverse event occurs in a population.”¹² When Massachusetts General-Brigham hospitals evaluated the rate of anaphylaxis in employees post COVID vaccination, they found anaphylaxis rates approximately 50-100 times greater than the rates CDC calculated using VAERS data. (Pfizer rate 2.7/10,000 vaccinees and Moderna rate 2.3/10,000 vaccinees).¹³ Anaphylaxis after vaccination has led to deaths. If this degree of underestimation holds true for other adverse events using the VAERS database, then the safety of COVID vaccines is considerably worse than it currently appears. This rate could be verified by querying the ten databases whose results have been hidden from the

DAILY BEAST (Jan. 28, 2021), <https://www.thedailybeast.com/white-house-asks-cdc-to-study-how-many-have-died-after-covid-vaccine-shots>.

⁸ Megan Redshaw, *64 Days and Counting — Why Won't the CDC Answer Our Questions?* THE DEFENDER (May 11, 2021), <https://childrenshealthdefense.org/defender/64-days-why-wont-cdc-answer-questions/>.

⁹ Code of Federal Regulations Title 21 § 600.3, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=600.3>.

¹⁰ CDC, *Selected Adverse Events Reported after COVID-19 Vaccination* (updated May 11, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>.

¹¹ Vincent West, *Denmark ditches J&J COVID-19 shots from vaccination programme*, REUTERS (May 3, 2021), <https://www.reuters.com/world/europe/denmark-excludes-jj-shot-vaccine-programme-local-media-reports-2021-05-03/>.

¹² CDC, Vaccine Adverse Event Reporting System (VAERS), <https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html>.

¹³ Blumenthal K. G., Robinson L. B., Camargo C. A., et al., *Acute Allergic Reactions to mRNA COVID-19 Vaccines*. JAMA, Vol. 325, No. 15, pp. 1562–1565 (Mar. 8, 2021), <https://jamanetwork.com/journals/jama/fullarticle/2777417>.

public.

16. Other problems with vaccine safety assessment may exist because of inadequate animal toxicology and pharmacokinetic studies of COVID vaccines. Animal experiments failed to measure the quantity, duration and organ distribution of spike protein production. The animal experiments, incomprehensibly, failed to inject the actual vaccine to be tested during certain pharmacokinetic and toxicology tests. For example, in study 2.6.5.5B, only 2 of the 4 lipid nanoparticle (LNP) components were labeled and injected into rats, and their distribution and persistence in many organs were assessed at animal necropsy, from 15 minutes to 48 hours post-injection. For most organs, at 48 hours the amount of the two LNP components in each organ was still increasing. Thus, the ultimate distribution and persistence of the LNPs are unknown. And we have no information regarding duration and persistence of the mRNA or spike protein production in organs based on this study.¹⁴

17. A surrogate for mRNA (coding for spike protein) was an entirely different mRNA (coding for luciferase) in LNP injected into mice. In study 2.6.5.5A, bioluminescence was measured in liver through 9 days as a surrogate measure, while no attempt was made to evaluate the presence of spike protein in animal tissues, including in the brains of the experimental animals.¹⁵ These surprising omissions have significant potential safety implications.

18. Given that only 1 to 13% of adverse reactions have been reported to the FDA and CDC via the VAERS passive reporting system, according to Lazarus et al., the high number of adverse events and deaths following COVID vaccines is alarming.¹⁶ While the Pfizer vaccine has now been used for five months and administered to more than 60 million Americans, FDA has issued no new guidance about the vaccine based on these troubling data, apart from expanding its use in children.

19. The FDA must be aware that the only avenue for an injured party to claim benefits as a result of a COVID vaccine injury is the Countermeasures Injury Compensation Program (CICP).¹⁷ The CICP requires petitioners to prove that the COVID vaccine caused their injuries; the program has an extremely short statute of limitations of one year. If the FDA, working with

¹⁴ Study 2.6.5.5.B Pharmacokinetics: Organ Distribution. SARS-CoV-2 mRNA Vaccine (English Portion) (BNT162, PF-07302048), pp. 15-18, <https://www.pmda.go.jp/drugs/2021/P20210212001/>.

¹⁵ *Id.*

¹⁶ See Lazarus et al., *Electronic Support for Public Health-Vaccine Adverse Event Reporting System*, AGENCY FOR HEALTHCARE RESEARCH AND QUALITY, DEPT. OF HEALTH AND HUMAN SERVICES (Sept. 30, 2010), <https://digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system>; Shimabukuro et al., *Safety monitoring in the Vaccine Adverse Event Reporting System (VAERS)*, VACCINE (Nov. 4, 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4632204/>; S. Rosenthal and R. Chen, *The reporting sensitivities of two passive surveillance systems for vaccine adverse events*, AM J PUBLIC HEALTH (Dec. 1995), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1615747/>.

¹⁷ Health and Human Services Administration, *Countermeasures Injury Compensation Program (CICP)*, <https://www.hrsa.gov/cicp>.

the vaccine manufacturers, does not compile and publish an accurate list of adverse reactions, which is required for licensing, then these petitioners will have virtually no opportunity to prove injury or receive compensation.

B. Effectiveness

20. As with safety data on COVID vaccines, effectiveness data continue to evolve. Recently CDC acknowledged “vaccine breakthrough cases” where vaccinated subjects fall ill and potentially transmit the virus. CDC acknowledges that a “small percentage of people who are fully vaccinated against COVID-19 will still get sick and some may be hospitalized or die from COVID-19. It’s also possible that some fully vaccinated people might have infections, but not have symptoms (asymptomatic infections).”¹⁸

21. As of April 26, 2021, CDC reported over 9,000 “breakthrough cases” and 132 COVID-caused deaths among vaccinated people.¹⁹ CDC tracks reports of breakthrough cases via the National Notifiable Diseases Surveillance System (NNDSS)²⁰ and has recently stopped reporting breakthrough cases absent death or hospitalization.²¹ The British government has also identified efficacy problems stating, “The resurgence in both hospitalisations and deaths is dominated by those that have received two doses of the vaccine, comprising around 60% and 70% of the wave respectively.”²²

22. The U.K. data modelers attribute these rates to the high level of vaccine uptake in the most at-risk elderly age group.²³ Overall, the U.K. believes “evidence shows vaccines are *sufficiently* effective in reducing hospitalisations and deaths in those vaccinated.”²⁴ The U.K. caveat “sufficiently” is significant compared to the unqualified “effective” label that the FDA currently permits to be communicated to the public.

¹⁸ CDC, *What You Should Know About the Possibility of COVID-19 Illness After Vaccination*; (updated April 21, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html>.

¹⁹ CDC, *COVID-19 Breakthrough Case Investigations and Reporting* (updated April 30, 2021), <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html>.

²⁰ CDC, *National Notifiable Diseases Surveillance System (NNDSS)*, <https://wwwn.cdc.gov/nndss/>.

²¹ CDC, *COVID-19 Breakthrough Case Investigations and Reporting* (April 30, 2021), <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html>.

²² *SPI-M-O: Summary of further modelling of easing restrictions – Roadmap Step 2*, p. 10 (Mar. 31, 2021), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/975909/S1182_SPI-M-O_Summary_of_modelling_of_easing_roadmap_step_2_restrictions.pdf.

²³ *Id.*

²⁴ Gov.UK; *COVID-19 Response-Spring 2021 (Summary)* (Feb. 22, 2021), <https://www.gov.uk/government/publications/covid-19-response-spring-2021/covid-19-response-spring-2021-summary>.

C. Misbranding as “Safe, Effective and FDA Approved”

23. Recently the FDA sent a warning letter “RE: Unapproved and Misbranded Products Related to Coronavirus Disease 2019 (COVID-19).”²⁵ FDA warned that labeling COVID therapies as Safe, Effective or FDA Approved when they are not proven to be so by FDA standards violates § 505(a) of the FDCA, 21 U.S.C. § 355(a). The same standard should apply to COVID vaccines, as any such products are misbranded drugs and violate § 502 of the FDCA and 21 U.S.C. § 352.

24. The introduction or delivery for introduction of any such product into interstate commerce is prohibited under § 301(a) and (d) of the FDCA and 21 U.S.C. § 331(a) and (d). The FDA specifically warned a vendor: “We advise you to review your websites, product labels, and other labeling and promotional materials to ensure that you are not misleadingly representing your products as *safe and effective* for a COVID-19-related use for which they have *not been approved* by FDA and that you do not make claims that misbrand the products in violation of the FD&C Act.”

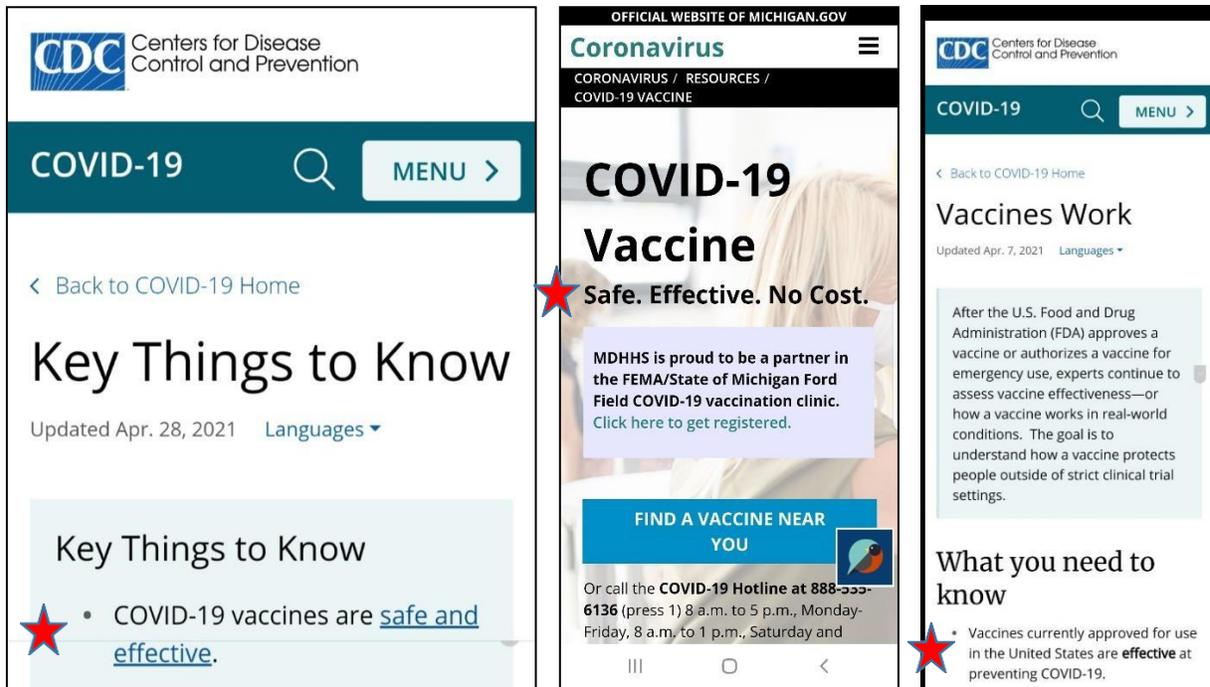
25. FDA must ensure against misrepresenting COVID vaccine products as “safe and effective” when FDA has not so designated them. FDA’s description of COVID vaccines pursuant to § 564(d)(3) of the Act states: “based on the totality of scientific evidence available to FDA...it is reasonable to believe that Pfizer-BioNTech COVID-19 Vaccine *may be effective* in preventing COVID-19 when used in accordance with this Scope of Authorization (Section II), pursuant to Section 564(c)(2)(A) of the Act.” The FDA language on effectiveness provides a qualification similar to the above-mentioned U.K. regulatory language. FDA’s precise technical language to manufacturers does not match its unequivocal “effective” claims on official government websites, including that of the CDC, as illustrated below.²⁶

²⁵ FDA, *Warning Letter to Mercola.com, LLC* (Feb. 18, 2021), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mercolacom-llc-607133-02182021>.

²⁶ CDC, *Key things to know about COVID-19 vaccines* (May 10, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html>;

CDC, *Safety of COVID-19 vaccines* (updated May 11, 2021), <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html>;

FDA, *Letter to Pfizer* (May 10, 2021), <https://www.fda.gov/media/144412/download>.



D. EUA revocation, additional EUAs, and off-label use clarification for COVID therapies

26. On February 4, 2020 the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the virus that causes Coronavirus Disease (COVID-19). Based on this determination, the Secretary on March 27, 2020 declared that circumstances justify emergency use of drugs and biological products during the COVID-19 pandemic pursuant to § 564 of the FDCA (21 U.S.C. § 360bbb-3).

27. Since December 2020, several manufacturers have received EUAs for COVID vaccines. One of the criteria for these authorizations, beyond the existence of an emergency, is that there are “no adequate, approved, and available alternatives.”²⁷ Many medical professionals and elected officials have objected to the inconsistent handling of EUAs for alternative treatments. Dr. Peter McCullough testified to the Texas Senate on March 10, 2021 that an 85% lower mortality rate from COVID would have been possible if government agencies had publicly recommended

²⁷ FDA, *Emergency Use Authorization* (updated May 11, 2021), <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>;

FDA, *FAQs on Emergency Use Authorizations (EUAs) for Medical Devices During the COVID-19 Pandemic* (updated April 23, 2021), <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/faqs-emergency-use-authorizations-euas-medical-devices-during-covid-19-pandemic>.

early treatments.²⁸ Now that COVID cases and deaths are decreasing because many if not most Americans are immune, the relative benefit of COVID vaccines has diminished.²⁹

28. Three U.S. Senators asked the FDA to clarify why it revoked the previously granted EUAs for hydroxychloroquine (HCQ) and chloroquine (CQ) and under what authority it regulates the practice of medicine. The Senators also asked what authority states have to regulate the prescribing and dispensing of drugs.³⁰ FDA issued and revoked EUAs for HCQ and CQ donated to the Strategic National Stockpile in a way that confused medical professionals, resulting in their reluctance to prescribe the drugs, including those not under EUA. FDA improperly recommended against the use of chloroquine drugs in outpatients, and against early treatment, which is when these antiviral drugs are likely to be effective. FDA appears to have collaborated with officials in dozens of states and even with certain pharmaceutical and pharmacy companies to restrict the prescribing and dispensing of chloroquine drugs against COVID. These unprecedented actions require explanation. The FDA must immediately revoke its recommendations for the limited use and withholding of these drugs during a life-threatening pandemic and must publicize its revocation widely.

29. Medical professionals also question FDA's approval of Investigational New Drug (IND) human trials performed by the University of Pittsburg (REMAP-COVID)³¹ and the University of Philadelphia (PATCH)³² using knowingly borderline lethal doses of HCQ in humans. There were more deaths in the HCQ arm than in the control arm of the REMAP-COVID study and in the other two large multicenter studies, the Solidarity and Recovery studies, that used excessive doses. The PATCH study ended after enrolling only 5 subjects.

30. In other FDA guidance regarding the chloroquine drugs, FDA made the misleading claim that “Hospitalized patients were likely to have greater prospect of benefit (compared to

²⁸ Dr. Peter McCullough’s testimony to the Texas Senate HHS Committee (Mar. 10, 2021), <https://www.youtube.com/watch?v=QAHi3IX3oGM>.

²⁹ Dr. Peter McCullough et al., *SARS-CoV-2 mass vaccination: Urgent questions on vaccine safety 2 that demand answers from international health agencies, regulatory 3 authorities, governments and vaccine developers* (May 8, 2021), <https://www.andrewbostom.org/wp-content/uploads/2021/05/Bruno-et-al.-Vaccine-Safety-Urgent-Manuscript-Preprint-May-8-2021.pdf>.

³⁰ Senators Ted Cruz, Mike Lee, Ron Johnson, *Letter to FDA Commissioner Stephen Hahn* (Aug. 18, 2020), <https://www.hsgac.senate.gov/imo/media/doc/2020-08-18%20RHJ%20Letter%20to%20FDA%20on%20HCQ%20+%20CQ.pdf>.

³¹ UNIVERSITY OF PITTSBURG, Department of Critical Care, *UPMC Leads Global Efforts to Fast-track COVID-19 Therapies*, <https://www.ccm.pitt.edu/node/1110>.

³² *Penn Launches Trial to Evaluate Hydroxychloroquine to Treat, Prevent COVID-19*, PENN MEDICINE NEWS (April 3, 2020), <https://www.pennmedicine.org/news/news-releases/2020/april/penn-launches-trial-to-evaluate-hydroxychloroquine-to-treat-prevent-covid19>;

The PATCH Trial (Prevention And Treatment of COVID-19 With Hydroxychloroquine) (PATCH), CLINICALTRIALS.GOV (updated Dec. 10, 2020), <https://clinicaltrials.gov/ct2/show/NCT04329923>.

ambulatory patients with mild illness),” and that chloroquine drugs have a “slow onset of action.” In its justification for restricting the use of chloroquine drugs, FDA also opined that “it is no longer reasonable to believe that oral formulations of HCQ and CQ may be effective in treating COVID-19, nor is it reasonable to believe that the known and potential benefits of these products outweigh their known and potential risks.”³³

31. These claims fly in the face of substantial evidence of positive effects of the drugs when used early in the disease at usual, approved, therapeutic doses. FDA has chosen to ignore the many trials that were properly conducted. The FDA buttresses its contention of the dangers of these drugs based in part on the FDA-approved trial and other trials that administered excessive, non-therapeutic doses of HCQ and resulted in more deaths in the treated group than the placebo group.

32. Similarly, FDA exhibited bias regarding the effective and safe use of ivermectin for prophylactic use of COVID. In March 2021, the agency stated: “The FDA has not reviewed data to support use of ivermectin in COVID-19 patients to treat or to prevent COVID-19; however, some initial research is underway.”³⁴ Yet already on April 10, 2020, FDA had issued a public warning against the use of ivermectin because, it claimed, Americans were purchasing over the counter (OTC) veterinary ivermectin as a COVID treatment.³⁵ Research from Australia had been published online a week earlier, on April 3, 2020, supporting use of ivermectin for COVID based on in vitro studies.³⁶

33. Thus, FDA was aware at least 13 months ago that Americans were using ivermectin to treat and prevent COVID. How could FDA not have reviewed data on ivermectin during an entire year after it was informed about this use? That was a year during which dozens of studies about the drug’s use were available as publications or preprints for both prophylaxis and treatment; during which there was a Senate hearing on the drug; and during which half a million Americans died from the disease, who had not been treated with effective medications because of FDA guidance.

34. Furthermore, ivermectin has been used OTC for COVID in many countries and regions with excellent reported treatment success. The drug's safety has been established with at

³³ FDA Letter revoking EUA for Hydroxychloroquine (Jun. 15, 2020), <https://www.fda.gov/media/138945/download>.

³⁴ FDA, *Why You Should Not Use Ivermectin to Treat or Prevent COVID-19* (updated May 10, 2021), <https://www.fda.gov/consumers/consumer-updates/why-you-should-not-use-ivermectin-treat-or-prevent-covid-19>.

³⁵ FDA Letter to Stakeholders, *Do Not Use Ivermectin Intended for Animals as Treatment for COVID-19 in Humans* (April 10 2020), <https://www.fda.gov/animal-veterinary/product-safety-information/fda-letter-stakeholders-do-not-use-ivermectin-intended-animals-treatment-covid-19-humans>.

³⁶ Leon Caly, Julian D. Druce, *The FDA-approved drug ivermectin inhibits the replication of SARS-CoV-2 in vitro*, *ANTIVIRAL RESEARCH*, vol. 178, 104787 (Jun. 2020), <https://reader.elsevier.com/reader/sd/pii/S0166354220302011>.

least a billion doses used, and the drug is on the World Health Organization's list of essential drugs.

35. Many medical professionals suspect FDA's feigned ignorance about the drug was a prerequisite to issuing EUAs for COVID vaccines, given the EUA requirement that no approved drug may be available for the same indication. Ivermectin and hydroxychloroquine, both of which have extremely long biological half lives, can be given infrequently as prophylaxis for COVID. Hydroxychloroquine or chloroquine are used weekly to prevent malaria, and they have been used in the same way to prevent COVID. Ivermectin can be used once or twice yearly to prevent river blindness (onchocerciasis), and it has been used weekly or bi-weekly to prevent COVID. Many clinical trials have documented the benefits of both drugs for COVID prevention. Yet FDA has remained silent about these benefits, even though the efficacy of these preventive treatments probably supercedes that of COVID vaccines.

36. This petition encourages FDA to expeditiously evaluate existing ivermectin research and issue accurate guidance for its use against COVID, e.g., where “18 randomized controlled treatment trials of ivermectin in COVID-19 have found large, statistically significant reductions in mortality, time to clinical recovery, and time to viral clearance.”³⁷ Additional studies have found it highly effective for both pre- and post-exposure prophylaxis of COVID.³⁸

37. Finally, reflecting on the FDA’s regulatory history is helpful: A proven association between the 1976–1977 swine influenza vaccine and approximately 400 cases of Guillain–Barré syndrome halted that particular national vaccination campaign.³⁹ The reported deaths following

³⁷ P. Kory, G. Meduri et al., *Review of the Emerging Evidence Demonstrating the Efficacy of Ivermectin in the Prophylaxis and Treatment of COVID-19*, AMERICAN JOURNAL OF THERAPEUTICS (May-Jun 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8088823/>.

Ahmed, Sabeena et al., *A five-day course of ivermectin for the treatment of COVID-19 may reduce the duration of illness*, INTERNATIONAL JOURNAL OF INFECTIOUS DISEASES, vol. 103, pp. 214-216 (Feb. 2021), <https://pubmed.ncbi.nlm.nih.gov/33278625/>;

Jans D. A. and Wagstaff K. M., *The broad spectrum host-directed agent ivermectin as an antiviral for SARS-CoV-2?* BIOCHEMICAL AND BIOPHYSICAL RESEARCH COMMUNICATIONS, vol. 538, pp. 163-172 (2021), <https://pubmed.ncbi.nlm.nih.gov/33341233/>.

Formiga, Fabio Rocha et al., *Ivermectin: an award-winning drug with expected antiviral activity against COVID-19*, JOURNAL OF CONTROLLED RELEASE, vol. 329, pp. 758-761 (Jan. 2021), <https://pubmed.ncbi.nlm.nih.gov/33038449/>.

Bhowmick, Subhrojyoti et al., *Safety and Efficacy of Ivermectin and Doxycycline Monotherapy and in Combination in the Treatment of COVID-19: A Scoping Review*, DRUG SAFETY, pp. 1-10 (Apr. 16, 2021), <https://pubmed.ncbi.nlm.nih.gov/33864232/>.

³⁸ *Ivermectin for COVID-19: real-time meta analysis of 55 studies*, COVID ANALYSIS (version 81, May 15, 2021), <https://ivmmeta.com/>.

³⁹ See CDC, H1N1 Flu, FACT SHEET: GUILLAIN- BARRÉ SYNDROME (GBS) (Dec. 15, 2009), https://www.cdc.gov/h1n1flu/vaccination/factsheet_gbs.htm#:~:text=Getting%20GBS%20from%20a%20vaccination,got%20the%20swine%20flu%20vaccine.

that swine flu vaccination campaign, 30 out of 40-45 million vaccinees,⁴⁰ were insignificant compared to the current reported death toll of 4,434 due to COVID vaccines, Today's death rate is more than 50 times higher than that which ended the swine flu vaccine campaign.

38. Regarding the halted swine flu vaccine program, the CDC's *Emerging Infectious Diseases Journal* concluded, "In 1976, the federal government wisely opted to put protection of the public first."⁴¹ FDA should learn from this past experience and again put protection of the public first. It is imperative that the FDA swiftly take action to authorize alternative treatments.

E. Children

39. According to the National Center for Health Statistics data as of May 5, 2021, 282 children have died "involving COVID," whereas over 560,000 Americans have died "involving COVID."⁴² Three thousand children have been diagnosed with a multi-system inflammatory disorder, of whom about 1%, or approximately 30, have died. Thus the relative risk for children due to COVID is very low.

40. By contrast, recent VAERS reports include the deaths of several children following COVID vaccination.⁴³ Five of the child death reports footnoted below involve apparent cardiac related deaths, and two were infants. There is one reported death in a 15 year old after receiving the Pfizer BioNTech vaccine, and another reported death of a 15 year old after receiving a Moderna

⁴⁰ Rick Perlstein, *Gerald Ford Rushed Out a Vaccine. It Was a Fiasco*, THE NEW YORK TIMES (Sept. 2, 2020), <https://www.nytimes.com/2020/09/02/opinion/coronavirus-vaccine-trump.html>; Donald G. McNeil, Jr., *Don't Blame Flu Shots for All Ills, Officials Say*, THE NEW YORK TIMES (Sept 27, 2009), <https://www.nytimes.com/2009/09/28/health/policy/28vaccine.html>.

⁴¹ Sencer D. J., Millar J., *Reflections on the 1976 Swine Flu Vaccination Program*, EMERGING INFECTIOUS DISEASES, Vol. 12, No. 1, pp. 29-33 (Jan. 2006), https://wwwnc.cdc.gov/eid/article/12/1/05-1007_article.

⁴² CDC, *Weekly Updates by Select Demographic and Geographic Characteristics*, Provisional Death Counts for Coronavirus Disease 2019 (COVID-19) (updated May 12, 2021), https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAge.

⁴³ VAERS reports include:

A 1-year-old, <https://medalerts.org/vaersdb/findfield.php?IDNUMBER=1261766&WAYBACKHISTORY=ON>;

a 2-year-old, <https://medalerts.org/vaersdb/findfield.php?IDNUMBER=1255745&WAYBACKHISTORY=ON>;

two 15-year-olds, <https://www.medalerts.org/vaersdb/findfield.php?IDNUMBER=1187918> and <https://www.medalerts.org/vaersdb/findfield.php?IDNUMBER=1242573>;

two 16-year-olds, <https://www.medalerts.org/vaersdb/findfield.php?IDNUMBER=1225942>;

a 17-year old, <https://www.openvaers.com/openvaers/1199455>;

and an infant, <https://www.medalerts.org/vaersdb/findfield.php?IDNUMBER=1166062>.

vaccine. Each child must have been enrolled in a clinical trial, since their ages would have precluded them getting the vaccine legally under the EUA. There were only about 1,000 children in the 12-15 year age group in the vaccine arm of Pfizer’s trial and probably about the same number in the vaccine arm of Moderna’s trial. Thus, the death rate following either vaccination in this age group, assuming these children were trial enrollees, is approximately 2 in 2,000 or 0.1%.

41. There are 74 million children in the United States. So far, 282 have died "involving Covid." Two hundred eighty-two in 74 million is a rate of 0.00038%. While many children may not have been exposed to COVID, CDC estimated that 22.2 million children aged 5-17 had had COVID and 127 had died, at the May 12, 2021 meeting of the Advisory Committee on Immunization Practices, or 0.00057%.⁴⁴ Available evidence strongly suggests that the vaccine is much more dangerous to children than the disease.

42. A recent opinion piece in the *British Medical Journal* noted that “the likelihood of severe outcomes or death associated with COVID-19 infection is very low for children, undermining the appropriateness of an emergency use authorization for child covid-19 vaccines.”⁴⁵ The authors also suggested child vaccinations could strategically harm vaccination efforts and increase vaccine hesitancy.⁴⁶

F. Servicemembers' Prior Consent

43. Certain citizens and elected officials have recently encouraged the President of the United States to waive U.S. Servicemembers’ right to prior consent for COVID vaccines.⁴⁷ According to 10 U.S.C. §1107(f), only the President of the United States may order such a waiver if he determines, in writing, that obtaining consent is not in the national security interest. The intent of any waiver of consent must be related to a member's participation in a “particular military operation,” as opposed to the broad sweep some are encouraging.

44. Such a waiver is only permissible when obtaining prior consent is infeasible or contrary to the best interests of the military member. Clearly, prior consent for current servicemembers is feasible for COVID vaccines.⁴⁸ Because the President’s authority is contingent on the standards set forth in § 505(i)(4) of the FDCA and 21 U.S.C. § 355(i)(4), and since the chain of command requires consultation with HHS, the FDA may issue guidance to the President on this

⁴⁴ Helen Branswell, *CDC advisory group gives green light to Pfizer’s Covid vaccine for adolescents*, STAT (May 12, 2021), <https://www.statnews.com/2021/05/12/cdc-advisory-group-gives-green-light-to-pfizers-covid-vaccine-for-adolescents/>.

⁴⁵ W. Pegden, V. Prasad, S. Baral, *Covid vaccines for children should not get emergency use authorization*, BMJ (May 7, 2021), <https://blogs.bmj.com/bmj/2021/05/07/covid-vaccines-for-children-should-not-get-emergency-use-authorization/>.

⁴⁶ *Id.*

⁴⁷ Jimmy Panetta, *Letter to President Biden* (Mar. 24, 2021), https://www.documentcloud.org/documents/20521870-panetta_dod-covid-vaccine-waiver.

⁴⁸ 21 U.S.C. § 50.23: Exception from general requirements, https://www.ecfr.gov/cgi-bin/text-idx?node=se21.1.50_123&rgn=div8.

matter.⁴⁹

45. The specific law on EUA vaccines was codified in 10 U.S.C. § 1107a.⁵⁰ The § 1107a language is similar to § 1107(f) to ensure that troops are granted prior consent and have the “option to accept or refuse administration of a product.” National leaders should continue to honor and respect servicemembers’ rights. No President has ever waived servicemembers’ prior consent under 10 U.S.C. § 1107(f) or 10 U.S.C. § 1107a, and FDA should advise that current circumstances do not warrant such drastic action.

G. Coercion and Compulsion

46. COVID vaccines are optional in accordance with 21 C.F.R. § 360bbb-3(e)(1)(a) as EUA products.⁵¹ Yet throughout the United States, schools, businesses, government and industry are using coercive tactics to encourage, incentivize and compel COVID vaccination as a condition of employment, education and daily living. It is unlikely that most Americans would support such coercion if they were fully informed that COVID vaccines are for emergency use only, investigational, unapproved, and that individuals have the explicit right to refuse by law. Some states are considering or have approved legislation or executive action to bar vaccine mandates.⁵² Some professional medical associations also have expressed opposition to these coercive tactics.⁵³

47. Coercion and compulsory vaccination are inconsistent with the legal requirements to inform both healthcare workers administering EUA vaccines and vaccine recipients of the significant known and unknown benefits and risks of such use. Most importantly, the FDA must ensure all parties are aware of the “option to accept or refuse” administration of all EUA products and that alternatives are available. These disclosure requirements are entirely inconsistent with coercion, and government agencies should not publish information that violates the law. Information on the government websites of the Equal Employment Opportunity Commission

⁴⁹ *Id.*

⁵⁰ 10 U.S.C. § 1107a - Emergency use products, <https://www.govinfo.gov/app/details/USCODE-2010-title10/USCODE-2010-title10-subtitleA-partII-chap55-sec1107a/summary>.

⁵¹ § 360bbb–3. Authorization for medical products for use in emergencies, <https://www.govinfo.gov/content/pkg/USCODE-2011-title21/pdf/USCODE-2011-title21-chap9-subchapV-partE-sec360bbb-3.pdf>.

⁵² Pearson L., Brofsky J., et al., *50-state Update on Pending Legislation Pertaining to Employer-mandated Vaccination*, HUSCH BLACKWELL (updated April 20, 2021), <https://www.huschblackwell.com/newsandinsights/50-state-update-on-pending-legislation-pertaining-to-employer-mandated-vaccinations>.

⁵³ Dr. Paul M. Kempen, *Open Letter from Physicians to Universities: Allow Students Back Without COVID Vaccine Mandate*, ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS (Apr. 24, 2021), <https://aapsonline.org/open-letter-from-physicians-to-universities-reverse-covid-vaccine-mandates/>.

(EEOC)⁵⁴ and the Occupational Safety and Health Administration (OSHA)⁵⁵ in fact ignore these federal disclosure requirements.

48. The armed forces' experience with the very first EUA vaccine mandate against anthrax is instructive.⁵⁶ The military now administers the anthrax vaccine on a voluntary basis with informed consent, but only after a federal court halted the mandatory anthrax vaccine program because the FDA had improperly issued a license.⁵⁷

49. The only language in the EUA law, 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(I-III), that could possibly be construed to imply mandates is the term “consequences” in clause III. Both statutory analysis and legislative history suggest that it is far more likely that this term applies to health-related consequences only, i.e., medical risks and benefits, since that is the topic of that statute section and because it does not refer to punitive measures or consequences, such as termination of employment or education.⁵⁸

50. Another hazard of coercive policies and broad liability for industry is reliance on subpar manufacturers. One of the COVID vaccine manufacturing subcontractors today, Emergent BioSolutions, is the same company, with the same President and Board Chairman, which the FDA cited under its previous name, BioPort, for numerous violations of Good Manufacturing Practices.⁵⁹ The image below, taken from an FDA form in 2000, shows the citation to BioPort for

⁵⁴ EEOC, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEOC Laws*, §§ K1 & K7 (updated Dec. 16, 2020), <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>.

⁵⁵ Jeff Yoders, *OSHA Imposes New Guidance For Employer-Required COVID-19 Vaccines*, ENR (May 3, 2021), <https://www.enr.com/articles/51691-osha-imposes-new-guidance-for-employer-required-covid-19-vaccines>.

⁵⁶ FDA, *Anthrax Vaccine Adsorbed (AVA) EUA –ARCHIVED INFORMATION*, <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information#anthrax>.

⁵⁷ *Determination and Declaration Regarding Emergency Use of Anthrax Vaccine Adsorbed for Prevention of Inhalation Anthrax*, FEDERAL REGISTER (Feb. 2, 2005), <https://www.federalregister.gov/documents/2005/02/02/05-2027/determination-and-declaration-regarding-emergency-use-of-anthrax-vaccine-adsorbed-for-prevention-of?fbclid=IwAR22J58y3SQ2tVoEUIngZVU-PmRxou0P05i9WqS4SUiOcj9HyaiUJ8Dvrg>.

⁵⁸ Parasidis E., Kesselheim A. S., *Assessing The Legality Of Mandates For Vaccines Authorized Via An Emergency Use Authorization*, HEALTH AFFAIRS (Feb. 16, 2021), <https://www.healthaffairs.org/doi/10.1377/hblog20210212.410237/full/>.

⁵⁹ Richard Luscombe, *Emergent chief sold \$10m in stock before company ruined 15m Covid vaccines*, THE GUARDIAN (Apr. 26, 2021), <https://www.theguardian.com/business/2021/apr/26/emergent-biosolutions-robert-kramer-stock-covid-vaccines-error>.

deviations from acceptable manufacturing standards for vaccines.

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		CDER/OCBQ 1401 Rockville Pike, HFM-604, Suite 200N Rockville, MD 20852 (301) 827-6191	
NAME OF INDIVIDUAL TO WHOM REPORT ISSUED TO: ROBERT G. KRAMER		PERIOD OF INSPECTION 10/10-26/00	C.F. NUMBER 1873886
TITLE OF INDIVIDUAL ROBERT G. KRAMER / CHIEF OPERATING OFFICER		TYPE OF ESTABLISHMENT INSPECTED Vaccine/Blood Products Manufacturer	
FIRM NAME BioPort Corporation		NAME OF FIRM, BRANCH OR UNIT INSPECTED same	
STREET ADDRESS 3500 N. Martin Luther King, Jr. Blvd.		STREET ADDRESS OF PREMISES INSPECTED same	
CITY AND STATE (Zip Code) Lansing, MI 48909		CITY AND STATE (Zip Code) same	
DURING THE INSPECTION OF YOUR FIRM WE OBSERVED:			
1. The design and construction of the filling suite (Rms 307, 308, 309), environmental monitoring, cleaning, and employee practices do not assure sterility of products filled in the suite, in that,			

51. Today, Emergent BioSolutions, despite apparent FDA oversight, shipped out unauthorized bulk COVID vaccine ingredients for finishing and filling. Emergent BioSolutions shipped those ingredients to another entity, and the shipments eventually reached buyers in at least four other countries, according to the *New York Times*.⁶⁰ The FDA halted distribution in the U.S. and cited quality deviations⁶¹ that mirrored those that American servicemembers witnessed 20 years ago with the anthrax vaccine.⁶² People need to be informed about these manufacturing deviation patterns given the importance and wide use of these products.

52. States may lawfully mandate certain vaccines. But that is not the case for investigational, unapproved EUA medical products. The preemption doctrine,⁶³ based on the Supremacy Clause of the U.S. Constitution, Article VI., § 2,⁶⁴ requires that the federal requirements for informed consent supersede state laws and regulations that may violate EUA provisions. The FDA should support, defend and enforce federal laws that govern biologics,

⁶⁰ Chris Hamby, *Baltimore Vaccine Plant's Troubles Ripple Across 3 Continents*, THE NEW YORK TIMES (May 6, 2021), <https://www.nytimes.com/2021/05/06/world/baltimore-vaccine-countries.html>.

⁶¹ FDA, HHS, Form FDA 483, Inspectional Observations (Apr. 20, 2021), <https://www.fda.gov/media/147762/download>.

⁶² Historic FDA Form 483 Deviation Report Documenting that “The manufacturing process for Anthrax Vaccine is not validated.” <https://nebula.wsimg.com/30662205620a26a4b21274dc49888891?AccessKeyId=0BA19F97E21CB8613CD7&disposition=0&alloworigin=1>.

⁶³ *Preemption*, CORNELL LAW SCHOOL, Legal Information Institute, <https://www.law.cornell.edu/wex/preemption>.

⁶⁴ U.S. Const. art. VI., § 2, “This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.” <https://www.archives.gov/founding-docs/constitution-transcript>.

including EUA products. The option to refuse COVID vaccines is codified in federal law, and President Biden has affirmed this, saying, “I don't think it [vaccination against COVID] should be mandatory. I wouldn't demand it to be mandatory.”⁶⁵

H. Conclusion to Statement of Grounds

53. The FDA’s mission is “protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products.”⁶⁶ President Roosevelt’s signing of the Federal Food, Drug, and Cosmetic Act (FDCA) closed many safety and efficacy loopholes and improved the landscape of consumer protection forever.⁶⁷ The 1962 Harris-Kefauver amendment⁶⁸ set in motion regulatory standards for biologics licensure that require proven efficacy, and the 1972 review sought to ensure proof of efficacy and no misbranding for biologics. These historic advances require reflection. The preamble to the 1972 review stated, “The importance to the American public of safe and effective vaccines...and other biological products cannot be overstated.”⁶⁹

54. Biologics, as with all drugs and devices, must have adequate directions for use and be proven safe and effective before FDA approval and licensure. The FDA erred with the anthrax vaccine, and it took a Citizen Petition⁷⁰ and federal court decision to make the FDA comply with the FDCA.⁷¹ At other times, the FDA has upheld its mission without prompting to make tough regulatory rulings, as the Supreme Court has acknowledged.⁷² With this Petition, we look forward

⁶⁵ Julia Manchester, *Biden: Coronavirus vaccine should not be mandatory*, THE HILL (Apr. 12, 2021), <https://thehill.com/homenews/campaign/528834-biden-coronavirus-vaccine-should-not-be-mandatory>.

⁶⁶ FDA, *What We Do*; <https://www.fda.gov/about-fda/what-we-do#mission>.

⁶⁷ FDA, *80 Years of the Federal Food, Drug, and Cosmetic Act* (Nov. 7, 2018), <https://www.fda.gov/about-fda/fda-history-exhibits/80-years-federal-food-drug-and-cosmetic-act>.

⁶⁸ FDA, *Kefauver-Harris Amendments Revolutionized Drug Development* (Oct. 9, 2012), <https://www.fda.gov/consumers/consumer-updates/kefauver-harris-amendments-revolutionized-drug-development>.

⁶⁹ HHS, FDA, *Biological Products March 1936-March 1978*, Preamble, p. 56, [37 Fed. Reg. 16679](https://www.federalregister.gov/documents/1978/03/30/37-fed-reg-16679).

⁷⁰ Citizen Petition, FDA Docket 01P-0471/CP1, <https://img1.wsimg.com/blobby/go/4fa7f468-a250-4088-926e-3c56a998df1f/downloads/citizen%20petition%20ava%20rempfer%20dingle.pdf?ver=1620969217312>, and Response thereto, https://downloads.regulations.gov/FDA-2001-P-0119-0003/attachment_1.pdf.

⁷¹ *Doe # 1 v. Rumsfeld*, 297 F. Supp. 2d 119, 135; see par. F, reference to Citizen Petition, FDA docket 01p-0471, <https://nebula.wsimg.com/2617051f041708e6b5335b6c885478d7?AccessKeyId=0BA19F97E21CB8613CD7&disposition=0&alloworigin=1>.

⁷² U.S. Reports: *Weinberger v. Hyson, Westcott & Dunning*, 412 U.S. 609 (1972), <https://tile.loc.gov/storage-services/service/ll/usrep/usrep412/usrep412609/usrep412609.pdf>.

to the FDA’s appropriate, tough regulatory action to bring its COVID vaccine regulations and guidance into line with federal law.

55. Although EUA law is relatively recent, we ask the FDA to be ever cognizant of its longstanding, statutory mission and duty to protect the public health and to ensure that the American public receives only safe and effective vaccines. Most Americans are not aware of the strict compliance requirements for EUA COVID vaccines nor do they know that these biologics are “investigational” and “unapproved medical products.”⁷³ They do not know that the FDA has not fully approved these vaccines as safe and effective under the FDCA. The reason Americans are unaware is because the FDA has failed to provide and enforce accurate public messaging. Reversing this trend is imperative; the FDA must comply with law.

56. Acting on this Citizen Petition will enhance the FDA’s credibility with the public. Given the obvious safety, effectiveness, labeling and branding concerns over COVID vaccines detailed above, along with anticipated comments on this docket, we respectfully appeal to the FDA to implement the actions requested in this Petition.

III. ENVIRONMENTAL IMPACT

57. The undersigned hereby state 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. §§ 25.30 and 25.31.

IV. ECONOMIC IMPACT

58. Economic impact information will be submitted upon request of the Acting Commissioner.

V. CERTIFICATION

59. The undersigned certify that, to their best knowledge and belief, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioners that are unfavorable to the Petition.

Respectfully submitted,

/s/ Meryl Nass
Meryl Nass, MD, Scientific Advisory Board
Member

/s/ Robert F. Kennedy, Jr.
Robert F. Kennedy, Jr., Board Chair and
Chief Litigation Counsel

⁷³ FDA, *Emergency Use Authorization for Vaccines explained* (updated Nov. 20, 2020), <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained>.