Electronic Submission

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

CITIZEN PETITION

January 19, 2022

The undersigned submits this petition under 21 CFR 10.30 and related relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request the Commissioner of Food and Drugs immediately execute the items listed below under "Actions Requested" for the protection of the vulnerable subpopulations of pregnant women, fetuses and children, per 45 CFR 46.

I. ACTIONS REQUESTED

1) Revoke all Covid-19 vaccine Biologics License Application (BLA) approvals and emergency use authorizations (EUA) for all pediatric subgroups, ages 0 to 17.
2) Add Pregnancy as a Contraindication for all Covid-19 vaccine BLAs and EUAs.
3) Immediately suspend all ongoing clinical trials for all pediatric and pregnant subpopulations.
4) Add pregnancy and pediatric exclusion criteria for all ongoing or planned Covid-19 vaccine clinical trials.

II. STATEMENT OF GROUNDS

Per 45 CFR 46, Subparts B and D, additional protections are afforded to the "vulnerable" subpopulations of pregnant women, fetuses and children if participating in research meeting these criteria:[1,2,3,4]

- ✓ Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?
- ✓ Does the research involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens?
- ✓ Is the research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that

takes appropriate administrative action to make the policy applicable to such research?

Clearly the first two criteria would apply to any ongoing or planned covid-19 vaccine clinical trials:

- ✓ Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?
- ✓ Does the research involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens?

Moreover, if clinical trials in pregnant and pediatric patients were previously executed without proper legal protections, any current EUA or BLA could not be supported and would need to be revoked for these same subgroups.

The third criterion applies to any federally run or funded research (for example, United States Department of Health and Human Services (HHS), Centers for Disease Control and Prevention (CDC), The National Institutes of Health (NIH), Food and Drug Administration (FDA), Biomedical Advanced Research and Development Authority (BARDA)) OR research subject to federal regulation:

- ✓ Is the research involving human subjects conducted, supported, or otherwise subject to regulation by any Federal department or agency that takes appropriate administrative action to make the policy applicable to such research?

The HHS has defined "research subject to regulation" (and similar terms) as “intending to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the FDA).”[5]

In addition to submitting an EUA, all three manufacturers of currently approved (BLA) or authorized (EUA) covid-19 vaccines submitted an Investigational New Drug application (IND), thus subject to federal regulation (investigational product regulations): Pfizer Inc. IND number 19736; ModernaTX, Inc. IND number 19745; Janssen Biotech, Inc. IND number 22657.[6,7,8]

Moderna and Janssen Pharmaceuticals received direct funding from the federal government to support their vaccine research and development.[9] Pfizer/BioNTech reportedly “participated in [Operation Warp Speed] through federal purchase of doses only.”[9] Still, the July 2020 advance purchase contract between the United States and Pfizer for future doses of the vaccine was reportedly “enough to help expedite the clinical trials and justify reserving and

investing at risk in production capacity at three US manufacturing facilities."[10,11] In essence, Pfizer's research was supported financially at a federal level. Moreover, the NIH website clearly states their supportive role in the research and development of Pfizer's vaccine: "NIH's ongoing research allowed for BioNTech/Pfizer to quickly develop a vaccine and bring it to market based on NIH technologies," and "Comirnaty was developed from technology licensed from the NIH."[12,13]

Additionally, when one searches clinicaltrials.gov for "covid+ vaccine + BNT162b2 + pfizer", funded by NIH or "Other U.S. Federal agency," multiple trials appear, including one for healthy children aged 5 to 17, NCT04761822, run by the National Institute of Allergy and Infectious Diseases (NIAID), a division of NIH, and using Pfizer-BioNTech COVID-19 Vaccine as an intervention.[14,15] It is apparent that ongoing Pfizer vaccine trials are clearly "conducted or supported" by our federal government.

The Moderna and Janssen COVID-19 vaccines under emergency use authorization (EUA) are still being studied as "investigational vaccine[s]" as are the Pfizer/BioNTech vaccines in children 15 years old and younger.[6,7,8]In spite of unmet criteria under 45 CFR 46, the Pfizer/BioNTech vaccine was given BLA approval for pregnant women and children aged 16-17.[16] In any event, at the current time, the BLA approved "COMINARTY products are not orderable at this time" in the United States--only the "investigational vaccine" is available.[17,18,19] Per 45 CFR 46, current authorizations and approvals for these subgroups need to be revoked immediately.

The below protective criteria set forth in 45 CFR 46 have never been met for pregnant women, fetuses and children, resulting in "serious concerns about subject safety."[20]

Rights Afforded under 45 CFR 46	**What has occurred/is occurring**
"46.204 Research involving pregnant women or fetuses. Pregnant women or fetuses may be involved in research if all of the following conditions are met: (a) Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses"[3]	Per current Fact Sheets/Package Insert, for each vaccine, only a single rat or rabbit developmental toxicity study has been performed.[21-24] "Available data on [name of company] COVID-19 Vaccine/COMIRNATY administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy."[21-24]
"46.406 Research involving greater than minimal risk* and no	Research involving greater

prospect of direct benefit to individual subjects [children], but likely to yield generalizable knowledge about the subject's disorder or condition. HHS will conduct or fund research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject, only if the IRB finds that: (a) The risk represents a minor increase over minimal risk;** (b) The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations; (c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition;[4] **Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.[1] **Criteria for "minor increase over minimal risk" should include the following: (a) The procedure does not meet minimal risk criteria (b) The investigator has presented sufficient evidence about the procedures, population, and the qualifications of research personnel to assure the IRB that: • The increase in the probability and magnitude of harm is only slightly more than minimal risk. • Any potential harms associated with the procedure will be transient and reversible in consideration of the nature of the harm (restricted to time of procedure or short post-experimental period). • There is no or an extremely small probability that participants will experience as severe the potential pain, discomfort, stress, or harm associated with the	than minimal risk and no prospect of direct benefit (PDB) to an individual, healthy child seems paradoxical. The Office for Human Research Protections (OHRP) gives an example of research in this category: "For example, it would be reasonable to approve a malaria vaccine safety protocol under 46.406 on healthy children living in an area where malaria is endemic (presuming the risk was determined to be no more than a minor increase over minimal risk). In this case the condition would be living in an environment where the risk for malaria is high."[25] "Although the children are healthy they have the condition of being a child at risk for the common disease under study."[25] But unlike malaria, COVID-19, while "common," rarely manifests as severe disease in children, the infection fatality rate (IFR) "near zero."[26,27] This example also presumes risk to be "no more than a minor increase over minimal risk," i.e., "only slightly more than minimal risk." Anaphylaxis warnings alone, for all three vaccines, automatically should prohibit pediatric research in this category.[21-24] Clearly, as "The significant known and potential risks and benefits of [name of company] COVID-19 Vaccine, and the extent to which such risks and benefits are unknown," "potential

procedure.[25]	harms" under 46.406 are also unknown.[22-24] Regarding Comirnaty's stated risks of myocarditis and percarditis, "Information is not yet available about potential long-term sequelae."[21] "Administration of experimental drug products is neither "normal" or "routine" and thus is not "minimal" risk."[28]

III. ENVIRONMENT IMPACT

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

IV. ECONOMIC IMPACT

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

V. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,
Carol Taccetta, MD, FCAP
Carol Taccetta, MD, FCAP

VI. REFERENCES

1 https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html

2 https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html#c1

3 https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-b/index.html

4 https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html

5 https://www.fda.gov/science-research/good-clinical-practice-educational-materials/comparison-fda-and-hhs-human-subject-protection-regulations

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8 https://www.fda.gov/media/146303/download

9 https://crsreports.congress.gov/product/pdf/IN/IN11560

10 https://www.medicalcountermeasures.gov/newsroom/2020/pfizer/

11 https://www.piie.com/blogs/trade-and-investment-policy-watch/heres-how-get-billions-covid-19-vaccine-doses-world

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25 https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2005-july-28-letter-appendix-b/index.html

26https://services.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/

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28 https://www.fda.gov/media/84865/download