

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

June 3, 2021

VIA COMMENT ON DOCKET FDA-2021-N-0458

Re: *June 10, 2021 VRBPAC Meeting and ICAN Citizen Petition*

Dear Members of VRBPAC:

Attached is a Petition filed on May 28, 2021 by Del Bigtree and the Informed Consent Action Network (“ICAN”) requesting that the United States Food and Drug Administration (“FDA”) require certain minimal clinical trial data to be submitted to the FDA before approving any COVID-19 vaccine. The concerns raised in the Petition, including with regard to pediatric populations, demand your immediate attention.

ICAN respectfully requests that you review this Citizen Petition prior to the June 10, 2021 meeting to discuss use of COVID-19 vaccines in pediatric populations. We, as counsel to the petitioners, remain available to answer questions and provide any relevant additional information.

Very truly yours,



Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Caroline Tucker, Esq.
Jessica Wallace, Esq.

Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

VIA ELECTRONIC FILING

May 28, 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 a Citizen Petition filed by Del Bigtree and the Informed Consent Action Network (“ICAN”) regarding further data to be submitted to the United States Food and Drug Administration before any approval of a COVID-19 vaccine which raises exigent concerns that demand your immediate attention.

ICAN looks forward to receiving a timely decision. We, as counsel to the petitioners, remain available to answer questions and provide any relevant additional information.

Very truly yours,

/s/ Aaron Siri

Aaron Siri
Elizabeth Brehm
Jessica Wallace
SIRI & GLIMSTAD LLP
200 Park Avenue
17th Floor
New York, NY 10166
Telephone: (212) 532-1091
Facsimile: (646) 417-5967
Email: aaron@sirillp.com

200 Park Avenue, Seventeenth Floor, New York, NY 10166
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

VIA ELECTRONIC FILING

May 28, 2021

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

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

PETITION FOR ADMINISTRATIVE ACTION REGARDING FURTHER DATA TO BE SUBMITTED TO THE FDA BEFORE APPROVAL OF ANY COVID-19 VACCINE :
: **Docket No.** _____
:
:
:

CITIZEN PETITION

This petition for administrative action is submitted on behalf of Informed Consent Action Network¹ (“**Petitioner**”) pursuant to 21 C.F.R. § 10.30 and related relevant provisions of the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act to request that the Commissioner of Food and Drugs (the “**Commissioner**”) require that the sponsor produce the data outlined in the “Actions Requested” section below before approval of any COVID-19 vaccine.

Despite safety concerns and concerns about the durability of immunity from these products, these vaccines have been and likely will continue to be mandated indiscriminately for groups that, for different reasons, have essentially zero or close to zero risk of serious complications from COVID-19. To date, multiple private and public employers have mandated their employees to receive a COVID-19 vaccine under threat of termination. Additionally, numerous public and private universities have mandated their students to receive the vaccination as a condition of enrollment. These mandates are one size fits all and fail to take into account any critical information about the vaccine recipients age, comorbidities, risk of serious disease or death from COVID-19, and previous infection.

¹ Including, but not limited to, on behalf of its members, including those who work for Petitioner.

Because of the compelling need to ensure the safety and efficacy of any COVID-19 vaccine licensed by the FDA, including whether or not risks do not outweigh benefits, particularly in certain age categories, and in the face of indiscriminate mandates, and to allow Petitioner the opportunity to seek emergency judicial relief should the Commissioner deny its Petition, **Petitioner respectfully requests that FDA act on the instant Petition by June 18, 2021.**

A. ACTION REQUESTED

1. It is hereby requested that the FDA require that the following data be submitted to the FDA for review before approving any vaccine for COVID-19:

- a. Documentation of adverse events and reactions for *at least* twenty-four months for adults, thirty-six months for children and sixty months for infants and toddlers, or such longer duration as appropriate, and in no event ending prior to the subject reaching eight years of age;
- b. Data demonstrating that safety risks do not outweigh potential benefits for any age for which the vaccine is approved;
- c. Data reflecting that the vaccine does not cause DNA integration and germline transmission;
- d. Data on the safety and efficacy of the vaccine in individuals who currently have or have had a SARS-CoV-2 infection;
- e. Results of reproductive testing including proper immunological studies looking at potential reactivity of the vaccinated against the Syncytin 1 and 2 proteins;
- f. PCR tests used to qualify an event of COVID-19 for a trials' endpoint use a maximum of 28 amplification cycles; and
- g. Accurate data reflecting actual risk reduction and number needed to vaccinate to prevent one case of COVID-19.

B. STATEMENT OF GROUNDS

2. The current study designs for the Phase III clinical trials for the leading COVID-19 vaccines, including Moderna's, Pfizer's, and Janssen's, are inadequate to assess safety and efficacy.²

² NCT04368728 (Pfizer) available at <https://www.clinicaltrials.gov/ct2/show/NCT04368728>; NCT04470427 (Moderna) available at <https://www.clinicaltrials.gov/ct2/show/NCT04470427>, and NCT04505722 (Janssen) available at <https://www.clinicaltrials.gov/ct2/show/NCT04505722>.

3. Petitioner will suffer irreparable harm if the action requested herein is not granted because once the FDA approves a COVID-19 vaccine, states are expected to make this product mandatory, as numerous employers, universities, and schools already have. 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.”³ To that end, at least two bills have been introduced in New York requiring COVID-19 vaccines for all post-secondary students and for citizens of the state.⁴ Hence, without the FDA assuring proper safety and efficacy trials of the vaccine now, Petitioner will not have the opportunity to object to receiving the vaccine based on deficient clinical trials later.

4. Furthermore, if the vaccine is approved without an appropriate safety review, ethical considerations prevent a placebo-controlled study post-licensure, thereby preventing any such study from ever occurring. In fact, ethical considerations have already led to most trial participants crossing over from control to active arms of the trials. This is especially troubling because when parents assert that an approved vaccine injured their child, the FDA and CDC regularly deny these assertions by stating that no cause and effect has been established between the vaccination and the alleged injury. But as the FDA and CDC are well aware, without a placebo-controlled trial, cause and effect is very difficult and often impossible to establish.⁵

5. The public interest also weighs strongly in favor of the requested relief because conducting adequate safety reviews, DNA integration and germline transmission testing, safety testing for the infected and convalesced, reproductive testing, and adequate efficacy assessments (i) will comport with the best scientific practices, (ii) increase public confidence in the safety and efficacy of a product expected to be mandated, and (iii) not doing so will have the opposite result in that it will create uncertainties regarding the safety of COVID-19 vaccines and all other vaccines. A thorough evaluation of already-existing post-authorization data is critical before licensure.

6. Once a vaccine is approved, the opportunities to conduct these studies will have been missed. Three COVID-19 vaccines are currently widely available pursuant to emergency use authorization. There are no barriers for individuals who wish to be vaccinated to obtain the vaccine. Therefore, there is no adequate reason or benefit to rush through an FDA approval. On

³ https://nysba.org/app/uploads/2020/05/HealthLawSectionTaskForceCOVID-19Report_5.13.20-1.pdf (last visited August 11, 2020).

⁴ See New York bills S6495 available at <https://www.nysenate.gov/legislation/bills/2021/S6495> and A11179 available at <https://www.nysenate.gov/legislation/bills/2019/A11179>.

⁵ See <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 August 11, 2020); see also <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 August 11, 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 August 11, 2020).

the other hand, the risks of approving this vaccine and later having to address a serious safety or efficacy issue that was missed before licensure could have serious consequences.

a. Long term safety review in the face of unblinded trials with no existing placebo groups

7. At a minimum, all adverse events and reactions should be documented for each subject post-vaccination for *at least* twenty-four months for adults, thirty-six months for children and sixty months for infants and toddlers, or such longer duration as appropriate, and in no event end prior to the subject reaching eight years of age. These minimal timeframes provide an opportunity to capture adverse and non-specific health issues that any COVID-19 vaccine may cause before it is approved.

8. Especially given the fact that the placebo control groups have been vaccinated in each of the trials,⁶ safety in all participants must be reviewed for a significant period of time in order to determine the risks and any potential causality. Additionally, the FDA declined to require increased sample size as requested by Petitioner⁷ and declined to broaden the categories of adverse events that were tracked as requested by Petitioner.⁸ In light of these factors, the only way to adequately capture any rare, serious, and/or long-term safety effects is to require the manufacturer to conduct such studies prior to approval and during Phase III of the clinical trials.

9. To date, the three authorized COVID-19 vaccines were granted emergency use authorization after safety data was known for only a median of 7-8 weeks, depending on the vaccine. One COVID-19 vaccine manufacturer has begun the process of submitting its Biologics License Application after documenting safety data for only 6 months.⁹ Others are likely to follow suit.

10. Given that most clinical trial participants for the authorized COVID-19 vaccines have crossed over to active treatment, despite the FDA's previous statements about the importance of unblinded, placebo-controlled studies,¹⁰ the FDA must demand adequate safety data before licensure to ensure the long-term safety of the products.

⁶ For example, Moderna has made public that "As of April 13, all placebo participants have been offered the Moderna COVID-19 Vaccine and 98% of those have received the vaccine." This means the trial is unblinded and there is no more placebo group. <https://investors.modernatx.com/news-releases/news-release-details/moderna-provides-clinical-and-supply-updates-covid-19-vaccine>.

⁷ <https://www.regulations.gov/search?filter=Docket%20No.%202020-P-1601>.

⁸ *Id.*

⁹ See <https://www.nasdaq.com/articles/pfizer-biontech-initiate-bla-process-with-fda-for-the-covid-19-mrna-vaccine-quick-facts>.

¹⁰ Dr. Fink, the Deputy Director for Clinical Review in the Division of Vaccines and Related Products Applications, Office of Vaccines in CBER in the FDA, stated at an October 22, 2020 VRBPAC meeting:

In our EUA guidance released earlier this month, we stated that CBER does not consider issuance of an EUA for a COVID-19 vaccine in and of itself as grounds to immediately unblind ongoing clinical trials and offer vaccine to placebo recipients. The reason why we have made this statement is that a COVID-19 vaccine made available under an EUA will still remain investigational. As I've

11. According to a BMJ article, “An approval based on six months of data would represent one of the fastest for a novel vaccine in FDA history. Among the six ‘first in disease’ vaccines approved by the FDA since 2006, pre-licensure pivotal trials were a median of 23 months in duration, according to a recent analysis.”¹¹

12. Three manufacturers’ COVID-19 vaccine protocols call for approximate two-year long clinical trials. The FDA has not made clear what minimum period of follow-up it will require before approving any of these vaccines. However, other groups including a World Health Organization group which included FDA regulators, have called for a minimum of a years’ data.¹²

13. Compounding the concerns related to inadequate clinical trial data is the well-known fact that safety surveillance during the post-marketing period is insufficient and unreliable and that underreporting to VAERS, specifically, is a concerning and ongoing issue.

14. An AHRQ-funded study by Harvard Medical School tracked reporting to VAERS over a three-year period at Harvard Pilgrim Health Care involving 715,000 patients and found that “fewer than 1% of vaccine adverse events are reported.”¹³ A U.S. House Report similarly stated: “Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events.”¹⁴

15. Similarly, the under-reporting of anaphylaxis cases after COVID-19 vaccine is seriously concerning, along with the overall underreporting of all adverse reactions from these vaccines. According to the CDC, “Anaphylaxis after COVID-19 vaccination is rare and occurred in approximately 2 to 5 people per million vaccinated in the United States based on events reported to VAERS.”¹⁵ This is in stark contrast to a recent study at Mass General Brigham that assessed anaphylaxis in a clinical setting after the administration of COVID-19 vaccines and found “severe

outlined... safety and effectiveness data to support an EUA may be collected under a relatively short follow up period, a median of two months following completion of the vaccination regime, much shorter if compared with data that have supported licensure of other preventative vaccines and shorter than the follow up that we would expect to support eventual licensure of a COVID-19 vaccine. Therefore, **continuation of placebo-controlled follow up after Emergency Use Authorization will be important and may actually be critical to ensure that additional safety and effectiveness data are accrued to support submission of a licensure application**... Once a decision is made to unblind an ongoing placebo controlled trial, that decision cannot be walked back. And that controlled follow up is lost forever.”

<https://www.fda.gov/media/143982/download> at 195-196 (emphasis added).

¹¹ <https://www.bmj.com/content/373/bmj.n1244>.

¹² See [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(20\)31821-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)31821-3/fulltext).

¹³ <https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>.

¹⁴ <https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf>.

¹⁵ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>.

reactions consistent with anaphylaxis occurred at a rate of 2.47 per 10,000 vaccinations.”¹⁶ This is equivalent to 50 times to 120 times more cases than what VAERS and the CDC are reporting for a condition that occurs almost immediately after vaccination and which vaccine providers are repeatedly advised to report.

16. If anaphylaxis is being underreported, consider the level of underreporting for serious adverse events that do not occur immediately after vaccination and are not easily identified. This should seriously concern the FDA as there are serious safety signals that are likely being missed and for the ones that are identified, such as anaphylaxis or CVST in conjunction with thrombocytopenia, the actual rate seen in VAERS may be only the tip of the iceberg. Ignoring and casting aside these issues in the drive to approve a COVID-19 vaccine, vaccinate the country, and promote vaccine confidence may eventually be the undoing of the very confidence the agency seeks to instill.

17. A Physician Assistant in New York brings to life the frontline perspective on underreporting to VAERS in an email the Physician Assistant sent to the FDA on April 15, 2021. The email remains unanswered:

I am writing this email with high level importance regarding what I believe is gross under reporting of possible covid 19 vaccine related adverse events/side effects/possible immune mediated adverse events. I work in a small community hospital in Upstate New York and as a medical provider and professional have taken on the responsibility for my hospital of reporting to VAERS the significant influx of patients we are seeing in our emergency room and hospital wards in the past few months with new medical problems or sudden worsening of medical problems following covid 19 vaccination. In the last 4 weeks I have reported 50 cases to VAERS and 4 possible deaths. These are only the patients I have taken care of or who were brought to my attention by ER providers or some of my colleagues and I'm sure are not all. The only reason we are starting to capture these cases is I brought awareness to our hospital that the question needs to be asked of patients when they are coming in the ER if they have recently had their covid 19 vaccination and I have volunteered to be the person for now who reports cases to VAERS.

I do not feel that hospital systems were prepared or adequately notified of this possibility or how we should be managing it. There was no notification or training about who should be reported, what should be reported and how far out post vaccination that possible immune mediated adverse events would be seen. Pfizers EUA recommends a minimum of 6 weeks post vaccination to capture this data. VAERS notes that ANY hospitalization post vaccination, infection with covid 19, inability to perform daily functions, vaccine

¹⁶ <https://jamanetwork.com/journals/jama/fullarticle/2777417>.

administration errors, deaths should be reported and that reporting is MANDATORY. If it is mandatory then why was no education sent out to hospital systems and administrators??? I've contacted the FDA, Moderna, Pfizer, our DNV/hospital accrediting body, our state health department and many hospital system leaders and physicians in my state with either no answer in regards to how we deal with this issue or a complete unawareness that this is even necessary or mandatory. Had I not taken on this task none of these cases would of been reported to VAERS. Just yesterday we had a pt in the hospital for covid 19 infection despite being 3 weeks out from both vaccines and had a nurse not contacted me her case would of gone unreported. The safety of these vaccines for the public lies with a passive reporting system that is in place, but if hospital systems and medical providers are not educated on the importance of reporting, especially an EUA product, very large volumes of problems will go unreported and the vaccines could be fully licensed for use without complete and accurate information on possible immediate and long term side effects. I reported 5 patients with deep vein thrombosis/pulmonary emboli following vaccination with Pfizer/Moderna which is the same condition the pause is currently for with the J and J vaccine. I'm sure there are many more out there I am unaware of. I have contacted 2 large tertiary hospitals within 1 hr from us and there is no system for reporting in either. A colleague of mine is seeing the same thing in her hospital and cases upon cases of patients with acute strokes, myocardial infarction, blood clots, covid 19 infection, new autoimmune conditions, arrhythmia, seizures/neurological conditions and bleeds are not being reported to VAERS or the drug companies. Every case of covid 19 is being recorded in the state but the question if infection is following vaccination is not even on the questionnaire, so the data will never be captured.

This is NOT true transparency and puts all Americans health and possible future health at risk.

Most physicians and nurses, health care staff don't even know that they should be asking patients who are getting admitted about their covid 19 vaccines and patients don't know that there possibly could be a link to their current acute medical problem and the vaccine. We will never know unless the data is captured. This issue must be addressed ASAP and I am pleading with the FDA to bring awareness of this to hospital systems as the FDA is responsible for protecting public health by ensuring the safety, efficacy and

security of human and veterinary drugs, vaccines and other biological products for human use.¹⁷

18. Despite requesting a response, the FDA has not answered this email and, in addition, this Physician Assistant now faces potential discipline at work for reporting numerous cases to VAERS. The Physician Assistant's employer "want[s] to do an internal audit on the patients reported." The employer has told the Physician Assistant that VAERS does not call for reports for emergency room patients and wants "proof that miscarriages need to be reported." The employer is asking the Physician Assistant "how long out from vaccination should we report." This Physician Assistant's experience is that an ER doctor will document the fact that a patient is there having a stroke and was vaccinated a week ago, but then the admitting doctor will omit that from the records and it is not mentioned in the patient's chart moving forward. The Physician Assistant learns the information from the nurse for the patient and then reports the case to VAERS. This Physician Assistant knows of other health care providers with the same experience at other hospitals. If this is indicative of what is happening across the country – lack of education, understanding, and use of VAERS, at best – this would explain why less than 1% of adverse events are reported to VAERS.

19. As explained before, unless and until underreporting to VAERS is addressed, it will continue to blind health agencies, medical professionals, and patients from what is really occurring in the clinic and will render true informed consent impossible. Certainly, this demands then that the safety studies conducted pre-approval take on an even more significant importance. If the safety data collected post-approval is not accurate or reliable, then the pre-approval clinical trials are the only opportunity for adequate and reliable data to be collected.

20. Even with a clear understanding of the severe underreporting to VAERS, the reports that *have* been made raise significant questions as to the safety profile of the COVID-19 vaccines. The number of reported adverse events in VAERS are enough to suggest safety signals that must be followed up on. As of May 7, there have been 3,919 reported deaths,¹⁸ 11,572 hospitalizations, and 17,190 serious adverse events. Aside from anaphylaxis and vaccine-induced immune thrombotic thrombocytopenia, the FDA has not recognized any other safety signal arising from these unprecedented numbers of serious adverse events.

21. According to Tom Shimabukuro of the CDC's COVID-19 Vaccine Task Force and his presentation to the Advisory Committee on Immunization Practices on January 27, 2021:

FDA uses data mining to identify disproportional adverse event reporting for vaccines, including COVID-19 vaccines – Identifies, with a high degree of confidence, adverse event-vaccine pairs reported **at least twice as frequently as expected for a COVID-19**

¹⁷ <https://www.icandecide.org/wp-content/uploads/2021/05/PA-email.pdf>.

¹⁸ Despite this number appearing in a VAERS database search for deaths reported following any COVID-19 vaccine, the CDC reports an even higher number. See <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html> ("VAERS received 4,647 reports of death" among people who received a COVID-19 vaccine" between December 14, 2020 and May 17, 2021.).

vaccine compared to the VAERS database – i.e., lower bound of the 90% confidence interval surrounding the empirical Bayesian geometric mean ($EB05 \geq 2$) compared to all other U.S.-licensed vaccines.¹⁹

22. Putting aside the fact that this signal/data-mining process now assumes the VAERS database reports are “normal” and only detects reports disproportionate to reports made for all other licensed vaccines, and despite its known limitations, the data in VAERS clearly shows that, of all deaths reported to VAERS since 2000, the deaths reported in 2021 make up **64.66% of the total deaths**. This means that the number of deaths reported in just over four months of 2021 following vaccination for COVID-19 alone eclipses all of the deaths reported in the prior twenty years from every vaccine on the market. This is astounding. If this does not rise to the level of a “signal,” it is unclear what ever would.

23. The FDA must explain why COVID-19 vaccine adverse events are being compared to “all other U.S.-licensed vaccines” in order to detect a signal and why the deaths reported have not created a signal to be thoroughly and immediately investigated.

24. Also troubling is that the CDC explains, with regard to reported deaths in VAERS following COVID-19 vaccination: “CDC and FDA physicians review each case report of death as soon as notified **and CDC requests medical records to further assess reports**. A review of available clinical information, including death certificates, autopsy, and medical records has not established a causal link to COVID-19 vaccines.”²⁰ However, when the BMJ asked the FDA: “In what proportion of cases have CDC/FDA staff contacted families of the deceased for further details about VAERS reports?” the FDA responded as follows:

A letter expressing condolences for the death of a family member and an explanation of what VAERS does is sent to all who report on the death of a family member. According to the reporter’s selected Communication Preference an electronic note may be sent. If no preference is specified by the time the letter is generated, a paper letter is sent. Condolence letters are only sent if the reporter is identified by visual review to be a relative.

Because the VAERS system is not designed to determine causality of adverse events, there is not a mechanism to follow-up with families for additional details. The determination of the cause of death is done by the certifying official who completes the death certificate or the pathologist who conducts the autopsy. While some reported adverse events may be caused by vaccination, others are not and may have occurred coincidentally.²¹

¹⁹ <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-01/06-COVID-Shimabukuro.pdf> at 15 (emphasis added).

²⁰ <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>.

²¹ <https://www.bmj.com/content/372/bmj.n149/rapid-responses>.

25. It remains unclear how many, if any, of the reported deaths have been followed-up on by the FDA or the CDC. Yet what is clear is the CDC’s statement that whatever review has taken place “has not established a causal link to COVID-19 vaccines.” This review may encompass 50% of the reported deaths. It may encompass 90%. Or it may be 0%. It is the FDA’s duty and responsibility to investigate every reported death and react appropriately.

26. Historically, other vaccines, such as smallpox, have been pulled from the market after significantly fewer reported deaths.²² Here, there are shocking numbers of deaths and other serious adverse events reported on a daily basis and there is no signal detected or investigated, let alone any emergency use authorizations withdrawn for any vaccines.

27. Further, the importance of capturing all potential health issues for the duration of the clinical trial can be seen in the designs of the clinical trials of numerous drugs, including for example, Enbrel²³, Lipitor²⁴, and Botox,²⁵ 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 was safety tested in a placebo-controlled trial for two years before being licensed by the FDA in 2012.²⁶ Nevertheless, despite this two year period, in February 2020 the drug was voluntarily removed from the U.S. market 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.²⁷ Especially given recent discussions of potential needed boosters or annual vaccinations for COVID-19,²⁸ these trials of drugs taken over longer periods of time become more relevant.

28. The FDA states that the length of study for phase III clinical trials is typically “1 to 4 years”²⁹ and that the duration of a clinical trial should “reflect the product and target condition.”³⁰ In accord with this guidance, and the fact that a COVID-19 vaccine will be an entirely novel product, the safety review period should be at least twenty-four months for adults, thirty-six months for children and sixty months for infants and toddlers, or such longer duration as appropriate, and in no event end prior to the subject reaching eight years of age. 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 limited in time and boosters and annual vaccines

²² See <https://wwwnc.cdc.gov/eid/article/12/1/05-1007>.

²³ See https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/103795s5503lbl.pdf (last visited August 11, 2020).

²⁴ See https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020702s056lbl.pdf (last visited August 11, 2020).

²⁵ See https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/103000s5302lbl.pdf (last visited August 11, 2020).

²⁶ See https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/022529lbl.pdf (last visited August 11, 2020).

²⁷ See <https://www.fda.gov/drugs/drug-safety-and-availability/fda-requests-withdrawal-weight-loss-drug-belviq-belviq-xr-lorcaserin-market> (last visited August 11, 2020); see also <https://www.health.harvard.edu/blog/weight-loss-drug-belviq-recalled-2020040919439> (last visited August 11, 2020).

²⁸ See, e.g., <https://www.nytimes.com/2021/04/16/world/pfizer-vaccine-booster.html>.

²⁹ <https://www.fda.gov/patients/drug-development-process/step-3-clinical-research> (last visited August 11, 2020).

³⁰ <https://www.fda.gov/media/102332/download> (last visited August 11, 2020).

are already being discussed, thereby requiring repeated injections of the product during a person's life.

29. Safety data for a median of seven to eight weeks post-vaccination was the standard for three COVID-19 vaccines to receive emergency use authorization. This was inadequate to capture serious related adverse events including anaphylaxis and vaccine induced Thrombosis with Thrombocytopenia Syndrome. Likewise, 6 months' worth of data will also be inadequate to capture any adverse events that may occur outside of that time frame caused by these novel vaccines. The FDA must require data for at least the full Phase III clinical trial duration originally provided for in each sponsor 'clinical trial protocol.

b. Data demonstrating that safety risks do not outweigh potential benefits for each approved age group

30. The above section discusses only a fraction of the post-marketing data already available. As is needed for reported deaths, all other serious side effects must be thoroughly investigated for potential causation. For example, clotting and coagulopathies are frequently reported following COVID-19 vaccination. These events and whether they can be attributed to tropisms of the spike protein must be fully investigated before licensure.

31. Only after a full safety profile is analyzed can a true weighing of benefits versus risks take place. Over a year after the start of the pandemic, those at highest risk of severe COVID-19 disease or death have been identified.

32. The following chart depicts COVID-19 infection fatality rates (in percentages) by sex and age group as calculated by the authors of *Age-specific morality and immunity patterns of SARS-CoV-2*:³¹

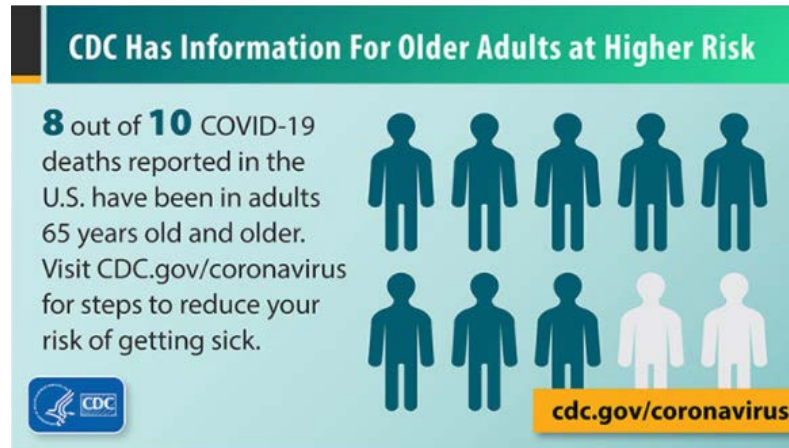
| Age group (years) | Male | Female | Mean |
|-------------------|-------|--------|-------|
| 0-4 | 0.003 | 0.003 | 0.003 |
| 5-9 | 0.001 | 0.001 | 0.001 |
| 10-14 | 0.001 | 0.001 | 0.001 |
| 15-19 | 0.003 | 0.002 | 0.003 |
| 20-24 | 0.008 | 0.005 | 0.006 |
| 25-29 | 0.017 | 0.009 | 0.013 |
| 30-34 | 0.033 | 0.015 | 0.024 |
| 35-39 | 0.056 | 0.025 | 0.040 |
| 40-44 | 0.106 | 0.044 | 0.075 |
| 45-49 | 0.168 | 0.073 | 0.121 |
| 50-54 | 0.291 | 0.123 | 0.207 |
| 55-59 | 0.448 | 0.197 | 0.323 |
| 60-64 | 0.595 | 0.318 | 0.456 |
| 65-69 | 1.452 | 0.698 | 1.075 |
| 70-74 | 2.307 | 1.042 | 1.674 |

³¹ See <https://www.nature.com/articles/s41586-020-2918-0>.

| | | | |
|-------|--------|-------|-------|
| 75-79 | 4.260 | 2.145 | 3.203 |
| 80+ | 10.825 | 5.759 | 8.292 |

This data makes clear that the risks of death even after contracting SARS-CoV-2 are extremely low, especially for most age groups younger than 65 years old. For example, according to this article, only 6 out of 100,000 20-24 year-olds who contract COVID-19 will likely die from it.

33. The CDC agrees with this data:³²



34. The chances of younger individuals contracting the virus and experiencing anything other than mild disease is also incredibly rare. The CDC acknowledges that “Most children with COVID-19 have mild symptoms or have no symptoms at all.”³³

35. Given the stark differences between chance of infection and chance of severe disease and death being so closely tied with age and underlying conditions, the benefit/risk analysis should differ for these different groups as well. The FDA must demand data from the manufacturers proving that the potential benefit of any vaccine outweighs the minimal risk to most age groups of COVID-19.

c. DNA integration and germline transmission tests

36. Despite the CDC’s assertion that “[t]he genetic material delivered by the viral vector does not integrate into a person’s DNA,”³⁴ “studies have shown that replication-incompetent adenoviral vectors randomly integrate into host chromosomes at frequencies of 0.001-1% of infected cells.”³⁵

³² <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/older-adults.html>.

³³ <https://www.cdc.gov/coronavirus/2019-ncov/daily-life-coping/children/symptoms.html>.

³⁴ <https://www.cdc.gov/vaccines/covid-19/hcp/viral-vector-vaccine-basics.html>.

³⁵ <https://pubmed.ncbi.nlm.nih.gov/12109211/>.

37. Another study indicates that segments of SARS-CoV-2 viral RNA can become integrated into human genomic DNA and that this newly acquired viral sequence is not silent, meaning that these genetically modified regions of genomic DNA are transcriptionally active (DNA is being converted back into RNA).³⁶

38. It is imperative that the manufacturers are required to submit data to show that viral integration into human DNA is not happening and cannot happen with the use of their COVID-19 vaccine.

39. Relatedly, according to the European Medicines Agency, viral or non-viral vectors may also be associated with a risk of vertical germline transmission of vector DNA.³⁷ While “currently there are no non-invasive means to monitor women for germline transmission,” male participants in the clinical trials can and should be monitored.³⁸

40. “Since one cycle of spermatogenesis takes approximately 64-74 days in man, the timing of the appearance of transduced progenitor daughter cells in the semen is predictable. This can be taken into account in the planning of germline transmission tests as part of clinical trial protocols.”³⁹ Further, “this can be accomplished by investigating sperm at different time points taking into account the duration of spermatogenesis...The earlier the differentiation stage at which germline transmission takes place in the spermatogenesis process, the greater the risk that the germline alteration is permanent and the greater will be the fraction of transduced sperm cells.”⁴⁰

41. The FDA has stated that “Petitioner has not provided, and we are not aware of, data suggesting distribution of this vector to the gonads”⁴¹ while ignoring the conclusion of the European Medicines Agency and others that viral and non-viral vectors may be associated with a risk of vertical germline transmission of vector DNA. Moreover, Petitioner concedes that it has not, as it is not able to, provide data suggesting distribution of the vector within viral vector COVID-19 vaccines to the gonads. Petitioner therefore requests that the agency require the manufacturer, which would have the capability of doing so, to determine whether or not there is distribution to the gonads. In the event that there is evidence of same occurring, then Petitioner would request full testing for germline transmission. If the manufacturer is not required to do this testing and if the agency does not require it for full licensure, then there is likely to be an absence of any evidence determining whether or not there is a distribution of the vector within the vaccine to the gonads and therefore a need for full germline testing. The manufacturer is in the best position to gather this data.

³⁶ <https://www.biorxiv.org/content/biorxiv/early/2020/12/13/2020.12.12.422516.full.pdf>.

³⁷ See https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-non-clinical-testing-inadvertent-germline-transmission-gene-transfer-vectors_en.pdf (last visited August 11, 2020).

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ See Denial of Citizen Petition for Siri & Glimstad at 22, available at <https://www.regulations.gov/document/FDA-2020-P-2096-0009>.

42. Requiring these tests would add very little burden to the sponsor and will provide comfort that the vaccine is not having deleterious effects on human DNA or on the male germline.

d. Vaccination in individuals who currently have or have previously had SARS-CoV-2 infections and potential dangers arising from same

43. Some medical professionals have opined that vaccinating individuals infected with SARS-CoV-2 is potentially harmful.⁴² It has become well known that many people infected with SARS-CoV-2 are asymptomatic and may not be aware that they are currently infected. Therefore, screening for infection or antibodies prior to vaccination has been suggested, however the FDA has not required this to date. Unless the convalescent will not be included as part of the licensure of the vaccine, data regarding the actual risks and benefits of vaccinating during or following SARS-CoV-2 infection is critical and should be required before FDA approval.

44. Numerous medical professionals have opined that if an individual who is vaccinated has viral antigens present in any tissues in the body, the antigen specific immune response triggered by the vaccine will target those tissues and will cause inflammation and damage at those locations and well beyond the local site of vaccination.

45. If viral antigens are present in the vascular endothelium or other layers of the blood vessel in the vaccinated, especially in the elderly population and others with cardiovascular disease, the antigen specific immune response incited by the vaccine may likely damage the vascular endothelium. This damage to the endothelium caused by the vaccine may cause blood clot formation with the potential for major thromboembolic complications.

46. Recent data from the UK reflects that individuals with prior infections have the most intense vaccine-related adverse reactions.⁴³

47. There are some very prominent examples of death and complications from COVID-19 vaccination of the recently infected. These examples include Dr. J. Barton Williams of TN, Mr. Christopher Sarmiento of NM, and Ms. Brandy Parker-McFadden of TN.⁴⁴ These people had prior infections and developed serious post-vaccine complications and are only three prominent examples of what is likely a far wider issue.

48. The FDA should require data to determine the safety profile of vaccinating individuals who have already had and who are currently infected with SARS-Co-V-2 before approving any COVID-19 vaccine.

⁴² See <https://noorchashm.medium.com/a-letter-of-warning-to-fda-and-pfizer-on-the-immunological-danger-of-covid-19-vaccination-in-the-7d17d037982d>.

⁴³ <https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1>.

⁴⁴ <https://www.wkrn.com/news/nashville-woman-unable-to-walk-claims-pfizer-covid-19-vaccine-is-to-blame/>.

e. Reproductive testing including proper immunological studies looking at potential reactivity of the vaccinated against the Syncytin 1 and 2 proteins

49. Close conformational and functional similarity of the SARS CoV-2 spike protein to the Syncytins has been observed. Syncytins are proteins essential for reproduction and this similarity could elicit a cross-reactive auto-immune reaction targeted to these proteins which could impact reproductive endpoints. This is supported by the observations that there is impaired spermatogenesis in some during and following the natural COVID-19 infection as well as the localization of spike protein to testes.⁴⁵ Additionally, a placental pathology has been observed in some COVID-infected women reminiscent of pre-eclampsia, and Syncytin 1 knockout mice exhibit similar placental pathology coupled with the inability to carry to full term.⁴⁶ There have also been noted a significant number of miscarriages that have been reported in the VAERS reporting system following vaccination for COVID-19 to date. These all support the premise that the COVID-19 vaccines which direct the body to make the SARS-CoV-2 spike protein may be causing reproductive harm either directly through spike protein or through a cross-reaction mechanism with the endogenous Syncytins.

50. This issue of a potential for cross-reaction to the Syncytins through the use of COVID-19 vaccines was raised by scientists over a year ago.⁴⁷ Before approval, the FDA should require data from laboratory immunological studies which demonstrate that this potential has been experimentally, rather than theoretically, addressed. These types of assays are quite easy to conduct and would not take a significant amount of time to carry out.

f. PCR tests used to qualify an event of COVID-19 for a trials' endpoint use a maximum of 28 amplification cycles

51. Petitioner previously requested that the FDA ensure that the PCR tests used to qualify an event of COVID-19 for trials' endpoints use a maximum of 24 amplification cycles.⁴⁸ Petitioner explained that there are serious issues associated with the trials' use of the PCR test as the linchpin in determining whether a participant has COVID-19 disease. PCR tests are qualitative

⁴⁵ See <https://beta.documentcloud.org/documents/20404854-histopathology-and-ultrastructural-findings-of-fatal-covid-19-infections-on-testis>.

⁴⁶ See Shin Qiao et al. 2017 Inducible knockout of Syncytin-A gene leads to extensive placental vascular deficiency, implications for preeclampsia. Clin Chim Acta Nov. 474:137-146, available at <https://www.sciencedirect.com/science/article/abs/pii/S0009898117303686>.

⁴⁷ See https://dryburgh.com/wp-content/uploads/2020/12/Wodarg_Yeadon_EMA_Petition_Pfizer_Trial_FINAL_01_DEC2020_signed_with_Exhibits_geschwarzt.pdf.

⁴⁸ See <https://www.regulations.gov/search?filter=FDA-2020-P-2180>.

and not quantitative.⁴⁹ They are not standardized.⁵⁰ They have an incredibly high rate of false positives and even a positive result does not mean an individual can infect others.⁵¹ The trials must account for these facts. They must require that COVID-19 cases are only classified as such when participants are symptomatic and suffering with at least moderate to severe COVID-19.

52. The number of PCR cycles it takes to amplify a sample containing viral remains to the point where they can be detected is called its cycle threshold. If PCR tests are going to be used in the COVID-19 Vaccine trials to identify cases of COVID-19, then the cycle threshold must be set at a reasonable number.

53. Dr. Anthony Fauci, when asked about transmission and testing, has explained this serious issue with PCR tests as follows: “What is now sort of evolving into a bit of a standard that if you get a cycle threshold of 35 or more, that the chances of it being replication competent are minuscule...you almost never can culture virus from a 37 threshold cycle so...if somebody does come in with 37, 38, even 36, you gotta’ say, you know, it’s just dead nucleotides, period.”⁵²

54. According to the CDC’s data, it is extremely difficult to detect *any* live virus in a sample above a threshold of 33 cycles.⁵³ One study that the CDC relied upon reports finding no

⁴⁹ See <https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html> (“The most widely used diagnostic test for the new coronavirus, called a PCR test, provides a simple yes-no answer to the question of whether a patient is infected... ‘We’ve been using one type of data for everything, and that is just plus or minus — that’s all,’ Dr. Mina said. ‘We’re using that for clinical diagnostics, for public health, for policy decision-making.’ But yes-no isn’t good enough, he added. It’s the amount of virus that should dictate the infected patient’s next steps. ‘It’s really irresponsible, I think, to forgo the recognition that this is a quantitative issue,’ Dr. Mina said.”).

⁵⁰ See *Understanding cycle threshold (CT) in SARS-CoV-2 RT-PCR* at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/926410/Understanding_Cycle_Threshold_Ct_in_SARS-CoV-2_RT-PCR.pdf (“Cycle threshold (Ct) is a semi-quantitative value that can broadly categorise the concentration of viral genetic material in a patient sample following testing by RT PCR as low, medium or high – that is, it tells us approximately how much viral genetic material is in the sample... Ct values cannot be directly compared between assays of different types – not all laboratories use the same assay, and some may use more than one.”) (last visited November 3, 2020); see also <https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html> (“The Food and Drug Administration said in an emailed statement that it does not specify the cycle threshold ranges used to determine who is positive, and that ‘commercial manufacturers and laboratories set their own.’”).

⁵¹ See <https://www.nytimes.com/2020/08/29/health/coronavirus-testing.html> (“In three sets of [PCR] testing data that include cycle thresholds, compiled by officials in Massachusetts, New York and Nevada, up to 90 percent of people testing positive carried barely any virus, a review by The Times found...Any test with a cycle threshold above 35 is too sensitive, agreed Juliet Morrison, a virologist at the University of California, Riverside. ‘I’m shocked that people would think that 40 could represent a positive,’ she said. A more reasonable cutoff would be 30 to 35, she added. Dr. Mina said he would set the figure at 30, or even less.”) (last visited November 3, 2020). Importantly, in discussing PCR testing in the context of pertussis, the CDC warns that “[t]he high sensitivity of PCR increases the risk of false-positivity.”). See <https://www.cdc.gov/pertussis/clinical/diagnostic-testing/diagnosis-confirmation.html>.

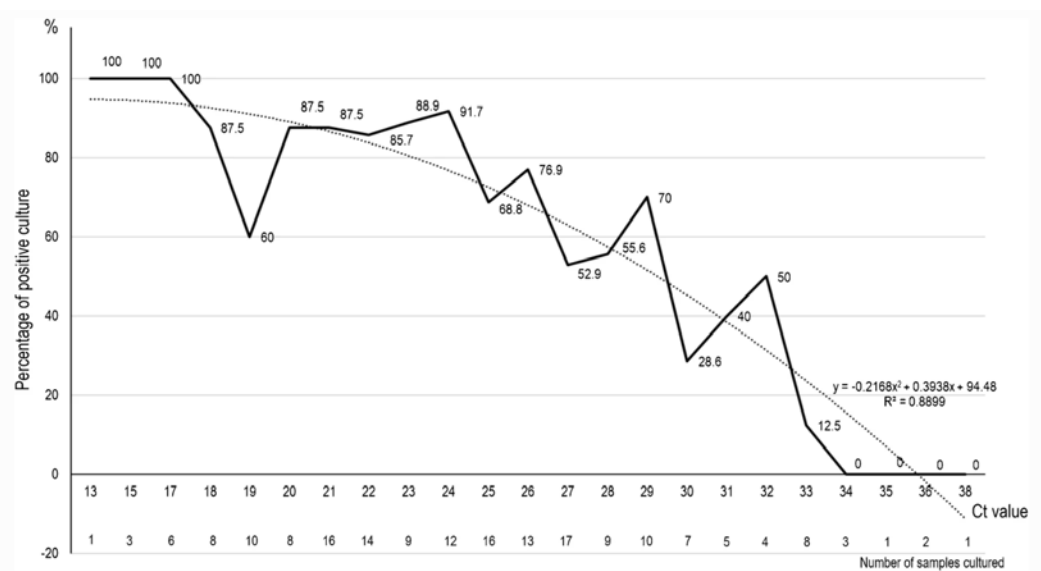
⁵² See https://www.youtube.com/watch?v=a_Vy6fgaBPE&feature=youtu.be&t=230 (last visited May 27, 2021).

⁵³ See <https://www.cdc.gov/coronavirus/2019-ncov/hcp/duration-isolation.html> (last visited November 3, 2020).

“live” virus in any samples whose cycle threshold is greater than 24.⁵⁴ All studies that the CDC relied upon were conducted on symptomatic people.

55. Moreover, an analysis of several different studies by a team at Oxford similarly concluded that positive PCR test results from samples with cycle thresholds over 24 should not be taken to indicate the presence of any actual virus. This study concluded that, “[a] binary Yes/No approach to the interpretation RT-PCR unvalidated against viral culture will result in false positives with possible segregation of large numbers of people who are no longer infectious and hence not a threat to public health.”⁵⁵

56. This figure shows the significant relationship between cycle threshold value and culture positivity rate:



57. Percentage of positive viral culture of SARS-CoV-2 PCR-positive nasopharyngeal samples from Covid-19 patients, according to Ct value (plain line). The dashed curve indicates the polynomial regression curve⁵⁶

58. The figure shows that a cycle threshold value of 35 means 10% positive cultures (or 90% negative cultures) for COVID-19. In order to have at least a 50% chance of a positive culture, a PCR test should be at or lower than 30 amplification cycles. The study further concluded that “patients with Ct [cycle threshold] values equal or above 34 do not excrete infectious viral particles.”

⁵⁴ See <https://pubmed.ncbi.nlm.nih.gov/32442256/> (“SARS-CoV-2 Vero cell infectivity was only observed for RT-PCR Ct < 24.”) (last visited November 3, 2020).

⁵⁵ <https://www.medrxiv.org/content/10.1101/2020.08.04.20167932v4.full.pdf> (last visited November 3, 2020).

⁵⁶ See <https://link.springer.com/article/10.1007/s10096-020-03913-9> (last visited November 3, 2020).

59. The COVID-19 Vaccine trial protocols do not disclose the cycle thresholds being used for the PCR tests in order to assess the primary endpoints. Petitioner previously demanded that these cycle thresholds must not be higher than 24.

60. The FDA denied that request as follows:

[W]e disagree that it is necessary to require a maximum of 24 amplification cycles for PCR tests. PCR tests are used to show if individuals have active SARS-CoV-2 infection by detecting the virus's genetic material...

We have determined that requiring a maximum of 24 amplification cycles for PCR tests to qualify a diagnosis of COVID-19 is not justified because **such a requirement, in and of itself, is arbitrary and would not ensure testing validity.** While generally the fewer number of amplification cycles on a sample that shows a positive indicates a higher viral load, the number of amplification cycles used to detect genetic material is not necessarily the same across different PCR tests – meaning that the same sample tested on multiple PCR tests may take different numbers of amplification cycles to get the same result. Accordingly, different amplification cycle cut-offs may be justified for different PCR tests. **The variability across tests is one reason why Petitioner's request would not be justified.**

Another reason why Petitioner's request is not justified is that **the number of amplification cycles used is just one factor that affects the reliability of a PCR result.** Other factors that help ensure reliable testing include: sufficiently sensitive analytical Limit of Detection; robust performance when there are interfering substances in the sample; and good sensitivity when testing known positive and known negative clinical samples. Rather than impose an across-the-board amplification cycle cutoff, we believe that the better approach is the one taken in FDA's June 2020 Guidance, which explains sponsors' obligation to ensure reliable testing. Not only does the June 2020 Guidance emphasize sponsors' responsibility for using reliable testing, but FDA's review of INDs also helps ensure that investigations are designed in ways that allow meaningful scientific inferences to be drawn. Indeed, FDA reviews reports regarding the validation of SARS-CoV-2 testing that sponsors include in their IND submissions.

Accordingly, we have determined that FDA's existing guidance and IND review process already provides adequate oversight with

respect to testing. **We do not believe that Petitioner’s proposed cutoff of 24 amplification cycles is scientifically justified.**⁵⁷

61. Despite these statements from the FDA, in April of this year, the CDC did, in fact, change the guidance for PCR testing with regard to the number of cycles needed in order to classify a test as “positive” for “breakthrough” purposes. The new CDC guidance calls for clinical specimens for sequencing to “have an RT-PCR Ct value ≤ 28 .”⁵⁸ The objective of studying breakthrough cases is stated as follows: “Investigate SARS-CoV-2 infections among people who received COVID-19 vaccine to identify trends or clustering in demographic, the administered vaccine, or the infecting virus.” Meaning, once an individual has been vaccinated, in order for a subsequent infection to be considered a breakthrough case (demonstrating lack of efficacy of the vaccine), the PCR test must use 28 or fewer cycles. The FDA must explain why this threshold has been established for vaccinated individuals but has not been established: (i) in clinical trials in order to evidence a positive case for efficacy studies; or (ii) in all other individuals tested throughout this country for the previous 16 months during which “positive” results, based on unlimited cycle thresholds, have shut down this country and upended Americans’ lives and freedoms.

62. The COVID-19 vaccine trial protocols do not disclose the cycle thresholds being used for the PCR tests in order to assess the primary endpoints. These cycle thresholds must not be higher than 28, a limit now established by the CDC.

g. Accurate data reflecting actual risk reduction and number needed to vaccinate

63. The FDA must demand accurate data that reflects the actual risk reduction and number needed to vaccinate in order to prevent one case of COVID-19 from each COVID-19 vaccine manufacturer.

64. Pfizer’s COVID-19 vaccine trial data at the time of EUA shows 170 observed COVID-19 cases (in 44,000 participants): 162 cases in the placebo group versus 8 in the vaccine group. Moderna observed 95 cases (in 30,000 participants): 90 in the placebo group versus 5 in the vaccine group. Both manufacturers claim approximately 95% efficacy based on relative risk reduction.

65. But it is more accurate to report the absolute risk reduction, which appears to be around 1%. “The absence of reported absolute risk reduction in COVID-19 vaccine clinical trials can lead to outcome reporting bias that affects the interpretation of vaccine efficacy.”⁵⁹

66. The FDA’s guidance, *Communicating Risks and Benefits: An Evidence-Based User’s Guide*, makes clear: “For patients to make informed decisions about their health care, they must understand the risks and benefits of their treatment options, including the numeric

⁵⁷ <https://www.regulations.gov/document/FDA-2020-P-2180-0070> (emphasis added).

⁵⁸ <https://www.cdc.gov/vaccines/covid-19/downloads/Information-for-laboratories-COVID-vaccine-breakthrough-case-investigation.pdf>.

⁵⁹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996517/>.

likelihoods. Unfortunately, many patients have difficulty understanding numerical information. Evidence-based recommendations are made for improving the communication of numerical information.”⁶⁰ The guidance goes on to state: “**when information is presented in a relative risk format, the risk reduction seems larger** and treatments are viewed more favorably **than when the same information is presented using an absolute risk format**. This is as true for the lay public as it is for medical students.”⁶¹ The FDA then recommends an evidence-based approach, guiding providers to: “**Provide absolute risks, not just relative risks. Patients are unduly influenced when risk information is presented using a relative risk approach; this can result in suboptimal decisions. Thus, an absolute risk format should be used.**”⁶²

67. Moreover, the data reviewed by the FDA to issue EUAs did not take into account the number needed to vaccinate. One study shows that the number needed to vaccinate with Pfizer’s COVID-19 vaccine to prevent one infection is 142 whereas the number needed to vaccinate with Moderna’s COVID-19 vaccine to prevent one infection is 88. The FDA should confirm whether these numbers are accurate and refuse to license any vaccine until the manufacturer provides data to do so.

68. As stated in *Outcome Reporting Bias in COVID-19 mRNA Vaccine Clinical Trials*: “by Omitting absolute risk reduction findings in public health and clinical reports of vaccine efficacy is an example of outcome reporting bias, which ignores unfavorable outcomes and misleads the public’s impression and scientific understanding of a treatment’s efficacy and benefits. Furthermore, the ethical and legal obligation of informed consent requires that patients are educated about the risks and benefits of a healthcare procedure or intervention.”⁶³

69. The Lancet recently discussed this issue in *COVID-19 vaccine efficacy and effectiveness – the elephant (not) in the room*.⁶⁴ The authors of this article explain that “the RRR [relative risk reduction] considers only participants who could benefit from the vaccine, [whereas] the absolute risk reduction (ARR), which is the difference between attack rates with and without a vaccine, considers the whole population.”⁶⁵ The article continues to explain why the relative risk is used: “ARRs tend to be ignored because they give a much less impressive effect size than RRRs: ...1.2% for the Moderna–NIH, 1.2% for the J&J,... [and] 0.84% for the Pfizer–BioNTech vaccines.”⁶⁶ Ultimately, the issues with clinical trials and the lack of uniformity among all of them compound the problems. “Uncoordinated phase 3 trials do not satisfy public health requirements... These considerations on efficacy and effectiveness are based on studies measuring prevention of mild to moderate COVID-19 infection; they were not designed to conclude on prevention of hospitalisation, severe disease, or death, or on prevention of infection and

⁶⁰ <https://www.fda.gov/media/81597/download> at 53.

⁶¹ <https://www.fda.gov/media/81597/download> at 56 (emphasis added).

⁶² <https://www.fda.gov/media/81597/download> at 60 (emphasis added).

⁶³ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7996517/>.

⁶⁴ See <https://www.thelancet.com/action/showPdf?pii=S2666-5247%2821%2900069-0>.

⁶⁵ *Id.*

⁶⁶ *Id.*

transmission potential. Assessing the suitability of vaccines must consider all indicators, and involve safety, deployability, availability, and costs.”⁶⁷

70. This is what the FDA must demand of vaccine manufacturers before any licenses are granted, especially of products that are given to completely healthy people who believe they are doing a service to others by receiving a vaccine at minimum risk to themselves.

C. ENVIRONMENTAL IMPACT

71. 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

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

E. CERTIFICATION

73. 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.

74. The Petitioner therefore respectfully urges that this request be granted forthwith.

Respectfully submitted,

/s/ Aaron Siri
Aaron Siri
Elizabeth Brehm
Jessica Wallace
SIRI & GLIMSTAD LLP
200 Park Avenue
17th Floor
New York, NY 10166
Telephone: (212) 532-1091
Facsimile: (646) 417-5967
Email: aaron@sirillp.com

⁶⁷ *Id.*