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

PETITION FOR ADMINISTRATIVE ACTION REGARDING REVOCATION OF THE EMERGENCY USE AUTHORIZATION GRANTED TO PFIZER-BIONTECH'S COVID-19 VACCINE FOR CHILDREN AGES 5 THROUGH 11 AND AUTHORIZATION FOR OTHER COVID-19 VACCINES FOR THIS AGE GROUP	**:**	**Docket No.:**

CITIZEN PETITION

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CITIZEN PETITION

This petition for administrative action is submitted on behalf of Informed Consent Action Network ("**Petitioner**") pursuant to 21 CFR § 10.30 and related and 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**") revoke the June 17, 2022 reissuance of the Emergency Use Authorization ("**EUA**") letter of authorization for use of Pfizer-BioNTech's COVID-19 vaccine in children ages 5 through 11,[1] as well as the June 17, 2022 reissuance of the EUA for use of Moderna's COVID-19 vaccine in 6- to 11-year-olds,[2] pursuant to 21 U.S.C. § 360bbb-3 (the "**EUA Statue**").

The Food and Drug Administration ("**FDA**") lacked the legal authority and had no need to issue an EUA for Pfizer's product for 5- to 11-year-old children for numerous reasons, including because there is no health emergency for children. For the reasons set forth herein, it was also improper to issue an EUA for these children when (i) the data does not demonstrate that the known benefits outweigh the known risks, (ii) the trial was underpowered, and (iii) there are serious concerns regarding how the trials were conducted. Even if the FDA had the legal authority or purported need at the time of issuance, it no longer does, as additional data since the authorization clearly shows the known benefits do not outweigh the known and potential risks. For the same reasons, the FDA likewise lacked the legal authority to issue an EUA for Moderna's vaccine for 6- to 11-year-old children.

Therefore, Petitioner respectfully requests that the Commissioner act on the instant Petition and (i) revoke the EUA granted to Pfizer-BioNTech's COVID-19 vaccine for children ages 5 through 11 and (ii) revoke the EUA granted to Moderna's COVID-19 vaccine for 6- to 11-year-olds.

A. ACTIONS REQUESTED

It is hereby requested that:

1. the June 17, 2022 reissuance of the EUA letter of authorization for the use of Pfizer-BioNTech's COVID-19 vaccine for children ages 5 through 11 be revoked pursuant to 21 U.S.C. § 360bbb-3(g);

2. the June 17, 2022 reissuance of the EUA letter of authorization for use of Moderna's COVID-19 vaccine in children ages 6 through 11 be provoked pursuant to 21 U.S.C. § 360bbb-3(g); and

3. the FDA require T-cell assessment from COVID-19 vaccine developers as a measure of evaluating vaccine efficacy.

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[1] https://www.fda.gov/media/150386/download. This product was first authorized in 5- to 11-year-olds via the October 29, 2022 reissuance of the EUA.

[2] https://www.fda.gov/media/144636/download.

B. STATEMENT OF GROUNDS

I. The Initial Granting of the EUA for Pfizer's Vaccine for 5- to 11-Year-Olds Was Unlawful

a. There was no emergency at the time the EUA was granted

4. Congress passed the law granting the FDA the authority to issue EUAs after the United States experienced September 11, 2001, and subsequent acts of terror, including envelopes with anthrax that were sent through the U.S. Postal Service.[3]

5. To create a legal route to distribute an unlicensed and therefore, experimental, medical product in the event of bioterrorism or a similar emergency, Congress enacted Section 564 of the Food, Drug, and Cosmetic Act ("**FDCA**"), codified at 21 U.S.C. § 360bbb-3 ("**Section 564**"). To invoke Section 564, there must be an emergency necessitating an action under the statute. Specifically, COVID-19 would have to cause serious or life-threatening disease or condition for 5- to 11-year-olds in order to justify an EUA. However, as shown below, on October 29, 2021, at the time the EUA was initially granted, there was and still is no emergency affecting the health or security of America's children and only a subset of identifiable children with underlying conditions are potentially at risk for serious or life-threatening disease. Notably, myriad studies have shown that COVID-19 is not a serious threat even to immunocompromised children.[4]

6. According to a December 2020 JAMA Network article, from March through October of 2020, children ages 5-14 had a one-in-a-million chance of dying *with* COVID-19,[5] and Johns Hopkins researchers analyzing 48,000 children diagnosed with COVID-19 found a mortality rate of **zero** among those who did not have a pre-existing medical condition such as leukemia.[6] As the Lancet noted, "In the USA, UK, Italy, Germany, Spain, France, and South Korea, deaths from COVID-19 in children remained rare up to February, 2021, at 0.17 per 100 000 population, comprising 0.48% of the estimated total mortality from all causes in a normal year."[7] The rate of

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[3] *See* https://wwwnc.cdc.gov/eid/article/13/7/06-1188_article (detailing "the need for and genesis of the EUA, its requirements, its broad application to civilian and military populations, and its features of particular importance to physicians and public health officials.").

[4] Chappell, H., *et al.*, *Immunocompromised children and young people are at no increased risk of severe COVID-19*, J. of Infection (Nov. 8, 2021), https://pubmed.ncbi.nlm.nih.gov/34785268/#:~:text=In%20those%20with%20no%20prior,No%20children%20died ("SARS-CoV-2 infections have occurred in immunocompromised children and young people with no increased risk of severe disease. No children died.").

[5] Woolf, MD, MPH, *et al.*, *COVID-19 as the Leading Cause of Death in the United States*, JAMA Network (December 17, 2020) https://jamanetwork.com/journals/jama/fullarticle/2774465.

[6] *Risk Factors for COVID-19 Mortality Among Privately Insured Patients: A Claims Data Analysis*, Fair Health (Nov. 11, 2020), https://collections.nlm.nih.gov/master/borndig/101774952/Risk%20Factors%20for%20COVID-19%20Mortality%20among%20Privately%20Insured%20Patients%20-%20A%20Claims%20Data%20Analysis%20-%20A%20FAIR%20Health%20White%20Paper.pdf.

[7] Bhopal, Sunil S., *Children and Young People Remain at Low Risk of COVID-19 Mortality*, Lancet (Mar. 10, 2021), https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(21)00066-3/fulltext.

hospitalization for COVID-19 according to the CDC has been similarly clinically insignificant, ranging from zero to a peak of 2.2 per 100,000 for children 12 to 15 in January 2021.[8]

7. Despite what has been an apparent continued effort to inflate COVID-19 numbers in children and induce fear among parents,[9] according to the CDC, just 10.6% of the total U.S. COVID-19 cases in October 2021 occurred in 5- to 11-year-olds.[10] As of October 28, 2021, the day prior to the FDA's grant of the EUA, the CDC recorded the rate of new admissions of patients under 18 years old with confirmed COVID-19 cases was 0.21 per 100,000.[11] Of those hospitalized, the CDC claims that 94 died, which represented just 1.7% of all deaths among U.S. Children in this age group.[12] The CDC also recorded that between October 2, 2020, and October 2, 2021, just 66 children between 5 and 11 had "COVID-19 associated" deaths.[13] And those deaths were *with* COVID, not necessarily *from* COVID, and further, there was no accompanying data regarding underlying conditions. Overall, the "crude" rate of "COVID-19 associated" deaths in 5- to 11-year-olds was, at best, extraordinary rare at 2 per million, assuming these 2 deaths per million were actually from COVID and not just children that died from other causes while testing positive for COVID.[14] Even at the time the EUA was granted, it was inarguable that this was not a severe or deadly pandemic for 5- to 11-year-old children as the data has clearly and consistently shown.

8. Michael Kurilla, M.D., Ph.D., Director of the Division of Clinical Innovation at the National Institutes of Health's National Center for Advancing Translational Sciences and a voting member of the Vaccines and Related Biological Products Advisory Committee, acknowledged this when he abstained from voting on whether or not to grant emergency use authorization to Pfizer's vaccine for 5-11-year-olds stating: "**I don't see the need for 'emergency use' of this vaccine across the entire age group**."[15]

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[8] https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html.

[9] CDC Director Walensky made the claim that vaccinating one million adolescents for COVID-19 would prevent 200 hospitalizations and 1 death over a four-month period. *See* https://twitter.com/cdcdirector/status/1408116464683569157. However, the hospitalization report relied upon for this analysis, just like the death count, does not distinguish whether the child hospitalizations are *for* COVID-19 or *with* COVID-19. In other words, if a child got hurt in an accident and was brought to the hospital and was tested as part of hospital protocol and tests positive, that child was counted as a child COVID-19 hospitalization even though the hospitalization could not have been prevented regardless of how many people were vaccinated. Evidencing this issue with Walensky's claims is the June 11, 2021 Morbidity and Mortality Weekly Report ("**MMWR**") of that analysis which revealed that 45.7% of the admissions had to be analyzed separately "because their primary reason for admission might not have been directly COVID-19-related." Havers, Fiona, P. *et al.*, *Hospitalization of Adolescents Aged 12–17 Years with Laboratory-Confirmed COVID-19 — COVID-NET, 14 States, March 1, 2020–April 24, 2021*, MMWR (June 11, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7023-H.pdf at page 851.

[10] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/03-COVID-Jefferson-508.pdf at 5.

[11] https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions.

[12] *Supra* note 10, at 19

[13] *Supra* note 10, at 20.

[14] *Id.*

[15] Branswell, Helen & Herper, Matthew, *Tracking the FDA Advisory Panel Meeting on COVID-19 Vaccines for Kids*, Stat News (Oct. 26, 2021), https://www.statnews.com/2021/10/26/pfizer-covid19-vaccine-kids-vrbpac-fda.

b. The clinical trial relied upon to authorize Pfizer's vaccine in 5- to 11-year-olds was deficient

9. Initially, it should be noted that the clinical trial relied upon to authorize the Pfizer vaccine for 5- to 11-year-olds was underpowered and inadequate to properly test efficacy and safety for several reasons:

- Cohort 1 of the trial included only 2,268 participants, 1,518 of whom received the vaccine and 750 of whom received a placebo.[16] Cohort 2 of the trial similarly included only 1,591 of whom received a vaccine and 778 of whom received a placebo.[17] Likewise, Pfizer's booster dose was studied in only "approximately 400 children."[18] That number of participants was inadequate to identify any potential adverse events, and the statistical significance of same, should the rate of injuries be less than a few in 3,109 (the total number of children who received the vaccine). As one voting member of the FDA's advisory committee, Michael Kurilla, M.D., Ph.D., explained, "The fact of the matter is you're basing a decision for millions of children on a study of 2,400, really … and that's uncomfortable. So you want caveats." Another voting committee member, Eric Rubin, M.D., Ph.D., editor of the New England Journal of Medicine ("NEJM"), made clear why it could be uncomfortable: "We're never going to learn about how safe the vaccine is unless we start giving it, and that's just the way it goes. That's how we found out about rare complications of the other vaccines."[19]

- Even the Advisory Committee for Immunization Practices acknowledged this in its meeting to consider the Pfizer's vaccine in 5- to 11-year-olds: "Serious concern of indirectness was noted. The body of evidence does not provide certainty that rare serious adverse events were captured due to the short duration of follow-up (median: 3.3 months)."[20] The follow up for Cohort 2 was even shorter at just 2.4 weeks.[21] The need for an adequately powered trial has been recognized by international scientists who have declared that "inadequately powered studies should themselves be considered a breach of ethical standards."[22]

- Equally problematic is that the trial was not representative of most American children. The trial excluded children with immunodeficiency or autoimmune

[16] Walter, Emmanuel B., *et al.*, *Evaluation of the BNT162b2 Covid-19 Vaccine in Children 5 to 11 Years of Age*, N. Eng. J. Med. (Jan. 5, 2022), https://www.nejm.org/doi/full/10.1056/nejmoa2116298; FDA Briefing Document, (Oct. 26, 2021), https://www.fda.gov/media/153447/download, at 19.

[17] FDA Briefing Document, *supra* note 16, at 17.

[18] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-pfizer-biontech-covid-19-vaccine-booster-dose.

[19] https://www.youtube.com/watch?v=laaL0_xKmmA&t=20971s.

[20] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/08-COVID-Oliver-508.pdf at 21.

[21] FDA Briefing Document, *supra* note 16, at 17.

[22] Klassen, *et al.*, *Children Are Not Just Small Adults: The Urgent Need for High-Quality Trial Evidence in Children*, Plos Medicine (Aug. 2008), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2504487/.

disease.[23] Additionally, the FDA acknowledges that even though children ages 5-11 had the highest seroprevalence rates of SARS-CoV-2 as of June 2021 at a rate of 42%,[24] children with a past virologic *or clinical* COVID-19 diagnosis were excluded from phase 1.[25] The trial also excluded those with a history of MIS-C or a severe adverse reaction to a vaccine.[26] Moreover, of the children receiving the vaccine, approximately 79.3% White, whereas only 5.9% were Black, 21% were Hispanic or Latino, and 5.9% were Asian.[27]

- In addition to concerns about properly monitoring for safety, there are issues about the trial's ability to properly assess efficacy. The trial was not intended to make findings regarding the vaccine's ability to prevent disease or hospitalization. Instead, it was limited to assessing antibody levels and comparing those levels to adult levels using immunobridging.[28] (This is because COVID rarely causes disease in children and hence not enough children would likely become infected during the trial to assess the real-life efficacy). As you are surely aware, immunobridging assumes a vaccine is effective if the geometric mean titers ("**GMT**") of anti-spike are similar to the anti-spike GMT among a different cohort of vaccinated individuals. Specifically, the primary outcome of Pfizer's clinical trial is to use immunobridging of SARS-CoV-2 serum neutralizing titers 1 month after the second dose among children 5 to 11 years compared to participants 16 to 25 years of age.[29] The latter is a cohort in which Pfizer represents that the vaccine has demonstrated efficacy against preventing symptomatic infection.[30] There is, however, a major flaw in assessing vaccine effectiveness ("**VE**") using immunobridging; **it assumes GMT titers generated against the outdated parental spike protein are sufficient to neutralize current and future SARS-CoV-2 spike protein variants in a different, younger, cohort.** Further, as acknowledged at recent Advisory Committee on Immunization Practices (ACIP) meetings, no correlate or protection is currently known for SARS-CoV-2. As numerous members of the Vaccine and Related Biological Products Advisory Committee (VRBPAC) recently pointed out, and a large body of literature in vaccinology underscores, antibody response does not necessary tell one if a vaccine

[23] https://www.nejm.org/doi/suppl/10.1056/NEJMoa2116298/suppl_file/nejmoa2116298_appendix.pdf at 5.

[24] https://www.fda.gov/media/153508/download at 7.

[25] *Supra* note 23, at 5.

[26] *Id.*

[27] FDA Briefing Document, *supra* note 16, at 21.

[28] As Dr. Woodcock and Dr. Marks have since explained: "It's important that the public recognize that, because young children are still growing and developing, it's critical that thorough and robust clinical trials of adequate size are completed to evaluate the safety and the immune response to a COVID-19 vaccine in this population. Children are not small adults." https://www.fda.gov/news-events/press-announcements/fda-will-follow-science-covid-19-vaccines-young-children.

[29] FDA Briefing Document, *supra* note 16, at 31.

[30] *See outcome measures,* https://clinicaltrials.gov/ct2/show/NCT04816643?term=Pfizer+3mcg&draw=2&rank=2.

will work.[31] One pediatric rheumatologist at the University of California, Los Angeles, Dr. Patrick Whelan, noted his sickest COVID-19 patients in intensive care, including children with multisystem inflammatory syndrome, have "had loads of antibodies ... So the question is, why didn't they protect them?"[32] Therefore, authorization of this vaccine for this age group which depends fully on antibody response is unjustified. Instead, the FDA should, at the least, demand a T-cell assessment from trial sponsors in order to better evaluate vaccine efficacy.[33]

- In addition to safety and efficacy issues, as noted above, the trial was not of sufficient duration. Safety data was only collected for a few months and "data on longer-term safety and the duration of efficacy and antibody responses in children are not yet available." As acknowledged in the FDA's Briefing Document for October 26, 2021 VRBPAC's meeting to vote on Pfizer's vaccine for 5- to 11-year-olds, "Post-licensure/post-authorization safety surveillance and observational studies in pediatric populations would be needed to evaluate for adverse reactions that occur too rarely to be detected in clinical trials."[34] Perhaps most concerning is that the FDA's benefit-risk assessment stated that it followed up with only 95.1% of cohort 1 participants.[35] It is not clear why Pfizer failed to follow up with the other 4.9%, especially in light of the small size of the trial to begin with.

- Even the adverse events that were picked up by the clinical trial pointed to serious issues from the start. Despite that COVID-19 poses a far lower risk to 5- to 11-year-olds, Pfizer's data indicated mild to moderate local reactions were more common than in 16- to 25-year-olds and that lymphadenopathy was more common than in those 12 and older.[36] Systemic adverse events occurred in "approximately 50%" of the vaccine participants and one vaccine recipient even withdrew from the study due to adverse events.[37]

- Finally, even despite all of these flaws, the study itself refuted the idea that vaccinating this age group would provide any real benefit. No child in the entire

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[31] *See* https://www.youtube.com/watch?v=x8rq247E80I&t=31027s starting at 3:32:09 (Dr. Rubin stated: "We don't really have the great, very specific, level of antibody that correlates highly with protection...It's hard to know where [among antibody levels] ...protection is occurring...We know what kind of antibody response can be generated, we just don't know if it works." The response to his concern is that this "is a reasonable criticism.").

[32] Block, Jennifer, *Vaccinating people who have had covid-19: why doesn't natural immunity count in the US?*, BMJ (Sept. 12, 2021), https://www.bmj.com/content/374/bmj.n2101.

[33] *See* https://drive.google.com/file/d/1OPfStqOnuKAEUkrjfFUouXMjDB_-tnmV/view.

[34] FDA Briefing Document, *supra* note 16, at 16; *see also* Walter, *supra* note 16 ("This study was also not powered to detect potential rare side effects of BNT162b2 in 5-to-11-year-olds. However, the safety of BNT162b2 observed in the study combined with widespread use of BNT162b2 in older populations should provide reassurance.").

[35] *Id.* at 31.

[36] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/02-COVID-Gurtman-508.pdf at 21; https://www.fda.gov/media/153510/download at 36.

[37] FDA Briefing Document, *supra* note 16, at 24, 25.

trial was hospitalized for COVID-19 or died of it.[38] This alone shows that there was and is no real risk to this age group for the vaccine to mitigate and therefore any adverse event, of which there were several, is of great consequence.

10. As a consequence of these grave study design issues, any data from the trial relied upon by the FDA to justify its benefit-risk assessment casts significant doubt on the accuracy of its conclusions. Based on what was known at the time of the EUA, the risks from the vaccine outweigh any determined benefits from this product.

II. The EUA for Pfizer's Vaccine Continues to Be Unlawful Because the FDA's Benefit-Risk Assessment Is Gravely Flawed, Particularly in Light of New Data.

a. There continues to be no emergency in this age group.

11. As was the case prior to authorization of this vaccine for use in 5- to 11-year-olds, there continues to be no emergency with respect to this age group. As NIAID Director and Chief Medical Advisor to the President, Dr. Anthony Fauci just noted, "We are certainly right now in this country out of the [acute] pandemic phase."[39] The CDC has now also acknowledged that 75.2% of American children aged 0-11 years show seroprevalence to SARS-CoV-2.[40]

12. Demonstrating the absence of risk to this age group is the low rate of hospitalization and the far lower death rate. A large study from the U.K. posted in July 2021 examined the fatality rate among all those under 18 and found death from SARS-CoV-2 to be incredibly rare – 0.005 percent.[41] CDC data indicates that there were just 8 in-hospital COVID-19 related deaths in children ages 0-17 between August 2020 and August 2021 (of approximately 73 million children in the country) with no information provided about any underlying conditions.[42] Further, based on data following the Delta variant, a report by the American Academy of Pediatrics found that "[i]n states where data was available, less than 2% of all child COVID-19 cases required hospitalization and 0.00% to 0.03% were fatal."[43] Notably, this metric does not necessarily correlate with severe

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[38] FDA Briefing Document, *supra* note 16, at 25.

[39] https://www.pbs.org/newshour/show/dr-fauci-on-why-the-u-s-is-out-of-the-pandemic-phase-2. Dr. Fauci expanded on these remarks, stating that by "phase" he meant "the acute stage of the pandemic phase." https://www.npr.org/2022/04/26/1094791782/why-are-masks-such-a-big-deal-for-so-many-psychologists-have-thoughts.

[40] https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7117e3-H.pdf at 1.

[41] Smith, Clare, *et al., Deaths in Children and Young People in England following SARS-CoV-2 infection during the first pandemic year: a national study using linked mandatory child death reporting data,* Research Square (July 7, 2021), https://www.researchsquare.com/article/rs-689684/v1

[42] Siegel, David A., *et al., Trends in COVID-19 cases, emergency department visits, and hospital admissions among children and adolescents aged 0–17 Years* — United States, August 2020–August 2021, MMWR (Sept. 2, 2021), https://stacks.cdc.gov/view/cdc/109525. See also https://datacenter.kidscount.org/data/tables/99-total-population-by-child-and-adult-populations#detailed/1/any/false.

[43] Hernandez, Joe, *Nearly 94,000 Kids Got COVID-19 Last Week. They were 15% of All New Cases*, NPR (Aug. 10, 2021), https://www.npr.org/sections/coronavirus-live-updates/2021/08/10/1026375608/nearly-94-000-kids-got-covid-19-last-week-they-were-15-of-all-new-infections; *see also Children and COVID-19: State-Level Data Report*,

cases of pediatric COVID-19 because it "may be inflated by the detection of mild or asymptomatic infection via universal screening."[44] In fact, one study that looked at 146 hospitalized pediatric COVID hospitalizations during a five-month period in 2020 found that, in an incredible 86% of those cases, COVID-19 was either incidental or minimally related to the reason for hospitalization.[45]

13. Additionally, a Stanford University study found that 45% of pediatric COVID-19 hospital admissions were unlikely to have been caused by SARS-CoV-2.[46] As Dr. Anthony Fauci has since observed, pediatric COVID-19 hospitalization statistics have been dubious from the start:

> The other important thing is if you look at children who are hospitalized, many of them are hospitalized *with* COVID as opposed to *because of* COVID. And what we mean by that [is] if a child goes into the hospital, they automatically get tested for COVID and they get counted as a COVID-hospitalized individual, when, in fact, they may go in for a broken leg or appendicitis or something like that. So it's overcounting the number of children who are, quote, "hospitalized *with* COVID" as opposed to *because of* COVID.[47]

14. Evidencing the inflation of already low numbers related to pediatric hospitalizations and deaths, on March 14, 2022, the CDC removed tens of thousands of deaths linked to COVID-19, including 416 (or 24%) of the pediatric deaths on this data tracking website. The agency explained that these deaths were "misclassify[ied]" and "were not COVID-19 related."[48] That tracker now shows that deaths in the 5-11-year-old age group account for <0.1% of the deaths tracked and only 6.7% of the cases.[49]

15. Notably, however, even at the time of its benefit-risk assessment, the FDA was utilizing an inflated COVID-19 hospitalization rate. According to COVID-NET data, by October 23, 2021, the weekly rate of COVID-19-associated hospitalization in 5- to 11-year-olds had ranged from 0 to 1.1 per 100,000.[50] But rather than use the average hospitalization rate since the start of the pandemic, which was .3725 per 100,000,[51] the FDA inexplicably used an arbitrary rate from

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AAP, https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/ ("In states reporting, 0.00%-0.02% of all child COVID-19 cases resulted in death.").

[44] Kushner, Lauren, E., *et al.*, *"For COVID" or "With COVID": Classification of SARS-CoV-2 Hospitalizations in Children*, Hospital Pediatrics (Aug. 1, 2021), https://hosppeds.aappublications.org/content/11/8/e151.long.

[45] Webb, Nicole E & Osburn, T. Shea, *Characteristics of Hospitalized Children Positive for SARS-CoV-2: Experience of a Large Center*, Hosp. Pediatr. (Aug. 2021), https://pubmed.ncbi.nlm.nih.gov/34011567/. The study also noted that the single COVID-19 death in the series was in a "medically complex patient admitted for respiratory failure." *Id.*

[46] Kushner, *supra* note 44.

[47] https://www.youtube.com/watch?v=Aktzp4jSXY8 at 3:18.

[48] https://covid.cdc.gov/covid-data-tracker/#demographics.

[49] *Id*.

[50] https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html

[51] *Id.* (calculated based on the weekly rate for 5–11-year-olds from March 7, 2020, to September 11, 2021).

"average of four weeks prior to September 11, 2021,"[52] which was 0.975 – approximately double the average rate. This had the effect of skewing the benefit risk assessment in favor of vaccination based on the formula used by the FDA.

16. Based on these facts, the current EUA for Pfizer's vaccine for this population is without legal foundation or necessity because COVID-19 does not present a current emergency for children.

b. The alleged benefits of Pfizer's vaccine for 5- to 11-year-olds are heavily outweighed by the known and potential risks.

17. Since it is exceedingly rare for a child to die or have a permanent injury from being infected with SARS-CoV-2, it must be determined that the vaccine presents even less risk. In order to grant and keep in place the EUA, the FDA must determine that the known benefits of the product outweigh the known or potential risks associated with its use. 21 U.S.C § 360bbb-3(c)(2)(B). Based on current data, it is beyond dispute that Pfizer's COVID-19 vaccine EUA as it relates to children ages 5- through 11-years-old was improper because the presently known benefits of this vaccine in children are heavily outweighed by an honest and accurate assessment of the known and potential risks.

18. Almost immediately after the FDA granted the EUA for use of Pfizer's vaccine in 12- to 16-year-olds in May 2021 (without consulting its advisory group or having a public discussion concerning the data), it became apparent that children receiving Pfizer's vaccine can still become infected with and transmit the virus. As the Director of the CDC explained on national television, "what [the COVID-19 vaccines] can't do anymore is prevent transmission."[53] Numerous science-driven, not policy driven, studies have found the same rate of infection among the vaccinated and unvaccinated, with each having the same viral load in their nasal cavity.[54] The CDC recently published a study showing that even those double vaccinated shed for 6-9 days after infection.[55] This is of immense significance since Pfizer represented that its vaccine was 90.7% effective in this age group[56] and all of the scenarios utilized in the FDA's benefit-risk assessment assumed a VE of at least 70% against cases and 80% against hospitalization.[57] Moreover, the

[52] https://www.fda.gov/media/153507/download at 3.

[53] https://twitter.com/CNNSitRoom/status/1423422301882748929.

[54] Riemersma, *et al.*, *Shedding of Infectious SARS-CoV-2 Despite Vaccination*, MedRxiv (Aug. 24, 2021) https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf; Brown, *et al.*, *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings-Barnstable County, Massachusetts, July 2021*, MMWR (Aug. 6, 2021), https://pubmed.ncbi.nlm.nih.gov/34351882/; Shitrit, *et al.*, *Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021*, Euro. Surveill. (Sept. 30, 2021), https://pubmed.ncbi.nlm.nih.gov/34596015/.

[55] *See* https://wwwnc.cdc.gov/eid/article/28/5/22-0197_article?ACS.

[56] https://www.fda.gov/media/153409/download at 10.

[57] *Supra* note 52.

FDA's benefit-risk model only assessed the benefits of the vaccine in a 6-month period after vaccination and it assumed "**constant vaccine efficacy**" during that time period.[58]

19. This turned out to be wholly inaccurate. Presently, Pfizer's VE in this population is far below the 50% VE threshold for EUA licensure[59] due in large part to the fact that "prior mRNA vaccination imprints serological responses toward [only] Wuhan-Hu-1 rather than variant antigens."[60] In fact, according to a February 2022 study, "Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant," Pfizer's vaccine efficacy fell rapidly in 5- to 17-year-olds, and by the end of January 2022, was just 12% effective.[61] This means that, according to this study, 12,500 children would need to be vaccinated in order to prevent a single, non-severe COVID-19 infection. A CDC study was only slightly more generous. It found that two doses of a Pfizer vaccine received less than 5 months earlier were just 31% effective in preventing symptomatic or asymptomatic Omicron infection among children 5-11.[62]

20. Even earlier, by July 2021, Israel was reporting that Pfizer's VE had fallen to 63%, simultaneous with an increase in daily cases.[63] Mere weeks later, in the midst of the Delta wave, Israel was reported that VE had fallen dramatically to 39%.[64] By September 2021, studies were showing that vaccination rate had very little correlation with case rate and thus higher vaccination did not equate to fewer cases.[65] Ultimately by January 2022, a study showed that VE in 5- to 11-year-olds dropped to 12% after the Omicron variant became dominant.[66]

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[58] *Supra* note 52, at 3.

[59] https://www.fda.gov/media/139638/download at 17.

[60] Roltgen, Katharina, *Immune imprinting, breadth of variant recognition, and germinal center response in human SARS-CoV-2 infection and vaccination*, Cell (Mar. 17, 2022), https://www.cell.com/action/showPdf?pii=S0092-8674%2822%2900076-9 .

[61] See Dorabawila, Vajeera, *et al., Effectiveness of the BNT162b2 Vaccine Among Children 5-11 and 12-17 Years in New York after the Emergence of the Omicron Variant*, MedRxiv (Feb. 28, 2022), https://www.medrxiv.org/content/10.1101/2022.02.25.22271454v1.full-text (Table 1).

[62] Fowlkes, Ashley L., *et al., Effectiveness of 2-Dose BNT162b2 (Pfizer BioNTech) mRNA Vaccine in Preventing SARS-CoV-2 Infection Among Children Aged 5–11 Years and Adolescents Aged 12–15 Years — PROTECT Cohort*, July 2021–February 2022, MMWR (Mar. 18, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7111e1.htm.

[63] *Israel Sees Drop in Pfizer Vaccine Protection Against Infections*, Reuters (July 6, 2021), https://www.reuters.com/world/middle-east/israel-sees-drop-pfizer-vaccine-protection-against-infections-still-strong-2021-07-05/.

[64] Lovelace, Berkeley, *Israel Says Pfizer Covid Vaccine Is Just 39% Effective as Delta Spreads, But Still Prevents Severe Illness*, CNBC (July 23, 2021), https://www.cnbc.com/2021/07/23/delta-variant-pfizer-covid-vaccine-39percent-effective-in-israel-prevents-severe-illness.html.

[65] Subramanian, *et al., Increases in COVID-19 Are Unrelated To The Levels of Vaccination Across 68 Countries and 2947 Counties in the United States,* Euro. J. of Epidemiology (Sept. 9, 2021) https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/pdf/10654_2021_Article_808.pdf

[66] Dorabawila, *supra* note 61.

21. According to the CDC, the benefit of being vaccinated during Omicron amounted to spending "an average of one half day less sick in bed than unvaccinated [children]."[67] In the broader population, Pfizer's vaccine is only 31% effective against emergency department admission just nine months after the second dose.[68] A paper recently published in the Lancet shows that even three doses of Pfizer's vaccine wane in efficacy even for serious illness in just three months.[69] Individuals receiving four doses fared no better: An April 2022 study in the New England Journal of Medicine found, "Vaccine efficacy against any SARS-CoV-2 infection was 30% (95% confidence interval [CI], −9 to 55) for BNT162b2."[70] It is unsurprising then that on May 17, 2022, the FDA authorized a booster dose for 5- to 11-year-olds after just 5 months of their original series.[71] These additional doses carry an even greater risk of myocarditis and adverse events.[72] In sum, data is now irrefutable that Pfizer's product does not meet the necessary 50% efficacy threshold.[73]

22. Of note, one of the bases for authorization of the vaccine in this age group was prevention of "long COVID": "Prevention of symptomatic COVID-19 will also likely result in prevention of sequelae such as post-COVID symptoms (also known as "long COVID") and MIS-C."[74] Significantly, however, a May 2022 study showed that vaccination provides very little protection against long COVID.[75] In fact, the study showed that "[e]ven vaccinated people with mild breakthrough COVID-19 infections can experience debilitating, lingering symptoms that affect the heart, brain, lungs and other parts of the body."[76]

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[67] Fowlkes, *supra* note 62.

[68] Tartof, Sara, *et al., Durability of BNT162b2 vaccine against hospital and emergency department admissions due to the omicron and delta variants in a large health system in the USA: a test-negative case–control study,* Lancet (Apr. 22, 2022), https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(22)00101-1/fulltext

[69] *Id.*

[70] Regev-Yochay, G. *et al.*, *Efficacy of a Fourth Dose of Covid-19 mRNA Vaccine against Omicron*, N. Engl. J. Med. (Apr. 7, 2022), https://www.nejm.org/doi/full/10.1056/NEJMc2202542.

[71] *Supra* note 18.

[72] Patone, Martina, *et al.*, *Risk of Myocarditis Following Sequential COVID-19 Vaccinations by Age and Sex*, MedRxiv (Dec. 25, 2021), https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1.full.pdf (myocarditis risk increased during the 28 days following a third dose of Pfizer's covid-19 vaccine and "[a]ssociations were strongest in males younger than 40 years").

[73] *Supra* note 59, at 17.

[74] *Supra* note 1, at 37; *see also Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum*, (May 17, 2022), https://www.fda.gov/media/158575/download at 27 (suggesting a booster dose will decrease the chance of long COVID, which "can cause significant morbidity after initially mild infection, including in younger children").

[75] Al-Al, Ziyad, *et al.*, *Long COVID after Breakthrough SARS-CoV-2 Infection*, Nature Med. (May 25, 2022), https://www.nature.com/articles/s41591-022-01840-0.

[76] *Vaccinated People with Breakthrough SARS-CoV-2 Infection Can Experience Debilitating Long COVID*, News Med. Life Sciences (May 25, 2022), https://www.news-medical.net/news/20220525/Vaccinated-people-with-breakthrough-SARS-CoV-2-infection-can-experience-debilitating-long-COVID.aspx (citing Al-Al, *supra* note 74).

23. The dramatic waning in efficacy of Pfizer's COVID-19 vaccine, the need for more doses, and the extremely limited benefit only further emphasize the necessity of revoking the EUA for children ages 5-11.

24. The FDA recently acknowledged the issue of the variant susceptibility by pausing the distribution of some monoclonal antibody treatments because of their "reduced activity against the omicron variant."[77] More recently, on April 4, 2022, the FDA elected to revoke the EUA status of the monoclonal antibody treatment Sotrovimab, despite previously electing not to do so, because data showed Sotrovimab was "**unlikely** to be effective against the BA.2 sub-variant." (emphasis added).[78]

25. As with the monoclonal antibody treatments, Pfizer's vaccine was created based upon a very early and outdated variant of SARS-CoV-2.[79] Because of that, as detailed above, its efficacy against current variants is abysmal. If the FDA's policy is to revoke the EUA status of COVID-19 treatments that were formulated to be effective against earlier variants, then the EUA for the Pfizer vaccine must likewise be revoked, particularly where the variant susceptibility and consequent waning efficacy is proven and not theoretical as was the case with Sotrovimab.

26. The issue of waning immunity due to variants is all the more significant since the superior protective effect of natural immunity is now beyond dispute.[80] In a recent ground-breaking study, NIH researchers found, "For any given viral copy number, the odds of anti-N seropositivity were 13.67 times higher for the placebo arm than the vaccine arm."[81] Not only does this confirm vaccine-induced immunity is inferior to natural immunity, but it also demonstrates vaccine immunity appears to inhibit an individual's ability to acquire natural immunity to the nucleocapsid protein of the virus. Other studies have found the same effect. In March 2022, Stanford researchers found that "prior vaccination with Wuhan-Hu-1-like antigens followed by infection with Alpha or Delta variants gives rise to plasma antibody responses with apparent Wuhan-Hu-1-specific imprinting manifesting as relatively decreased responses to the variant virus

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[77] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron.

[78] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-sotrovimab-emergency-use-authorization.

[79] Harcourt, J. *et al.*, *Isolation and characterization of SARS-CoV-2 from the first US COVID-19 patient*, MedRxiv (Mar. 7, 2020), https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC7239045/.

[80] Gazit, Sivan, *et al., The Incidence of SARS-CoV-2 Reinfection in Persons with Naturally Acquired Immunity with and without Subsequent Receipt of a Single Dose of BNT162b2 Vaccine: A Retrospective Cohort Study*, Annals of Internal Medicine (Feb. 15, 2022), https://www.acpjournals.org/doi/10.7326/M21-4130; Flacco, Maria E., *et al., Risk of SARS-CoV-2 reinfection 18 months after primary infection: population-level observational study,* MedRxiv (Feb. 19, 2022), https://www.medrxiv.org/content/10.1101/2022.02.19.22271221v1 (finding 0.31% rate of reinfection in naturally immune 18-22 months after primary infection); see also Alexander, Paul E., How Likely Is Reinfection Following Covid Recovery?, Brownstone Institute (Dec. 29, 2021), https://brownstone.org/articles/how-likely-is-reinfection-following-covid-recovery/ (compiling studies).

[81] Follman, Dean, *et al., Anti-nucleocapsid antibodies following SARS-CoV-2 infection in the blinded phase of the mRNA-1273 Covid-19 vaccine efficacy clinical trial,* MedRxiv (Apr. 19, 2022), https://www.medrxiv.org/content/10.1101/2022.04.18.22271936v1

epitopes, compared with unvaccinated patients infected with those variant viruses," noting the extent to which this causes original antigenic sin "will be an important topic of ongoing study."[82]

27. According to the CDC's January 28, 2022 MMWR, unvaccinated individuals with prior COVID-19 infection had a lower rate of COVID-19-associated hospitalization than vaccinated individuals without a prior COVID-19 infection.[83] According to that Report, in California, the rate of COVID-19 cases in those with natural immunity (5%) was three times lower than for vaccinated individuals without prior COVID-19 infection (15.5%), and their rate of hospitalization was less than half of the vaccinated without prior COVID-19 infection (0.3% versus 0.7%).[84] Likewise, in New York, the rate of COVID-19 cases in those with natural immunity, 6.2%, was nearly three times lower than in the vaccinated without prior COVID-19, 18.2%.[85]

c. Known and potential risks from Pfizer's COVID-19 vaccine in 5- to 11-year-old children

28. Even if Pfizer's vaccine had maintained VE reasonably close to the 90.7% efficacy it claimed in its trial, the EUA should still be revoked in light of the real-world safety issues in 5- to 11-year-olds that were known at the time of the FDA's EUA and that have been identified since.

29. The FDA's benefit-risk assessment did not take the amount of children with natural immunity into consideration, despite, as noted, at least 42% of 5-11-year-olds had seroprevalence by June 2021.[86] As was acknowledged at ACIP's meeting, by Dr. Hong Yang, the author of the benefit-risk assessment presentation, the benefit-risk assessment did not make **any adjustments** for those children who already had superior protective immunity from prior infection because, she claimed, the FDA did not "have that data" regarding the protective effect of prior infection versus the vaccine and therefore the FDA considered everyone "susceptible to this disease."[87] That assertion is dubious given that by September 2021, there were over sixty studies suggesting natural immunity was equal to if not superior to vaccine-induced immunity.[88]

30. Nevertheless, Dr. Yang acknowledged during the October 26, 2021 ACIP meeting, if 45% of children in the 5- to 11-year-old age group had protective antibodies from prior infection, "[t]hen basically, you have 45 percent reduction of the other benefit," *i.e.*, a 45% reduction of the

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[82] Roltgen, *supra* note 59.

[83] Leon, Tomas M. *et al., COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York*, May–November 2021, MMWR (Jan. 28, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7104e1.htm# (Table 1 Figure).

[84] *Id.*

[85] *Id.*

[86] *Supra* note 24, at 7.

[87] https://www.fda.gov/media/154950/download at 257.

[88] https://www.icandecide.org/wp-content/uploads/2021/06/Letter-to-CDC-re-recovered-superior-to-vaccinated_2021_05_28.pdf (collecting studies); https://www.icandecide.org/wp-content/uploads/2021/10/Legal-update-Supplement-to-Petition-re-convalesced_FINAL.pdf (same).

benefit of the vaccine.[89] By that metric, accounting for the 42% of these children having natural immunity and applying it to the FDA's base modeling scenario #1 in males, the risk of hospitalization from just one adverse event, myopericarditis, in boys (118) is greater than the amount of COVID-19 hospitalizations that would be prevented by vaccination (156).[90] By that same metric, vaccination would prevent 39 ICU stays but at the risk of 57 vaccine-related myopericarditis ICU stays.[91] Presently, the rate of natural immunity is far higher. An April 2022 study showed 75.2% of children 0-11 had seroprevalence to SARS-CoV-2 as of February 2022.[92] Current NIH data shows the percentage is even higher at 89.4% of children 0-17 as of February 2022.[93] By now, the rate is almost certainly closer to 100% given the amount of time that has passed.

31. Data since the EUA bear this out. There have been thousands of reports of adverse events following the Pfizer COVID-19 vaccine in this population – most notably, heart damage including myocarditis. Even as early as June 2021, four months prior to VRBPAC's October 26, 2021 meeting to consider vaccination of 5- to 11-year-olds, the Committee acknowledged the growing issue of vaccine-induced myocarditis, particularly in individuals under 30 years old.[94]

32. Nevertheless, FDA chose to perform its the benefit-risk assessment utilizing an incident rate of 106 cases of myopericarditis cases per million children 5-15, which is well below the known rate of vaccine-induced myopericarditis. An April 2022 Kaiser Permanente study determined that that rate used by federal health authorities, including the FDA, was incorrect and the actual rate was nearly double, at 208 per million children vaccinated. The study observed that "[t]he true incidence of myopericarditis is markedly higher than the incidence reported to US advisory committees," noting they identified "approximately twice as many cases of myopericarditis following COVID-19 mRNA vaccination."[95] Likewise, a Hong Kong study

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[89] *Supra* note 87, at 258.

[90] *Supra* note 52, at 8.

[91] *Id.*

[92] Clarke, Kristie, *et al.*, *Seroprevalence of Infection-Induced SARS-CoV-2 Antibodies — United States, September 2021–February 2022*, MMWR (Apr. 26, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7117e3.htm.

[93] https://covid19serohub.nih.gov/.

[94] https://www.fda.gov/media/150641/download, at 3 ("Committee members generally acknowledged that COVID vaccines for use in the pediatric populations are needed; however, some members expressed concern that prior to vaccinating millions of healthy children, a better understanding of vaccine-induced adverse events, in particular potential long-term sequelae of myocarditis is needed."); https://www.fda.gov/media/150054/download, at p.12-26 (presentation by Dr. Tom Shimabukuro regarding vaccine-induced myocarditis/pericarditis cases in adolescents and young adults acknowledging "Median age of reported patients is younger and median time to symptom onset is shorter after dose 2" and that observed reports were higher than expected cases in ages 16-24.)

[95] Sharff, Katie A., *et al., Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large Integrated Health System: A Comparison of Completeness and Timeliness of Two Methods,* MedRXiv (Dec. 27, 2021), https://www.medrxiv.org/content/10.1101/2021.12.21.21268209v1.full.pdf.

determined that 37 per 100,000 males aged 12-17 were diagnosed with myocarditis following their second Pfizer COVID-19 shot.[96]

33. The long-term effects of vaccine-induced myocarditis in this age group is unknown and, unfortunately, will only be learned with time and at the expense of those children who have suffered, but there is the potential that these cases could potentially result in serious chronic conditions consistent with other forms of myocarditis.[97] We know that, in at least one case, this has resulted in the death of a young male.[98]

34. More broadly, there have been hundreds of adverse events beyond myocarditis that have been reported in children following COVID-19 vaccines. This alone should necessitate revocation of the EUA. In fact, VAERS data as of June 3, 2022, shows a total of 11,133 adverse events reported in 5- to 11-year-olds, of which 292 were rated as serious and 5 were deaths.[99] These numbers are all the more significant in light of the aforementioned fact that *at least* 74% of children have had prior COVID-19 infection, which has been shown to increase the severity of side effects. According to a study in the Lancet, "Systemic side-effects were more common (… 2.9 times after the first dose of BNT162b2) among individuals with previous SARS-CoV-2

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[96] Chua, Gilbert T., *et al.*, *Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination*, Clinical. Inf. Dis. (Nov. 28, 2021), https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab989/6445179.

[97] *See* Abe, Tadaaki, *et al.*, *Clinical Characteristics and Long-Term Outcome of Acute Myocarditis in Children*, Heart & Vessels (Oct. 13, 2012), https://pubmed.ncbi.nlm.nih.gov/23064719/. Numerous studies since have confirmed the seriousness of myocarditis. *See* Puchalski, M., *et al.*, *COVID-19 Vaccination-Induced Myocarditis in Teenagers: Case Series with Further Follow-Up*, Int. J. Env. Research & Pub. Health (Mar. 15, 2022), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8954790/pdf/ijerph-19-03456.pdf (finding persistent myocardium injury from COVID-19 vaccination after three months in all five members of teenage study group); Mevorach, *et al.*, *Myocarditis after BNT162b2 mRNA Vaccine against COVID-19 in Israel*, N. England J. Med. (Oct. 6, 2021), https://pubmed.ncbi.nlm.nih.gov/34614328/ ("The incidence of myocarditis…increased after the receipt of the BNT162b2 vaccine, particularly after the second dose among young male recipients," particularly in those 16-19.); Tano, *et al.*, *Perimyocarditis in Adolescents After Pfizer-BioNTech COVID-19 Vaccine*, J. of Pediatric Infectious Diseases Society (July 28, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8344528/ (study of 8 adolescent cases of post-vaccination myocarditis, three of whom were 15 years old); Marshall, *et al.*, *Symptomatic Acute Myocarditis in Seven Adolescents Following Pfizer-BioNTech COVID-19 Vaccination*, Pediatrics (June 4, 2021), https://pubmed.ncbi.nlm.nih.gov/34088762/ (study of seven adolescents with post-vaccine myocarditis including a 14-year-old); Schauer, *et al.*, *Myopericarditis After the Pfizer Messenger Ribonucleic Acid Coronavirus Disease Vaccine in Adolescents*, J. Pediatrics (July 2, 2021), https://www.sciencedirect.com/science/article/pii/S002234762100665X (study identified thirteen patients with post-vaccine myopericarditis with a median age of 15 years).

[98] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-05-19/03-COVID-Shimabukuro-508.pdf at 14 ("1 death in a male child with onset of fever 12 days after dose 1 and abdominal pain, vomiting, and death the following day (day 13 after dose 1); rapid clinical course, histopathologic evidence of myocarditis on autopsy, testing did not find evidence of viral infection at time of death, CDC continues to assist with case review").

[99] https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&STATE=NOTFR&WhichAge=range&LOWAGE=5&HIGHAGE=12 (11,133 adverse events); https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&SERIOUS=ON&STATE=NOTFR&WhichAge=range&LOWAGE=5&HIGHAGE=12 (292 serious adverse events); https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&DIED=Yes&STATE=NOTFR&WhichAge=range&LOWAGE=5&HIGHAGE=12 (5 deaths).

infection than among those without known past infection."[100] The sheer amount of VAERS reports is an "*abnormal* finding and a clear 'Safety Signal' that is being *knowingly* and *willfully* ignored by the CDC and FDA."[101]

35. Data from the CDC's V-safe monitoring system among adolescents ages 5-11 reveal that 57.7% experienced a local adverse reaction and 40.9% experienced a systemic adverse reaction (including, but not limited to, being unable to perform normal daily activities, unable to attend school, needing medical care, hospitalization) after the second dose of the Pfizer/BioNTech COVID-19 vaccine.[102] Further, 5.1% of parents of children aged 5-11 enrolled in V-safe reported that their child was "unable to perform normal daily activities" after dose 1 and 7.4% after dose 2.[103] Meaning, **our government's own data suggests the benefits of mass vaccination do not outweigh the risks**.

36. Even more concerning, an April 2022 study presented evidence that mRNA "vaccination induces a profound impairment in type I interferon signaling, which has diverse adverse consequences to human health." The article showed:

> Immune cells that have taken up the vaccine nanoparticles release into circulation large numbers of exosomes containing spike protein along with critical microRNAs that induce a signaling response in recipient cells at distant sites. We also identify potential profound disturbances in regulatory control of protein synthesis and cancer surveillance. These disturbances potentially have a causal link to neurodegenerative disease, myocarditis, immune thrombocytopenia, Bell's palsy, liver disease, impaired adaptive immunity, impaired DNA damage response and tumorigenesis. We show evidence from the VAERS database supporting our hypothesis. [104]

37. A paper published in the August 2021 issue of Science, Public Health Policy, and the Law made the startling finding that "estimates show that we must accept 4 reports of fatal and

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[100] Menni, Cristina, *et al., Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID Symptom Study app in the UK: a prospective observational study,* The Lancet (Apr. 27, 2021), https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00224-3/fulltext.

[101] Lindsay, Janci, *et al.*, *Letter to ACIP: "Considerations with Respect to Pediatric Populations for ACIP Meeting* November 2021," https://www.takescienceback.org/docs/2021/11/Considerations_with_Respect_to_Pediatric_Populations_for_ACIP_Meeting.pdf. It should be noted that this letter documents numerous other serious concerns regarding safety in this age group, all of which should be considered in any risk/benefit assessment.

[102] Hause, Anne M., *et al.*, *COVID-19 Vaccine Safety in Adolescents Aged 5-11 Years – United States, November 3 – December 19, 2021*, MMWR (Dec. 31, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm705152a1.htm.

[103] *Id.*

[104] Seneff, Stephanie, *et al.*, *Innate immune suppression by SARS-CoV-2 mRNA vaccinations: The role of G-quadruplexes, exosomes, and MicroRNAs*, Food & Chemical Tox. (Apr. 8, 2022), https://reader.elsevier.com/reader/sd/pii/S027869152200206X?token=EEEB125F51333F6292001B33F3DD878B975C1AB0EFC45DCC2BAA7F1781EF78D08A1CE71EBD74CEF0CEDBDACC1FDE27C5&originRegion=us-east-1&originCreation=20220429203851.

16 reports of serious side effect per 100,000 vaccinations in order to save the lives of 8 to 33 people. Bluntly, we would have to accept that 2 people might die to save the lives of three to 15 people."[105]

38. In addition to these known risks, potential risks must also be taken into account. Vaccinating against rapidly evolving viruses increases the risk of original antigenic sin and antibody dependent enhancement ("ADE"). Some experts also fear that doing so will lead to highly infectious and highly virulent variants of SARS-CoV-2 that will be resistant to any spike-based COVID-19 vaccines.[106] In fact, a February 2022 study demonstrated just that, "illustrat[ing] that infectivity strengthening mutations were the main mechanism for viral evolution, while vaccine-escape mutations become a dominating viral evolutionary mechanism among highly vaccinated populations."[107]

39. Since March 2021, Dr. Geert Vanden Bossche has been urging public health authorities about the dangers of mass vaccination during a pandemic:

> Deployment of current Covid-19 vaccines in mass vaccination campaigns combined with the ongoing widespread circulation of Sars-CoV-2 can only increase immune selective pressure on Sars-CoV-2 spike protein and hence, further drive its adaptive evolution to circumvent vaccine-induced humoral immunity. In this regard, the expectation of an increasing number of vaccinologists matches the current observation made by genomic epidemiologists in that S protein-directed immune escape variants are highly likely to further spread and expedite the occurrence of viral resistance to the currently deployed and future (so-called '2nd generation') Covid-19 vaccines. [108]

40. As Dr. Vanden Bossche predicted, official data published by the UK Health Security Agency now strongly suggest that the fully vaccinated have been suffering Antibody Dependent Enhancement since at least the beginning of January 2022. Astonishingly, this data shows COVID-19 death rates in vaccinated but unboosted individuals was higher than for those

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[105] Walach, Harald, *et al.*, *The Safety of COVID-19 Vaccinations—Should We Rethink the Policy?*, Science, Public Health, and the Law (Aug. 2021), https://www.publichealthpolicyjournal.com/_files/ugd/adf864_8c97b2396c2842b3b05975bfbd8254cb.pdf.

[106] *See* https://uploads-ssl.webflow.com/616004c52e87ed08692f5692/6244c3b09ad5701f3ec17765_GVB_s%2Banalysis%2Bof%2BC-19%2Bevolutionary%2Bdynamics.pdf (G. Vanden Bossche, March 2022). *See also* https://thehighwire.com/videos/the-vanden-bossche-warning/.

[107] Wang, Rui, *et al.*, *Emerging Vaccine-Breakthrough SARS-CoV-2 Variants*, ACS Infect. Dis. (Feb. 8, 2022), https://pubs.acs.org/doi/10.1021/acsinfecdis.1c00557.

[108] Vanden Bossche, Geert, *Why the ongoing mass vaccination experiment drives a rapid evolutionary response of SARS-CoV-2*, Voice for Science & Solidarity (June 21, 2021), https://www.voiceforscienceandsolidarity.org/scientific-blog/why-the-ongoing-mass-vaccination-experiment-drives-a-rapid-evolutionary-response-of-sars-cov-2. *See also* Lyons-Weiler, James, *Pathogenic priming likely contributes to serious and critical illness and mortality in COVID-19 via autoimmunity*, J. Translational Autoimmunity (Apr. 2, 2020), https://www.sciencedirect.com/science/article/pii/S2589909020300186.

who had never been vaccinated.[109] This data is all the more significant given NIAID Director Fauci's acknowledgement that "what happens in the U.K. usually happens here a few weeks later."[110]

41. Members of Congress share this same concern about ADE, as well as other concerns, which were articulated in their June 7, 2022 letter to FDA Commissioner Robert Califf:

> World renowned immunologists have raised concerns about the possibility of antibody dependent enhancement phenomenon (ADE) resulting from COVID vaccines, noting that ADE was a problem in earlier, unrelated COV vaccine trials. **What studies has the FDA relied upon when examining the possibility of ADE resulting from EUA COVID vaccines in children ages five and under, or any age group for that matter? Will the FDA affirm with 100% certainty that ADE is not a risk factor for children receiving this vaccine?**[111]

42. But the reality may unfortunately be darker. Official UK data revealed that the number of deaths among male teenagers 15 and to 19 between June 19, 2021, and September 17, 2021, was between 16% and 47% higher than the number of deaths in that age group during the same period in 2020.[112] The increase in deaths coincided with the time this age group began receiving COVID-19 vaccines, and COVID-19 deaths were too small to account for the excess. [113]

43. When the FDA was asked directly for the data supporting its statement that Pfizer's COVID-19 vaccine is effective to prevent the most severe consequences in 5- to 11-year-olds, the FDA pointed to its own EUA Review Memorandums from October 29, 2021, and May 17, 2022,

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[109] https://www.ons.gov.uk/peoplepopulationandcommunity/birthsdeathsandmarriages/deaths/bulletins/deathsinvolvingcovid19byvaccinationstatusengland/latest.

[110] *U.K. COVID cases are rising. Health officials are watching to see if the U.S. is next*, NPR (Mar. 19, 2022), https://www.npr.org/sections/health-shots/2022/03/19/1087682826/omicron-variant-ba2-surge; *see also* Offit, Paul, *Covid-19 Boosters — Where from Here?*, NEJM (Apr. 22, 2022), https://www.nejm.org/doi/full/10.1056/NEJMe2203329 ("[A]ll age groups are at risk for the theoretical problem of an 'original antigenic sin' — a decreased ability to respond to a new immunogen because the immune system has locked onto the original immunogen. An example of this phenomenon can be found in a study of nonhuman primates showing that boosting with an omicron-specific variant did not result in higher titers of omicron-specific neutralizing antibodies than did boosting with the ancestral strain. This potential problem could limit our ability to respond to a new variant).

[111] Letter from Congressmen to FDA Commissioner Robert M. Califf (June 7, 2022) https://posey.house.gov/uploadedfiles/fdalettercovidvaxquestionsjune82022.pdf (emphasis in original) (footnote omitted) (citing Sanchez-Zuno, Gabriela, *et al.*, *A review: Antibody-dependent enhancement in COVID-19: The not so friendly side of antibodies*, Int. J. Immunopathology & Pharma. (Sept. 14, 2021)).

[112] *Recent deaths in young people in England and Wales: Increase in Male Mortality in 15-19 year olds should be investigated*, HART (Oct. 11, 2021), https://www.hartgroup.org/recent-deaths-in-young-people-in-england-and-wales/.

[113] *Id.*

regarding use of Pfizer's vaccine and boosters in 5- to 11-year-olds.[114] The documents the FDA cited, however, reveal just how lacking the data is to support use of Pfizer's vaccine in this population. Examples of this from the May 17, 2022 Review Memorandum are the following:

> **While data on primary series vaccine effectiveness against COVID-19 hospitalization caused by the Delta variant are not available for ages 5-11 years**, vaccine effectiveness against COVID-19 hospitalization caused **by the Omicron variant in this age group has been estimated at 68% to 74% over a median follow-up period of approximately 1 month**, which is lower than estimates for primary series vaccine effectiveness against COVID-19 hospitalization caused by the Delta variant in adolescents and adults (approximately 90% in immunocompetent individuals). Data from observational studies have also indicated higher estimates of vaccine effectiveness against COVID-19 and serious outcomes in adults and adolescents among those who have received a booster dose than among those who have received only a primary series.
>
> . . .
>
> Additionally, **assuming** a pre-boost VE against hospitalization of 70%, **the Sponsor predicts** prevented hospitalizations of 16 (range: 0-16) based on the pandemic average COVID-19 incidence rate and 132 (range: 48-160) based on the Omicron peak incidence rate.
>
> . . .
>
> Since the overall **burden of COVID-19** (most notably more serious outcomes such as hospitalization and death) **is lower in children 5-11 years of age** compared with adults, **the individual-level and population-level benefits of a booster dose**, in particular among healthy vaccine recipients at low risk of severe COVID-19, **are expected to be lower in children 5-11 years of age than in adults and would depend largely on the incidence of COVID-19**[.][115]

44. Taken together, the EUA for use of the Pfizer vaccine in 5- to 11-year-olds is not only illegal because there is no emergency for children, but also because it was based on data which reflects that the known risks of the vaccine outweigh the known and potential harms from

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[114] Email from Jill Burkoff, Health Communications Specialist, FDA, to Elizabeth A. Brehm, Esq. (May 27, 2022 EST), available at https://www.icandecide.org/wp-content/uploads/2022/06/Email-from-Jill-Burkoff-Health-Communications-Specialist-FDA-to-Elizabeth-A.-Brehm-Esq.-May-27-2022-EST..pdf (citing https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-october-26-2021-meeting-announcement#event-materials; *Supra* note 1; Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum, (May 17, 2022), *supra* note 73.).

[115] Emergency Use Authorization (EUA) for an Unapproved Product Review Memorandum, (May 17, 2022), *supra* note 73 at 8, 23, 27 (emphasis added)

COVID-19. The data since the EUA have confirmed that the risks are far greater and the benefits far smaller than the FDA's benefit-risk assessment accounted for.

d. There was no legal emergency to justify emergency authorization of Moderna's COVID-19 vaccine in 6- to 11-year-olds.

45. For the same reasons set forth above, Moderna's vaccine presents a far greater risk than benefit to 6- to 11-year-olds, particularly since Moderna's vaccine presents an even higher risk profile to this age group than Pfizer's vaccine.

46. Like Pfizer's, Moderna's clinical trial was similarly underpowered. It included only 4,016 participants in part 2, only 2,998 of whom received the vaccine.[116]

47. The risks of the Moderna vaccine to this age group are even more significant than those of the Pfizer vaccine. French and Nordic studies found an increased incidence of myocarditis after a second dose of Moderna's vaccine among adolescent and young males versus Pfizer's.[117] Canada also identified a higher risk of myocarditis in Moderna's vaccine.[118] The risk of this vaccine is so significant that Sweden, Denmark, Norway, Finland, Germany, and France have ceased administering or recommended against the use of Moderna's vaccine in young adults and/or young adult males.[119]

48. A very large April 20, 2022 study of 23 million Nordic residents confirmed that mRNA shots sharply raised the risk of heart damage in those who received them last year and Moderna's vaccine was significantly more dangerous particularly for young men.[120] Data from the study showed a trend toward deadlier outcomes in myocarditis patients who received Moderna's shot as opposed to Pfizer's or in those who received no vaccine. Nearly 5% of people who were hospitalized for myocarditis after receiving Moderna's vaccine died versus less than 1% of those who received Pfizer's vaccine or were unvaccinated.

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[116] Creech, Buddy, C., *et al.*, *Evaluation of mRNA-1273 Covid-19 Vaccine in Children 6 to 11 Years of Age*, N. Eng. J. Med. (May 26, 2022), https://www.nejm.org/doi/full/10.1056/NEJMoa2203315.

[117] *Meeting Highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 29 November – 2 December 2021*, European Medicines Agency (Mar. 12, 2021), https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-committee-prac-29-november-2-december-2021.

[118] Statement from the Council of Chief Medical Officers of Health (CCMOH): *Update on COVID-19 Vaccines and the Risk of Myocarditis and Pericarditis,* Public Health Agency of Canada (Oct. 1, 2021), https://www.canada.ca/en/public-health/news/2021/10/statement-from-the-council-of-chief-medical-officers-of-health-ccmoh-update-on-covid-19-vaccines-and-the-risk-of-myocarditis-and-pericarditis.html ("Vaccine safety surveillance data in Canada also suggest relatively higher rates of myocarditis and/or pericarditis reported after Spikevax (Moderna) vaccination compared to Comirnaty (Pfizer-BioNTech).").

[119] Hart, Robert, *Germany, France Restrict Moderna's Covid Vaccine for Under-30s Over Rare Heart Risk—Despite Surging Cases*, Forbes (Nov. 10, 2021), https://www.forbes.com/sites/roberthart/2021/11/10/germany-france-restrict-modernas-covid-vaccine-for-under-30s-over-rare-heart-risk-despite-surging-cases/?sh=68eebadf2a8a.

[120] Karlstad, Oystein, *SARS-CoV-2 Vaccination and Myocarditis in a Nordic Cohort Study of 23 Million Residents*, JAMA Cardiology (Apr. 20, 2022), https://pubmed.ncbi.nlm.nih.gov/35442390/.

49. The known benefits of Moderna's vaccine for 6- to 11-year-olds do not outweigh the known and potential risks.

C. ENVIRONMENTAL IMPACT

50. 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

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

E. CERTIFICATION

52. 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.

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

Respectfully submitted,

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