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VIA ELECTRONIC FILING

May 20, 2022

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
Attn: Commissioner Robert M. Califf, M.D.
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Dear Commissioner Califf,

Enclosed is a Citizen Petition filed by Informed Consent Action Network ("**ICAN**") requesting that the Commissioner of the Food and Drug Administration revoke the May 10, 2021 reissuance of the Emergency Use Authorization letter of authorization for use of Pfizer-BioNTech's COVID-19 vaccine in children ages 12 through 15, and refrain from authorizing or approving Moderna's current COVID-19 vaccine for 12- to 17-year-olds.

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

Respectfully submitted,

/s/ Aaron Siri

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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 12 THROUGH 15 AND AUTHORIZATION FOR MODERNA'S COVID-19 VACCINE FOR CHILDREN AGES 12 THROUGH 17	:	**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 C.F.R. § 10.35 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 May 10, 2021 reissuance of the Emergency Use Authorization ("**EUA**") letter of authorization for use of Pfizer-BioNTech's COVID-19 vaccine in children ages 12 through 15,[1] and refrain from authorizing Moderna's request for emergency use authorization of its vaccines in 12- to 17-year-olds, pursuant to 21 U.S.C. § 360bbb-3.

The Food and Drug Administration ("**FDA**") lacked the legal authority and had no need to issue an EUA for Pfizer's product for 12- to 15-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 authorization clearly shows the known benefits do not outweigh the known and potential risks. Because there is no health emergency for children, the FDA likewise lacks the legal authority to issue an EUA for Moderna's vaccine for 12- to 17-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 12 through 15, and (ii) refrain from authorizing Moderna's current COVID-19 vaccine for 12- to 17-year-olds.

A. ACTIONS REQUESTED

It is hereby requested that:

1. the May 10, 2021 reissuance of the EUA letter of authorization for the use of Pfizer-BioNTech's COVID-19 vaccine for children ages 12 through 15 be revoked pursuant to 21 U.S.C. § 360bbb-3(g);

2. the FDA refrain from authorizing Moderna's current COVID-19 vaccine for children ages 12 through 17; and

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

[1] https://www.fda.gov/media/144412/download.

B. STATEMENT OF GROUNDS

I. The Initial Granting of the EUA for Pfizer's Vaccine for 12- to 15-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.[2]

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 12- to 15-year-olds in order to justify an EUA. However, as shown below, on May 10, 2021 at the time the EUA was granted, there was not then and still is no emergency now 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.[3]

6. From March through October of 2020, children ages 5-14 had a one-in-a-million chance of dying *with* COVID-19,[4] 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.[5] 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."[6] The rate of hospitalization for COVID-19 according

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[2] *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.").

[3] 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.").

[4] 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.

[5] *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.

[6] 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.

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.[7]

7. Despite what has been an apparent continued effort to inflate COVID-19 numbers in children and induce fear among parents,[8] 12- to 17-year-olds made up just 9% of all U.S. COVID-19 cases in April 2021.[9] As of May 9, 2021, the day prior to the FDA's grant of the EUA, the rate of new admissions of patients under 18 years old with confirmed COVID-19 cases was 0.14 per 100,000.[10] Between January and April 2021, of the 204 12- to 17-year-olds who were "likely hospitalized primarily for COVID-19," **not a single one died**.[11] Even ACIP acknowledged in its meeting to determine whether to recommend this vaccine that, "[b]etween January 1, 2020 and April 30, 2021, there were 127 COVID-19 deaths among adolescents 12-17 years of age, which accounted for 1.3% of all deaths among adolescents during the same time period"[12] And those 127 deaths were *with* COVID, not necessarily *from* COVID, with no accompanying data regarding underlying conditions. Even at the time the EUA was granted, it was clear that this was not a severe or deadly pandemic for children as the data has clearly and consistently shown.

b. The clinical trial relied upon to authorize Pfizer's vaccine in 12- to 15-year-olds was deficient

8. Initially, it should be noted that the clinical trial relied upon to authorize the Pfizer vaccine for 12- to 15-year-olds was underpowered and inadequate to properly test efficacy and safety for several reasons:

- The trial included only 2,260 participants, half of whom received the vaccine and half of whom received a placebo.[13] Meaning, only 1,131 children were vaccinated. That number of participants is inadequate to identify any potential adverse events, and the statistical significance of same, should the rate of injuries be above one in

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

[8] 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.

[9] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-05-12/04-COVID-Oliver-508.pdf, at 13.

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

[11] *See* Havers, Fiona P., *supra* note 8.

[12] https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/summary-2021-05-12-508.pdf, at 14.

[13] Mahase, Elisabeth, *Covid-19: Pfizer Reports 100% Vaccine Efficacy in Children Aged 12 to 15*, BMJ (Apr. 1, 2021), https://www.bmj.com/content/373/bmj.n881.

2,500. Even the CDC's Grading of Recommendations, Assessment, Development, and Evaluation of Pfizer's vaccine in 12- to 15-year-olds, which was relied upon by ACIP in recommending the vaccine,[14] acknowledged this: "For evaluation of potential harms, data were reviewed from the Phase II/III randomized control trial. There was serious concern of indirectness because the body of evidence does not provide certainty that rare serious adverse events were captured due to the short follow-up and sample size. There was also very serious concern for imprecision, due to the width of the confidence interval."[15] 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."[16] Significantly, however, with respect to this vaccine in this population, we know that the rate of serious injury is at least 1 in 1,131.

- One of the children who participated in this trial, Maddie de Garay, suffered numerous serious adverse events immediately after receiving her second Pfizer shot. Despite the clear medical records and documentation of her immediate and serious injuries, in the data Pfizer turned over to the FDA for evaluation of an EUA, Maddie's life-altering reaction was classified as mere "functional abdominal pain."[17] Maddie's injuries have adversely altered her life, left her in debilitating pain and dependent on a wheelchair to get around, and on an NG tube for sustenance. Clearly, the risk of adverse events from this vaccine in this population is so great that even an underpowered clinical trial identified a devastating and life altering serious adverse event, even if Pfizer didn't acknowledge it as such.

- Equally problematic is that the trial was not representative of most American children. It only included "healthy participants" and excluded those who were previously infected with SARS-CoV-2.[18] This resulted in excluding a large proportion of American children since at least 37% of children were estimated by the CDC to have been infected with SARS-CoV-2 as of May 2021[19] and 43% are estimated to have chronic health condition.[20] Moreover, the 12- to 15-year-olds in the trial were approximately 86% White and only 12% Hispanic or Latino, and only 567 boys were vaccinated in the trial.

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[14] *Supra* note 12, at 9.

[15] https://www.cdc.gov/vaccines/acip/recs/grade/covid-19-pfizer-biontech-vaccine-12-15-years.html.

[16] 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/.

[17] https://www.fda.gov/media/148542/download, at 30.

[18] Also excluded were those with "other medical conditions that may make the participant inappropriate for the study," and those who have had a severe adverse reaction to any other vaccine.

[19] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-11-2-3/03-Covid-Jefferson-508.pdf, at 7.

[20] Bethell, C.D., *et al.*, *A national and state profile of leading health problems and health care quality for US children: key insurance disparities and across-state variations*, Acad. Pediatr. (May-June 2011), https://pubmed.ncbi.nlm.nih.gov/21570014/.

- 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.[21] (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 12 to 15 years compared to participants 16 to 25 years of age.[22] The latter is a cohort in which Pfizer represents that the vaccine has demonstrated efficacy against preventing symptomatic infection.[23] 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, no correlate or protection is currently known for SARS-CoV-2. As numerous members of VRBPAC recently pointed out, and a large body of literature in vaccinology underscores, antibody response does not necessary tell one if a vaccine will work.[24] 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?"[25] 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.[26]

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[21] 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.

[22] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-biontech-announce-positive-topline-results-pivotal.

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

[24] *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.").

[25] 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.

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

- In addition to safety and efficacy issues, 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." However, even from the limited data available, 10.7% of the participants reported Grade 3 or higher adverse events within the trial.[27] As described above, at least one participant, Maddie de Garay, suffered severe vaccine-related adverse events but "[n]one of the events were considered to be associated with vaccination."[28] That the trial was inadequate to detect adverse events was evidenced clearly on June 23, 2021 when the CDC reported the alarming numbers of reported myocarditis and pericarditis cases occurring after COVID-19 vaccination.[29] This adverse event was not picked up in the clinical trial. The FDA acknowledged at the time of the EUA, "Following authorization of the vaccine, use in large numbers of individuals 12-15 years of age may reveal additional, potentially less frequent and/or more serious adverse events not detected in the trial safety population…"[30]

  Even the adverse events that were picked up by the clinical trial pointed to serious issues from the start. From data from the 12-15 -year-old age groups, 7 of the 1,131 vaccinated participants had at least one serious adverse event, compared to only 2 of the 1,129 participants in the unvaccinated group. This means that the vaccinated had a statistically significant higher risk of severe adverse events than those unvaccinated.[31]

- Finally, 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 trial got severe disease. None were hospitalized for COVID-19 or died of it.[32] 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.

9. 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.

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[27] *Supra* note 15.

[28] *Supra* note 12, at 11.

[29] https://www.cdc.gov/vaccines/acip/meetings/downloads/min-archive/summary-2021-06-23-508.pdf, at 9 (noting 791 reports of myocarditis and pericarditis following receipt of Pfizer-BioNTech).

[30] *Supra* note 17, at 39.

[31] *See* https://www.nejm.org/doi/suppl/10.1056/NEJMoa2107456/suppl_file/nejmoa2107456_appendix.pdf at 9.

[32] *Supra* note 12, at 9 ("There were no COVID-19 hospitalizations or cases of MIS-C among vaccinated or placebo participants in the available body of evidence, so these outcomes were not included in the evidence profile ….").

II. The EUA for Pfizer's Vaccine Continues to Be Unlawful

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

10. As was the case prior to authorization of this vaccine for use in 12- to 15-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."[33] The CDC has now also acknowledged that 74.2% of American children aged 12-17 years show seroprevalence to SARS-CoV-2.[34]

11. 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.[35] 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.[36] 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."[37] Notably, this metric does not necessarily correlate with severe cases of pediatric COVID-19 because it "may be inflated by the detection of mild or asymptomatic infection via universal screening."[38] As Dr. 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

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[33] 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.

[34] https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7117e3-H.pdf. It should be noted that the FDA has acknowledged that "The unknown benefits and data gaps associated with the Pfizer-BioNTech COVID-19 vaccine when used in adolescents 12-15 years of age" include "Effectiveness in individuals previously infected with SARS-CoV-2." *Supra* note 17, at 38.

[35] 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

[36] 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.

[37] 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*, 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.").

[38] 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.

> 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.[39]

12. 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 "misclassified" and "were not COVID-19 related."[40] That tracker now shows that deaths in the 12-15-year-old age group account for 0% of the deaths tracked and only 4.8% of the cases.[41]

13. 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 12- to 15-year-olds are heavily outweighed by the known and potential risks

14. 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 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 12 through 15 was improper because the presently known benefits of this vaccine in children definitively do not outweigh an honest and accurate assessment of the known and potential risks.

15. Almost immediately after the FDA granted this EUA (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."[42] 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.[43] The CDC recently published a study showing that even those double

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[39] https://www.youtube.com/watch?v=Aktzp4jSXY8.

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

[41] *Id*. CDC notes only 789 deaths "involving COVID-19 in children ages 5-18 years old. There is no breakdown of deaths in 12- to 15-year-olds, no data about deaths from COVID-19, and no data about any underlying conditions involved in any of the deaths. *See* https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3.

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

[43] 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*

vaccinated shed for 6-9 days after infection.[44] This is of immense significance since a large part of ACIP's consideration and recommendation of the vaccine[45] was based on the assumption that the purported 100% VE demonstrated in the trial would remain roughly the same.[46]

16. This turned out not to be accurate. Presently, Pfizer's VE in this population barely meets the FDA's 50% VE threshold for EUA licensure due in large part to the fact that "prior mRNA vaccination imprints serological responses toward [only] Wuhan-Hu-1 rather than variant antigens."[47] A study that estimated Pfizer's VE against COVID cases and hospitalizations during December 2021 and January 2022 showed that among 852,384 12-17-year-old fully-vaccinated children, VE against cases declined from 66% to 51% and VE against hospitalization for those ages declined from 85% to 73%. This waning of protection was after a period of approximately six weeks.[48] A CDC study found that two doses of Pfizer's vaccine received less than 5 months earlier were only 59% effective among 12- to 15-year-olds in preventing Omicron infection and noted that the "wide and overlapping confidence intervals" indicate that this estimate may not be significantly different from the 31% estimate of VE for 5- to 11-year-olds.[49] The CDC points to another similar recent report of VE of 45-51% against Omicron-associated ED and urgent care visits among 5- to 15-year-olds.[50]

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/.

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

[45] We must rely on analyses by ACIP as VRBPAC, the FDA's advisory committee, was not convened to discuss recommendations for Pfizer's vaccine in the 12- to 15-year-old age range until after the FDA had authorized it. Incredibly, when VRBPAC did eventually meet on June 10, 2021, the committee members were asked not to focus on effectiveness, but instead "to focus their discussion on safety issues" since, according to VRBPAC member Dr. Dorian Fink, "we have a very well-established regulatory precedent for demonstrating effectiveness in pediatric populations including in the situation where clinical endpoint efficacy for the vaccine has previously been demonstrated in adults." https://www.fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-10-2021-meeting-announcement at 40:30.

[46] "The VE efficacy observed at a median 2-month follow-up may be different from the efficacy observed with ongoing follow-up. However, in consideration with the strength of association, it is unlikely that the efficacy estimate for symptomatic COVID-19, which [sic] changed substantially enough to fall below the FDA-defined efficacy threshold for licensure under an EUA to less than 50% efficacy. The WG also noted that longer-term efficacy from the adult RCT suggests that short-term efficacy will translate to longer-term efficacy." *Supra* note 12, at 11 (emphasis added).

[47] 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 .

[48] *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.

[49] 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.

[50] *See* Klein, Nicola P., *Effectiveness of COVID-19 Pfizer-BioNTech BNT162b2 mRNA Vaccination in Preventing COVID-19–Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among*

17. Even earlier, by July 2021, Israel was reporting that Pfizer's VE had fallen to 63%, simultaneous with an increase in daily cases.[51] Mere weeks later, in the midst of the Delta wave, Israel was reported that VE had fallen dramatically to 39%.[52] 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.[53] Ultimately by January 2022, a study showed that VE in 12- to 15-year-olds dropped as low as 50% after the Omicron variant became dominant.[54]

18. 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 [for 12 to 15 year olds]."[55] In the broader population, Pfizer's vaccine is only 31% effective against emergency department admission just nine months after the second dose.[56] 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.[57] 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."[58] It is unsurprising then that on January 5, 2022, the CDC recommended adolescents 12 to 17 years old receive a booster dose within just 5 months of their original series.[59] These additional doses carry an even greater risk of myocarditis and adverse events.[60]

Nonimmunocompromised Children and Adolescents Aged 5–17 Years — VISION Network, 10 States, April 2021–January 2022, MMWR (Mar. 4, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7109e3.htm?s_cid=mm7109e3_w.

[51] *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/.

[52] 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.

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

[54] Dorabawila, *supra* note 48.

[55] Fowlkes, *supra* note 49.

[56] Tartof, Sara, *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

[57] *Id.*

[58] 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.

[59] https://www.cdc.gov/media/releases/2022/s0105-Booster-Shot.html#:~:text=Today%2C%20CDC%20is%20endorsing%20the,initial%20Pfizer%2DBioNTech%20vaccination%20series.

[60] 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

19. This 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 12-15.

20. 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."[61] 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).[62]

21. As with the monoclonal antibody treatments, Pfizer's vaccine was created based upon a very early and outdated variant of SARS-CoV-2.[63] 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.

22. Further diminishing the benefits of vaccination is the current rate of natural immunity in this population. A recent study showed that, as of February 2022, **approximately 75% of children ages 12-17 had seroprevalence of infection-induced SARS-CoV-2 antibodies**.[64] Current NIH data shows the percentage is even higher at 89.4% of children 0-17 as of February 2022.[65] By now, the rate is almost certainly closer to 100% as more time has passed.

23. The superior protective effect of natural immunity is now beyond dispute.[66] In a recent ground-breaking study, NIH researchers found, "For any given viral copy number, the odds

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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").

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

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

[63] 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/.

[64] 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.

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

[66] 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).

of anti-N seropositivity were 13.67 times higher for the placebo arm than the vaccine arm."[67] 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 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."[68]

24. 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.[69] 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%).[70] 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%.[71]

c. Known and potential risks from Pfizer's COVID-19 vaccine in 12- to 15-year-old children

25. Even if Pfizer's vaccine had maintained VE reasonably close to the 100% efficacy it claimed in its trial, the EUA should still be revoked in light of the real-world safety issues that have been identified since its authorization in 12- to 15-year-olds.

26. Since the EUA, there have been thousands of reports of adverse events following the Pfizer COVID-19 vaccine in this population – most notably, heart damage including myocarditis.

27. Even as early as June 2021, VRBPAC acknowledged the growing issue of vaccine-induced myocarditis, particularly in individuals under 30 years old.[72] Although the FDA recently

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[67] Follman, Dean, *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

[68] Roltgen, *supra* note 47.

[69] 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).

[70] *Id.*

[71] *Id.*

[72] 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

utilized an incident rate of only 106 cases of myopericarditis cases per million children 5 to 15,[73] a more recent 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.[74] 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."[75]

28. Studies now confirm that the risk of cardiomyopathies in youth outweighs their risk for hospitalizations from COVID-19. In adolescent boys ages 12 to 15 with no medical comorbidities who received their second mRNA vaccine dose, "the cardiac adverse event rate was 3.7 to 6.1 times higher, than their 120-day COVID-19 hospitalization risk as of August 21, 2021, and 2.6-4.3-fold higher at times of high weekly hospitalization risk."[76]

29. 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.[77]

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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.)

[73] https://www.fda.gov/media/153507/download, at p.10.

[74] 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.

[75] *Id.*

[76] 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 (citing Witberg, Guy, *et al.*, *Myocarditis after Covid-19 Vaccination in a Large Health Care Organization*, N. Engl. J. Med. (Dec. 2, 2021), https://www.nejm.org/doi/full/10.1056/NEJMoa2110737; Hoeg, Tracy Beth, et al., *SARS-CoV-2 mRNA Vaccination-Associated Myocarditis in Children Ages 12-17: A Stratified National Database Analysis*, Medrxiv (Sept. 8, 2021), https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1; Pfizer Japanese Biodistribution Study, available at https://pandemictimeline.com/wp-content/uploads/2021/08/Pfizer-bio-distribution-confidential-document-translated-to-english.pdf; "Assessment Report: Covid-19 Vaccine Moderna prepared for EMA (Mar. 2021), available at https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf).

[77] *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

30. More broadly, there have been hundreds of adverse events in addition to myocarditis reported in children following COVID-19 vaccines which alone should necessitate revocation of the EUA. In fact, VAERS data as of May 6, 2022, shows a total of 31,549 adverse events reported in 12- to 17-year-olds, of which 1,812 were rated as serious and 44 were deaths.[78] There have been 1,790 reported vaccine-related hospitalizations among children ages 6-17 years old. 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 infection than among those without known past infection."[79] 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."[80]

31. Data from the CDC's v-safe monitoring system among adolescents ages 12 to 15 reveal that 25.4% of children ages 12 to 15 experienced an adverse health impact (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.[81] Meaning, **our government's own data suggests the benefits of mass vaccination do not outweigh the risks**.[82]

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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).

[78] https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&VAXTYPES=COVID-19&STATE=NOTFR&WhichAge=range&LOWAGE=12&HIGHAGE=18 (31,549 adverse events); https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&VAXTYPES=COVID-19&SERIOUS=ON&STATE=NOTFR&WhichAge=range&LOWAGE=12&HIGHAGE=18 (1,812 serious events); https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=AGE&EVENTS=ON&VAX=COVID19&VAXTYPES=COVID-19&DIED=Yes&STATE=NOTFR&WhichAge=range&LOWAGE=12&HIGHAGE=18 (44 reports of death).

[79] 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.

[80] Lindsay, *supra* note 76. 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 analysis.

[81] Hause, *et al.*, *COVID-19 Vaccine Safety in Adolescents Aged 12-17 Years – United States, December 14, 2020 – July 16, 2021*, MMWR (Aug. 6, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e1.htm.

[82] Delahoy, *et al.*, *Hospitalizations Associated with COVID-19 Among Children and Adolescents – COVID-NET, 14 States, March 1, 2020-August 14, 2021*, MMWR (Sept. 10, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7036e2.htm.

32. 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. [83]

33. 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. 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. [84]

34. 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. [85]

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[83] 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.

[84] *See* https://mcmillanresearch.com/wp-content/uploads/2022/03/GVBs-analysis-of-C-19-evolutionary-dynamics.pdf (G. Vanden Bossche, March 2022). *See also* https://thehighwire.com/videos/the-vanden-bossche-warning/.

[85] 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-

35. 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 ("**ADE**") 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 who had never been vaccinated.[86] 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."[87]

36. 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.[88] 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. [89]

37. Taken together, the EUA for use of the Pfizer vaccine in 12- to 15-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 COVID-19.

III. There Is No Legal Emergency to Justify Emergency Use Authorization for Moderna's COVID-19 Vaccine in 12- to 17-year-olds.

38. For the reasons set forth above, Moderna's current vaccine presents a far greater risk than benefit to 12- to 17-year-olds, particularly where Moderna's vaccine presents an even higher risk profile to this age group than Pfizer's vaccine.

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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.

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

[87] *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).

[88] *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/.

[89] *Id.*

39. Like Pfizer's, Moderna's clinical trial was similarly underpowered. It included only 3,732 participants, only half of whom received the vaccine.[90]

40. 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.[91] Canada also identified a higher risk of myocarditis in Moderna's vaccine.[92] 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.[93]

41. 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.[94] 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.

42. The known benefits of Moderna's current COVID-19 vaccine for 12- to 17-year-olds do not outweigh the known and potential risks.

C. ENVIRONMENTAL IMPACT

43. 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. §§ 25.30 and 25.31.

D. ECONOMIC IMPACT

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

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[90] https://clinicaltrials.gov/ct2/show/NCT04649151.

[91] *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.

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E. CERTIFICATION

45. 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.

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

Respectfully submitted,

/s/ Aaron Siri

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