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February 11, 2022

VIA ELECTRONIC SUBMISSION AND EMAIL

FDA-2022-N-0082

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Members of Vaccines and Related Biological Products Advisory Committee
Food and Drug Administration

Re: Upcoming VRBPAC Meeting on Amending the EUA for the Pfizer-BioNTech COVID-19 mRNA Vaccine for Administration to Children 6 Months to 4 Years of Age

Dear Members of VRBPAC:

We write to you on behalf of our client, Informed Consent Action Network (“**ICAN**”), regarding one of the most important issues in this country right now: COVID-19 vaccination in our youngest pediatric population. To date, the Pfizer-BioNTech COVID-19 vaccine, Comirnaty, is approved for children ages 16 and 17 and authorized for children ages 5 to 15. On February 15, 2022, the Vaccines and Related Biological Products Advisory Committee (“**VRBPAC**”) will meet to discuss amending the emergency use authorization (“**EUA**”) for the Pfizer-BioNTech COVID-19 vaccine for use in children ages 6 months to 4 years.

This letter will summarize the lack of benefit of COVID-19 vaccination in children and the absence of adequate safety and efficacy data to support **any** recommendation for the use of Pfizer’s COVID-19 vaccine among this pediatric demographic.

I. There is No Emergency Regarding COVID-19 in Children Ages 6 Months to 4 Years

There are nearly 73 million children living in the United States accounting for approximately 22% of our nation’s population.¹ Approximately 23.4 million of them are ages 0-5.

Among children 0-4 years old in the United States, according to the CDC, the weekly rate of COVID-19-associated hospitalizations peaked during the first week of 2022 at 15.5 per 100,000, and then quickly fell to 6 per 100,000 for the week ending January 29, 2022.² However, this metric does not correlate with severe cases of pediatric COVID-19 because it “may be inflated by the

¹ <https://www.childstats.gov/americaschildren/demo.asp>.

² https://gis.cdc.gov/grasp/COVIDNet/COVID19_3.html.

detection of mild or asymptomatic infection via universal screening.”³ At least one study analyzed 117 pediatric hospitalizations with confirmed cases of COVID-19, finding that 39.3% of pediatric COVID-19 hospital admissions were asymptomatic, 28.2% had only mild to moderate symptoms, and 45% of admissions were unlikely to have been caused by COVID-19.⁴ The CDC Director, Dr. Rochelle Walensky, has acknowledged the same. In a January interview, Dr. Walensky said, “In some hospitals that we’ve talked to, up to 40 percent of the patients who are coming in with COVID-19 are coming in not because they’re sick with COVID, but because they’re coming in with something else and have had COVID, or the Omicron variant, detected.”⁵ Therefore, by the CDC’s own admission, the COVID-19-associated case numbers are inflated. Dr. Anthony Fauci made a similar admission when he suggested that “many” of the children included in hospitalization numbers were “hospitalized *with* COVID as opposed to because of COVID.” As an example, Dr. Fauci explained that some children counted as being in the hospital with COVID are receiving treatment for “a broken leg or appendicitis” rather than for COVID and “so it’s overcounting.”⁶

Numerous studies suggest healthy children do not die from COVID-19 disease. A paper from a research team at Johns Hopkins analyzed approximately 48,000 children under 18 years old diagnosed with COVID-19 and **found a mortality rate of zero among children who did not have a pre-existing medical condition** such as leukemia.⁷ Neither the FDA nor the CDC have put forth data disputing this, and the available data is for “deaths involving COVID-19” as opposed to deaths caused by COVID-19.⁸

In the UK, scientists developed the same conclusions after analyzing the incidence of healthy children dying *from* COVID-19. Of the 25 childhood fatalities determined to be caused by COVID-19, only 6 (24%) of the children were determined to be healthy, corresponding to 0.48 deaths per million children.⁹ Scientists also noted that “it is possible, due to the hospital data only being available for the last five years, that some children and young people may have had a comorbidity that was not identified in this linkage.”¹⁰

Therefore, given the above data and the extraordinarily low risk of hospitalization and mortality from COVID-19 among healthy children, **there is no emergency need to justify**

³ <https://publications.aap.org/hospitalpediatrics/article-abstract/11/8/e151/179740/For-COVID-or-With-COVID-Classification-of-SARS-CoV?redirectedFrom=fulltext>.

⁴ *Id.*

⁵ Miller, Mickey, *CDC Director: Up to 40% of those in hospital with COVID there for other reasons*, (Jan. 11, 2022) <https://srtdf.org/cdc-director-up-to-40-of-those-in-hospital-with-covid-there-for-other-reasons/>.

⁶ <https://www.youtube.com/watch?v=Aktzp4jSXY8> at 3:20.

⁷ <https://thebl.com/us-news/study-finds-zero-covid-deaths-in-48000-healthy-children-undermining-cdc-pressure-to-vaccinate-them.html>. See also <https://www.wsj.com/articles/cdc-covid-19-coronavirus-vaccine-side-effects-hospitalization-kids-11626706868>.

⁸ <https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3>.

⁹ <https://assets.researchsquare.com/files/rs-689684/v1/0f1fbef9-0308-4ce1-9271-ed1e922c846d.pdf?c=1631885995>.

¹⁰ *Id.*

authorizing an experimental vaccine, BNT162b2, via Emergency Use Authorized (“EUA”) for use in children 6 months to 4 years of age.

II. The Clinical Trial and Resulting Data is Wholly Inadequate to Support Authorization for This Age Group

Pfizer’s clinical trial consists of four cohorts made up of children between the ages of 6 months and <2 years and children 2 years or older to <5-years-of-age with participants receiving either a 3mcg dose of BNT162b2 or placebo.¹¹ As of this writing, the clinical trial data has not been released to the public for scrutiny ahead of the upcoming VRBPAC meeting. Pfizer’s press release states that the Phase 1/2/3 trial initially enrolled 4,500 children between the ages of 6 months to 12 years¹² however, following amendments, additional children were enrolled and, according to Pfizer, there are roughly 8,300 children ranging from 6 months of age to 12 years in the current trial.¹³ There is no breakdown of many of those children are under 5 years of age.

A proper assessment of COVID-19 vaccine efficacy requires evaluating the vaccine’s ability to prevent COVID-19 disease. However, Pfizer’s clinical trial was only designed to determine if BNT162b2 prevented symptomatic infection, not disease, among both adults and adolescents. The BNT162b2 primary clinical trial outcome in children aged 6 months to 4 years, however, does not measure the vaccine’s ability to prevent symptomatic infection. Instead, it is using an inferior technique to measure vaccine efficacy: immunobridging. 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 6 months to 4 years compared to participants 16 to 25 years of age. The latter is a cohort in which Pfizer represents that the vaccine has demonstrated efficacy against preventing symptomatic infection.¹⁴

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.** Pfizer has a history of using outdated, clinically irrelevant reference strains to assess VE by immunobridging. For instance, Pfizer revealed, in a September 17, 2021 document submitted to the FDA, that it evaluated immunogenicity of the booster dose for older recipients between February and March of 2021 using a recombinant reference strain collected from a patient in Washington on January 20, 2020 (USA-WA1/2020).¹⁵ Its rationale for using this outdated strain was that “clinically relevant variant viruses will require development of

¹¹ <https://clinicaltrials.gov/ct2/show/NCT04816643?term=Pfizer+3mcg&draw=2&rank=2>.

¹² <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-emergency>.

¹³ *Id.*

¹⁴ See outcome measures, <https://clinicaltrials.gov/ct2/show/NCT04816643?term=Pfizer+3mcg&draw=2&rank=2>.

¹⁵ 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/>.

the appropriate neutralization assays specific for the purpose.”¹⁶ In other words, Pfizer did not take the time to clone the current, clinically relevant SARS-CoV-2 S-protein variant needed to properly assess VE by immunobridging. However, using a phylogenetically similar reference is crucial for evaluating an accurate risk-benefit analysis. Without properly doing so, any analysis is flawed.

In addition, neutralizing titers are being collected from the serum to analyze neutralizing activity of IgG. However, SARS-CoV-2 is a respiratory pathogen transmitted via mucosal surfaces that primarily line the respiratory tract. Therefore, measuring anti-spike secretory IgA in the saliva is more clinically relevant than measuring anti-spike IgG from the plasma.

Adequacy of the data is another serious concern. The data from the trials has not yet been made public, however Pfizer announced it was “initiat[ing] a rolling submission” of its data on February 1, 2022 “following a request from the [FDA].”¹⁷ Your committee will meet to discuss this incomplete data only two weeks later. This is incredible and cannot possibly be adequate time in which to confirm, analyze, and assess such critical data. It seems apparent that Pfizer itself did not believe the data was ready for submission and only began the process because it was asked to by the FDA. This decision must not be rushed; it is way too important.

III. There is a Clear Lack of Robust Immunogenicity in Children Between 2- and 4-Years of Age

On December 17, 2021, Pfizer announced that it would amend the clinical trial protocol because “non-inferiority was met for the 6- to 24-month-old population, but not for the 2- to under 5-year-old population in this analysis.”¹⁸ In other words, the adaptive immune response was significantly less robust in the >2-year to <5-year-olds compared to that of 16- to 25-year-old participants. To address the issue, Pfizer announced the addition of a third 3mcg dose to be administered at least two months after the second dose. This modification makes the Pfizer/BioNTech mRNA vaccine a three-dose primary series, increasing the probability of vaccine-associated adverse events in this vulnerable pediatric population. Crucially, the EUA amendment being sought by Pfizer is for only two 3mcg doses of BNT162b2 – not three – as the data for the third dose is not yet available and therefore has not been submitted to the FDA.¹⁹ **Amending the EUA to include two 3mcg doses of BNT162b2 to children aged 2- to 4-years of age is utterly unscientific, given that the adaptive immune response at this dose is inferior to that of 16- to 25-year-olds.**²⁰ What if the FDA amends the EUA now only to later discover that the third 3mcg dose results in a similarly inferior adaptive immune response? The FDA will

¹⁶ <https://www.fda.gov/media/152176/download>.

¹⁷ <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-emergency>.

¹⁸ <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-ongoing-studies-covid-19>.

¹⁹ <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-initiate-rolling-submission-emergency>.

²⁰ <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-ongoing-studies-covid-19>.

lose all remaining credibility. Regardless, authorizing only 2 doses of a known 3-dose series is likely unprecedented and flies in the face of science; the FDA would be operating in the dark and authorizing a product with the assumption, or hope, that the as-yet-unknown data will make that product effective.

IV. The Vaccine is Not Effective Against the Omicron Variant

The COVID-19 mRNA vaccines were genetically engineered over two years ago using sequencing data collected from a patient in Wuhan, China on December 26, 2019 (Wuhan-Hu-1).²¹ However, the current SARS-CoV-2 variant in the United States, the Omicron variant, has accumulated 30 non-silent mutations, three deletions, and one insertion in the spike protein, significantly altering the primary structure.²² Fifteen of the non-silent mutations are located in the domain accessible to antibodies, the receptor binding domain (“RBD”), of the S1 protein.²³ This alone suggests the affinity of vaccine-derived antibodies against the Omicron S protein will be significantly lower than the S protein from the parental strain. The science agrees. Over 13 pre-print studies reveal that Spikevax is significantly less effective at neutralizing the Omicron variant compared to the Delta variant. These studies find between a 20- and 127-fold reduction in the ability of vaccine-derived antibodies to neutralize the Omicron variant.²⁴

Epidemiological evidence is consistent with the aforementioned *in vitro* data. A Canadian study, led by Public Health Ontario, discovered the median VE against the Omicron variant to be <10% between 7 and 59 days after receipt of the second dose of a COVID-19 mRNA vaccine series.²⁵ In fact, the study found a negative vaccine efficacy between 2- and >8-months post-vaccination, indicating that **Omicron-infected individuals are more commonly vaccinated, not unvaccinated.**²⁶ Even the most recent MMWR publication released on February 1, 2022 suggests same. This study revealed that Omicron caused 45.8%, 64%, and 89.8% of symptomatic COVID-

²¹ Jackson, L. *et al.*, *An mRNA Vaccine against SARS-CoV-2 – Preliminary Report*, N Engl J Med. (Nov. 12, 2020), https://www.nejm.org/doi/10.1056/NEJMoa2022483?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed.

²² Garcia-Beltran, W., *et al.*, *mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron Variant*, MedRxiv (Dec. 14, 2021), <https://pubmed.ncbi.nlm.nih.gov/34931201/>.

²³ *Id.*

²⁴ Schmidt, *et al.*, *Plasma neutralization of the SARS-CoV-2 Omicron variant*, medRxiv (Dec. 13, 2021), <https://documentcloud.adobe.com/link/review?uri=urn:aaid:scds:US:3622e942-dfc0-48e5-b3df-c0e93646ec5d>; see also Aggarwal *et al.*, *SARS-CoV-2 Omicron: evasion of potent humoral responses and resistance to clinical immunotherapeutics relative to viral variants of concern*, medRxiv (Dec. 15, 2021) <https://documentcloud.adobe.com/link/review?uri=urn:aaid:scds:US:eb17a360-c011-4579-a0e3-09627419c204>; Roessler, A. *et al.*, *SARS-CoV-2 B.1.1.529 variant (Omicron) evades neutralization by sera from vaccinated and convalescent individuals*, MedRxiv (Dec. 11, 2021), <https://www.medrxiv.org/content/10.1101/2021.12.08.21267491v1>. See also Wilhelm, *et al.*, *Reduced Neutralization of SARS-CoV-2 Omicron Variant by Vaccine Sera and monoclonal antibodies*, medRxiv (Dec. 8, 2021), <https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v2>. See also Garcia-Beltran, W., *et al.*, *mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron Variant*, MedRxiv. (Dec. 14, 2021), <https://pubmed.ncbi.nlm.nih.gov/34931201/>.

²⁵ Buchan, S., *et al.*, *Effectiveness of COVID-19 vaccines against Omicron or Delta infection*, MedRxiv (Jan. 1, 2022), <https://www.medrxiv.org/content/10.1101/2021.12.30.21268565v1.full.pdf>.

²⁶ *Id.*

19 cases²⁷ among the unvaccinated, fully vaccinated, and fully vaccinated with a booster dose respectively, between November 7, 2021 and January 8, 2022.²⁸ This data strongly suggests the vaccine is less effective at protecting against infection caused by the Omicron variant (compared to the Delta variant).

A different study came to the same conclusions.²⁹ Scientists extracted COVID-19 test results and vaccination data from Danish nationwide registries and found that the efficacy of BNT162b2 at preventing infection was only 16.1% between 31 and 60 days, and -76.5% between 91 and 150 days after the second dose.

According to the FDA guidelines on the development and licensure of vaccines to prevent COVID-19, “the primary efficacy endpoint point estimate for a placebo-controlled efficacy trial should be at least 50%.”³⁰ Currently, the Pfizer/BioNTech COVID-19 vaccine does not meet that threshold in adults and there is no reason to believe this data will be any different in the pediatric population. Therefore, amending the EUA for children 6 months to 4 years would be contrary to the FDA’s own guidelines.

V. Adverse Events Following Vaccination are a Concern in Children

To date, public health agencies have identified certain serious, and sometimes fatal, adverse events that are likely caused by COVID-19 vaccines, including myocarditis, which occurs most often after the second dose.³¹ Myocarditis has been observed most frequently in younger people and more frequently in males.³² The long-term effects of myocarditis are not fully understood, but they have proven to be serious. Pfizer’s clinical trials for its vaccine are not large enough to monitor the rate of myocarditis. Pfizer admits the same in a document submitted to the FDA, in which it aptly observed:

The number of participants in the current clinical development program is too small to detect any potential risks of myocarditis associated with vaccination. Long-term safety of COVID-19 vaccine in participants 5 to <12 years of age will be studied in 5 post-authorization safety studies, including a 5-year follow-up study

²⁷ The remaining cases were caused by the delta variant among each group.

²⁸ Danza, P. *et al.*, *SARS-CoV-2 Infection and Hospitalization Among Adults Aged >18 Years, by Vaccination Status, Before and During SARS-CoV-2 B.1.1.529 (Omicron Variant Predominance – Los Angeles County, California, November 7, 2021 – January 8, 2022*, MMWR, (Feb. 1, 2022), https://www.cdc.gov/mmwr/volumes/71/wr/mm7105e1.htm?s_cid=mm7105e1_x.

²⁹ Holm Hansen, C., *et al.*, *Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162b2 or mRNA-1271*, MedRxiv, (Dec. 22, 2021), <https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v2.full.pdf>.

³⁰ See <https://www.fda.gov/media/139638/download>.

³¹ Witberg, G. *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>.

³² <https://www.fda.gov/media/151707/download>.

to evaluate long term sequelae of post-vaccination myocarditis/pericarditis.³³

The Vaccine Adverse Events Reporting System (“VAERS”) is a passive surveillance system designed to “detect unusual or unexpected patterns of adverse events, also known as ‘safety signals.’³⁴ As of January 28, 2022, 39 deaths, 551 cases of myocarditis, and 186 cases of pericarditis involving children between 6 and 17 years of age following the Pfizer-BioNTech COVID-19 vaccine have been reported to VAERS.³⁵ And, according to a study funded by the United States Health and Human Services, “fewer than 1% of vaccine adverse events are reported.”³⁶

In summary, data indicate that severe adverse events are occurring post-vaccination in all age groups, however especially in those under 18. Of concern, Pfizer’s clinical trial for 12-15-year-olds had <1,100 participants that received the vaccine. Consequently, the clinical trial was, at best, not large enough to assess risk of serious adverse events. This is concerning when thinking about vaccinating even younger children, based on yet another clinical trial that is underpowered and not likely to pick up on any serious and rare adverse events.

VI. COVID-19 Vaccines Do Not Prevent Infection or Transmission

According to Dr. Walensky, vaccinated and unvaccinated individuals infected with SARS-CoV-2 have similar viral loads and can both transmit the virus.³⁷ The science agrees with her. In a preprint paper titled *Shedding of Infectious SARS-CoV-2 Despite Vaccination*, the authors found that fully vaccinated individuals with symptomatic COVID-19 are just as contagious as unvaccinated individuals with symptomatic COVID-19.³⁸ These same scientists also concluded that fully vaccinated, asymptomatic individuals are also capable of shedding the virus.³⁹ In yet another study titled *Increases in COVID-19 are unrelated to level of vaccination across 68 countries and 2,497 counties in the United States*, researchers concluded that “countries with higher [sic] percentage of population [sic] fully vaccinated have higher COVID-19 cases per 1 million people.”⁴⁰

³³ <https://www.fda.gov/media/153409/download>.

³⁴ <https://wonder.cdc.gov/vaers.html>.

³⁵ <https://wonder.cdc.gov/controller/datarequest/D8;jsessionid=C85507B17A0F0097D9BD3218C2D6>.

³⁶ <https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>.

³⁷ <https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html>.

³⁸ Riemersma, K. *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>.

³⁹ *Id.*

⁴⁰ https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/pdf/10654_2021_Article_808.pdf.

The above research findings help explain why the state of Vermont, despite having the highest COVID-19 vaccination rate in the country,⁴¹ is currently experiencing the highest number of active COVID-19 cases the state has seen since the beginning of the pandemic.⁴²

Similarly, in the country of Singapore, 84% of the population is fully vaccinated against COVID-19,⁴³ but the country is nevertheless currently experiencing its largest wave of COVID-19 cases and deaths since the beginning of the pandemic.⁴⁴

Based on these data, the vaccine does not stop community transmission of COVID-19, including in the pediatric population which is already low risk for developing severe disease. Therefore, it is simply unscientific to suggest that vaccinating our youngest, most vulnerable pediatric population is required to slow the spread of SARS-CoV-2.

VII. Natural Immunity Must Be Part of the Risk/Benefit Analysis

VRBPAC must also consider natural immunity to SARS-CoV-2 in its risk-benefit analysis. On February 9, 2022, the CDC estimated that nearly 25.8 million (35.4%) children in the United States had already been infected with SARS-CoV-2.⁴⁵ These numbers are almost certainly significantly underestimated as many children have mild or no symptoms following a SARS-CoV-2 infection and therefore will not get tested.⁴⁶

As of February 9, 2022, there are at least 150 studies proving that natural immunity to COVID-19 is superior to vaccine-induced immunity.⁴⁷ One of the more recent epidemiological studies demonstrating the same comes from the CDC. A recent MMWR publication reveals that SARS-CoV-2 infection rates and hospitalizations were significantly higher among vaccinated individuals without a previous infection compared to those with natural immunity alone.⁴⁸

⁴¹ See <https://fortune.com/2021/08/12/vermont-covid-cases-vaccination-rate>. (“Vermont has the highest vaccination rate in the country and is outpacing the national vaccination rate”). In Vermont, 89% of individuals 12 and older have received at least one dose of a COVID-19 vaccine. <https://www.healthvermont.gov/covid-19/vaccine/covid-19-vaccine-dashboard>.

⁴² <https://www.worldometers.info/coronavirus/usa/vermont/>.

⁴³ <https://www.straitstimes.com/multimedia/graphics/2021/06/singapore-covid-vaccination-tracker/index.html?shell>.

⁴⁴ <https://www.worldometers.info/coronavirus/country/singapore/>.

⁴⁵ <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html>. See also <https://datacenter.kidscount.org/data/tables/101-child-population-by-age-group#detailed/1/any/false/574,1729,37,871,870,573,869,36,868,867/62,63,64,6,4693/419,420>. There are 72,822,113 children 0-17 in the U.S. as of 2020.

⁴⁶ Nikolopoulou, G. *et al.*, *COVID-19 in Children: Where do we Stand?*, Arch Med Res., (July 6, 2021), <https://www.ncbi.nlm.nih.gov/labs/pmc/articles/PMC8257427/>.

⁴⁷ See <https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/> See also <https://www.icandecide.org/wp-content/uploads/2021/10/Legal-update-July-6-petition.pdf>; https://www.icandecide.org/wp-content/uploads/2021/10/Legal-update-Supplement-to-Petition-re-convalesced_FINAL.pdf.

⁴⁸ Leon, T., *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),

Therefore, for tens of millions of children in the United States, there is no benefit to be conferred by vaccination.

VIII. Conclusion

Healthy children ages 6 months to 4 years in the United States are at effectively zero risk of dying from COVID-19. Even assuming that the vaccine is 100% effective against the Omicron variant and that no healthy child has natural immunity, the risk-benefit analysis would still not favor vaccination due to the threat of, even if nothing more, myo/pericarditis in young healthy children, of which the long-term cardiovascular sequelae are unknown. For instance, as of January 28, 2022, there have been 39 deaths, 551 cases of myocarditis, and 186 cases of pericarditis involving children between 6 and 17 years of age reported to VAERS after BNT162b2 vaccination. While association is not causation, we do know that healthy children do not spontaneously develop symptomatic heart inflammation. If the rate of heart inflammation alone in 6-month to 4-year-olds post-vaccination is higher than even 1 life-threatening case per million healthy children, then amending the EUA to include this age group is unscientific.

Accurate quantification of myo/pericarditis rates in children ages 6 months to 4 years in Pfizer's clinical trial is virtually impossible because it would require enrolling many fold more children than are currently enrolled. Consequently, regulatory agencies will have to rely on inaccurate post-marketing data to quantify the rate of heart inflammation. Taking such a risk is illogical given that the rate of healthy children dying from COVID-19 is hard to quantify and, in any case, infinitesimally low.

Setting aside the low death rates, the unknown risk of myo/pericarditis, and the failing vaccine efficacy against Omicron, **the primary reason VRBPAC should not amend the EUA is because two 3mcg doses of BNT162b2 did not stimulate a sufficient adaptive immune response in children between 2- and 4-years-of-age.** Currently, immunogenicity data for the third 3mcg dose 60 days after the second dose will not be submitted to the FDA "until the first half of 2022."⁴⁹ If VRBPAC decides to amend the EUA for two doses and it is later revealed that the third dose still does not stimulate an appropriate immune response, then the FDA will have to backtrack its decision, losing even more credibility in the process.

⁴⁹ <https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-ongoing-studies-covid-19>.

ICAN therefore requests that VRBPAC adhere to science and logic by declining to recommend Pfizer's COVID-19 vaccine for healthy 6-month to 4-year-old children.

Please consider your upcoming decision carefully.

Sincerely,

A handwritten signature in blue ink, appearing to read 'ASiri', is positioned above the typed names.

Aaron Siri, Esq
Elizabeth A. Brehm, Esq
Matthew Menendez, Ph.D.

Cc: Peter Marks, Peter.Marks@fda.hhs.gov
Janet Woodcock, Janet.Woodcock@fda.hhs.gov