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VIA FEDEX AND ELECTRONIC MAIL

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CDC COVID-19 Vaccine Task Force
Centers for Disease Control and Prevention
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Re: Adverse Events in Pediatric Population Following Covid-19 Vaccination

Dear Dr. Marks and Dr. Shimabukuro:

We write, yet again, on behalf of our client, Informed Consent Action Network ("**ICAN**"), regarding COVID-19 vaccination in the pediatric population. The Food and Drug Administration ("**FDA**") granted emergency use authorization of the Pfizer Covid-19 vaccine in children ages 5-11 on October 29, 2021 and is currently evaluating approval of the Pfizer COVID-19 vaccine for children ages 12-15. ICAN has previously communicated with the FDA and the Centers for Disease Control and Prevention ("**CDC**") regarding the use of Covid-19 vaccines in children and writes now with additional concerns about same.

A previous letter, dated October 22, 2021, was submitted on behalf of the de Garay family. The letter addressed a serious life-altering adverse event that their 12-year-old daughter Maddie experienced after receiving the Pfizer vaccination. Maddie was a participant in the Pfizer Covid-19 vaccination trial, and her catastrophic, life-altering adverse event was categorized by Pfizer as "functional abdominal pain." See Attachment A.

A second letter, submitted to the Vaccines and Related Biological Products Advisory Committee on behalf of ICAN and dated October 25, 2021, detailed that the available data reflected that the presumed benefits of Covid-19 vaccination in children did not outweigh their known risks. See Attachment B.

As regulatory agencies, the CDC and FDA have promised the public full transparency with regard to Covid-19 vaccines. The FDA and CDC have done a tremendous job promoting the Covid-19 vaccination to the American public, and the campaign has now been expanded to the pediatric population. The FDA and CDC should put the same effort into assuring the safety of these products.

The lack of any follow-up with regard to the serious injury sustained by Maddie de Garay from the Pfizer Covid-19 vaccine is alarming. She was one of only around a thousand 12- to 15-year-olds participating in the Pfizer clinical trial. Sadly, not only has the FDA and CDC ignored

her injury, which has put her in a wheelchair with a feeding tube, but we have received numerous reports of other children similarly injured by this product that you have been endlessly promoting. We detail two additional reports of seriously injured children below that the FDA and CDC have also ignored:

1. Donna Schaefer

Donna was a healthy and vibrant 15-year-old girl. She attended high school and was always on the honor roll. Donna was an active equestrian and participated in basketball and volleyball. Given her history of asthma, Donna's parents were concerned that if she contracted Covid-19, she could possibly have complications. Since the federal regulatory agencies promote the vaccine as "safe and effective" to the American public, Donna's parents felt that she should receive this vaccine to stay safe from Covid-19 and to lessen her chances of a severe bout of Covid-19. Thus, on June 16, 2021, Donna received her first Pfizer Covid-19 vaccination through their county's public health department. Within 24 hours of vaccination, Donna developed intractable headaches, the inability to write, and she could no longer ride horses or play sports. One week after vaccination, Donna presented to the emergency room with seizure-like activity. In retrospect, this was just the beginning of a series of catastrophic events that would leave Donna incapacitated and unable to live the life she once knew. Over the next several weeks, Donna returned to the emergency room several times with uncontrolled seizure-like activity. Her symptoms were blamed on "stress and anxiety."

On July 8, 2021, Donna's parents, still confident in the Covid-19 vaccination and not warned against further doses by any healthcare professionals, proceeded to have Donna vaccinated with her second dose of Pfizer's Covid-19 vaccine. Within two days of the second dose, seizure-like activity returned along with a myriad of other symptoms. To date, Donna's mother has logged over 40 symptoms including but not limited to fatigue, intractable headaches, insomnia, blurred vision, motor and oral tics, tinnitus, muscle pain, memory loss, ear pain, shortness of breath, chest pain, diaphoresis, and epistaxis. Donna has no answers from the medical profession and continues to suffer greatly. What she does know is that before she received the Covid-19 vaccine, she was a happy, healthy, and normally functioning individual. Donna, once an honor roll student, now attends school with accommodations and is unable to complete schoolwork without an individual dictating her work. She is unable to participate in sports or equestrian riding. Donna's mother believes that her symptoms were caused by the Covid-19 vaccine she received, and so, on August 31, 2021, she submitted a VAERS report detailing these events. The only follow-up from VAERS has been an email request for the vaccine lot number, and an email request on September 8, 2021 for Donna's medical records. There has been no follow-up from the CDC or the FDA.

2. Astrid Tridgen

Astrid was a typical, healthy 17-year-old teenager. She was a good student who enjoyed school, socialized with her friends, had a passion for agriculture, and started to become active with the local 4-H group. Astrid wanted a "normal school year" and did not want to be forced to quarantine with Covid-19 outbreaks at school. Thus, Astrid and her mother decided she would receive the Pfizer Covid-19 vaccination. They both felt the vaccination would be safe and effective given the information provided from the federal regulatory agencies. Astrid received her first

Pfizer vaccination on August 13, 2021 at a local hospital. She experienced some mild fatigue and arm pain after the first vaccination. On September 9, 2021 Astrid received the second Pfizer vaccination at her school Covid-19 clinic. By the next morning, she was unable to attend school because of severe pain in bilateral legs from the knees down. She presented to the local emergency room and was told these were normal aches and pains from the vaccination. Within the same day, she re-presented to the emergency room still in pain. Astrid could not move her legs and her toes were completely numb. Again, she was told this was a normal reaction to the vaccine. Two days later, she was taken to her primary care physician by her mother. The physician could not offer any help because the vaccine was "too new" and not enough information was known about the vaccination. Physical therapy was recommended. Astrid was seen by a different family physician who thought she may have Guillain-Barré syndrome. Subsequently, she was referred to neurology. MRI of the spine was completed and demonstrated normal results. Neurology told Astrid her symptoms were related to anxiety. Astrid continued to decline with neurologic symptoms including weakness and pain in both her legs, she had difficulty walking and resolved to using a wheelchair.

September 9, 2021 was the last day Astrid remembers a "normal life" and a "normal school year." Instead of returning to a normal life after vaccination, she now has the exact opposite. Astrid suffers on a daily basis with numerous symptoms including pain, weakness, fatigue, headaches, chest pain, tingling, and abdominal bloating. She no longer attends school and is considered homebound.

Conclusion

Shared decision-making[1] is a recognized standard of care in the practice of medicine. However, shared decision-making cannot take place when adverse events to Covid-19 vaccines are unacknowledged by our federal regulatory agencies and remain hidden from most of the American public. Every parent offered the Pfizer Covid-19 vaccine should be advised of the true safety profile of these products and the gaps in knowledge regarding their safety. Only then can a shared decision-making conversation with the child's treating physician take place and only then will a parent be truly informed prior to giving or withholding consent for the Covid-19 vaccine on behalf of their child. And in the tragic event of a life-altering adverse event, only then will a patient be able to seek adequate medical care from doctors who know what to look for and can study how to treat these patients.

Please provide a copy of the report and data that the CDC and FDA have relied upon to substantiate that the established benefits for children in receiving a Covid-19 vaccine outweigh the risks.

Sincerely Yours,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.

[1] *See* A M Stiggelbout; Shared decision making: really putting patients at the centre of healthcare; BMJ 2012;344:e256.

Exhibit A

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October 22, 2021

VIA EMAIL

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Re*: COVID-19 vaccination in pediatric populations*

Dear Mr. Becerra, Dr. Walensky, Dr. Woodcock, Dr. Marks, and Dr. Shimabukuro:

We write on behalf of Mr. Patrick de Garay, Mrs. Stephanie de Garay, and Maddie de Garay ("**the de Garay family**") regarding one of the most important issues in this country right now: COVID-19 vaccination in pediatric populations. To date, Pfizer's Comirnaty is approved for children ages 16 and 17 and authorized for emergency use in children 12 through 15, with authorization expected shortly for children 5 through 11. Before any additional authorizations or approvals for children are granted, it is imperative that you properly account for what occurred to Mr. and Mrs. de Garay's 12-year-old daughter, Maddie, in Pfizer's clinical trial.

The only rigorous way to ensure safety and efficacy is via appropriate clinical trials which do not ignore serious adverse events occurring in those trials. Pfizer's clinical trial for children aged 12-15 included 2,260 participants, half of who received the vaccine and half who received a placebo. Meaning, only 1,131 children were vaccinated and at least one of those children, Maddie de Garay, suffered a devastating, life-altering injury which, despite incontrovertible proof and the

cries of both the victim and her parents, has not been acknowledged by the sponsor ("**Pfizer**") or the Food and Drug Administration ("**FDA**").

For a virus for which children have a 99.998% chance of surviving, the FDA must ensure there is an even more remote chance of a serious adverse event from any vaccine intended to prevent harm from the virus.[1] Therefore, we implore you to carefully consider the following information.

A. COVID-19 in Children

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.[2] Neither the FDA nor the CDC have put forth data to dispute this.[3]

Despite what appears to be a continued effort to inflate COVID-19 numbers and induce fear among parents,[4] according to one study, the infection fatality rate for those aged 5 to 9 is less

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[1] *See* https://pubmed.ncbi.nlm.nih.gov/33137809/.

Age Group	Male Median% (95%CrI) [Individual serostudy range]	Female Median% (95%CrI) [Individual serostudy range]	Mean Median% (95%CrI) [Individual serostudy range]
0-4	0.003 (0.002-0.004) [0.001-0.006]	0.003 (0.002-0.003) [0.001-0.005]	0.003 (0.002-0.003) [0.001-0.006]
5-9	0.001 (0.000-0.001) [0.000-0.001]	0.001 (0.000-0.001) [0.000-0.001]	0.001 (0.000-0.001) [0.000-0.001]
10-14	0.001 (0.001-0.002) [0.000-0.002]	0.001 (0.000-0.001) [0.000-0.001]	0.001 (0.001-0.001) [0.000-0.002]
15-19	0.003 (0.002-0.003) [0.001-0.005]	0.002 (0.002-0.003) [0.001-0.005]	0.003 (0.002-0.003) [0.001-0.005]

Table S3. Ensemble model age- and sex-specific infection fatality ratio estimates and the respective ranges suggested by individual national-level seroprevalence surveys.

[2] https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/Risk%20Factors%20for%20COVID-19%20Mortality%20among%20Privately%20Insured%20Patients%20-%20A%20Claims%20Data%20Analysis%20-%20A%20FAIR%20Health%20White%20Paper.pdf.

[3] According to the Centers for Disease Control and Prevention ("**CDC**"), 605 children (under 19 years old) have died with a COVID-19 diagnosis (186 ages 0 through 4 years old, 419 ages 5 through 18 years old) in a 21.5-month period. *See* https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3. There has been no data released by the CDC showing whether these children died *from* COVID-19 or *with* COVID-19 or if these children had any pre-existing conditions. The data are for "deaths involving COVID-19." There is also no further age stratification and no understanding of how many of the children that died were 18 years old vs how many were 5 years old.

[4] 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. 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*

than 0.001 percent.[5] A large new study from the U.K. examining the fatality rate among all those under 18 found it to be similarly incredibly rare — 0.005 percent.[6] Based on data following the Delta variant, "[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."[7] This is not a severe or deadly pandemic for children as the data has clearly and consistently shown.

B. Potential Risks in Vaccinating Children for COVID-19

Since it is exceedingly rare for a child to have a permanent injury from being infected with SARS-CoV-2, it must be determined that the vaccine presents even less risk.

1. Maddie de Garay

Maddie de Garay was a typical 12-year-old little girl: full of energy, spunk, gymnastic moves, and TikTok dances. Maddie, along with her two brothers, took part in Pfizer's pediatric clinical trial for the COVID-19 vaccine. Since the day she received the second dose of the vaccine, the vibrant girl Maddie's parents once knew has disappeared, replaced with a girl who lives her life in agony.

Within 24 hours of arriving at the trial site with her dad and receiving her second shot, Maddie developed crippling, scream-inducing pain that landed her in the emergency room. She was experiencing abdominal, muscle, and nerve pain, described as the feeling of someone "ripping [her] heart out through [her] neck."

Over the next three months, Maddie was admitted to the hospital three times, visited doctors and emergency rooms more than that, and developed additional life-changing symptoms including: gastroparesis, erratic blood pressure, erratic heart rate, memory loss, brain fog, dizziness, fainting, seizures, verbal tics, motor tics, loss of feeling from her waist through her toes, muscle weakness, drastic and adverse changes in her vision, urinary retention, loss of bladder control, and the start of and severely irregular menstrual cycles. Maddie currently has an NG tube and uses a wheelchair for assistance.

The list of "post-vaccination symptoms" that her mother has detailed and tracked in an effort to help her daughter is over 23 pages long (through only August 2021) and is heartbreaking

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COVID-19. In other words, if a child gets hurt in an accident and brought to the hospital and is tested as part of hospital protocol and tests positive, that child may be counted as a child COVID-19 hospitalization even though the hospitalization could not be prevented regardless of how many people are vaccinated. Evidencing this issue with Walensky's claims is the June 11, 2021 Morbidity and Mortality Weekly Report 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. *See* https://www.cdc.gov/mmwr/volumes/70/wr/mm7023e1.htm?s_cid=mm7023e1_w.

[5] *See* https://www.nature.com/articles/s41586-020-2918-0.

[6] *See* https://www.wsj.com/articles/in-children-risk-of-covid-19-death-or-serious-illness-remain-extremely-low-new-studies-find-11625785260.

[7] 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* https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/children-and-covid-19-state-level-data-report/.

to read. It tells the story of a 12-year-old girl's life being drastically altered by worsening symptoms that, at times, had her saying she "couldn't do this anymore" and that she "wanted to give up."

Pfizer, on the other hand, reported this in its trial documents to the FDA as follows:

> "One participant experienced an SAE reported as generalized neuralgia, and also reported 3 concurrent non-serious AEs (abdominal pain, abscess, gastritis) and 1 concurrent SAE (constipation) within the same week. The participant was eventually diagnosed with functional abdominal pain. The event was reported as ongoing at the time of the cutoff date."[8]

The juxtaposition of Ms. de Garay's careful and tragic recording of her child's experience post-vaccination and Pfizer's description of same is shocking to the conscience. To equate Maddie's life-altering ailments that leave her unable to eat by mouth or to walk herself to the kitchen as "functional abdominal pain" is at best dishonest. To regulators, it should be criminal.

In fact, at least one doctor at the National Institutes of Health, Dr. Avindra Nath, is aware of Maddie's experience. When learning of her post-vaccination adverse events, he replied to Mrs. de Garay, "**We have certainly heard of a lot of cases of neurological complications form [sic] the vaccine** and will be glad to share our experience with them."[9]

Despite a May 24, 2021 letter sent to Dr. Marks, Dr. Woodcock, and Dr. Walensky (and others) from COVID-19 vaccine injured individuals pleading for acknowledgement and help,[10] and Dr. Nash's knowledge, *we will assume that, until this point, you have not been aware of Maddie's story and of Pfizer's "reporting" of same*. We make this assumption, despite evidence to the contrary, because it appears unthinkable that you would not have taken action or contacted the family had you actually been aware of her devastating injury. Either way, you are now on notice. Maddie's journey has been documented and is ongoing. All relevant medical records are being provided by email through a secure link. If Pfizer has not disclosed the truth, it is your responsibility as regulators to ensure that this is remedied forthwith.

Clinical trials are meant to identify and report incidents just like Maddie's in order to help determine the safety and efficacy of vaccines. It is troubling, to say the least, that this has happened and that this vaccine has been authorized without a reliable clinical trial – a trial that reported a life-altering injury as "functional abdominal pain" is plainly an unreliable trial. If Pfizer hid this serious adverse event, it calls into question all of the safety reporting from this trial.

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

[9] *See* appended May 2021 email exchange with Mrs. de Garay and Dr. Nash.

[10] https://www.c19vaxreactions.com/uploads/1/3/7/7/137732232/letter_initials_2.pdf. Communications with Dr. Woodcock following this letter included discussions about Maddie. In addition, Mrs. de Garay exchanged emails with the NIH about Maddie and other individuals communicated with the FDA and with VRBPAC about Maddie's story.

Every parent offered the Pfizer Covid-19 vaccine should be informed of Maddie's experience prior to giving or withholding consent on behalf of their child. Indeed, without a true picture of the benefits and risks of this product, no parent's consent can be truly informed. On a larger scale, regulators and their advisors should be informed of Maddie's experience prior to being asked to provide any further approval or recommendation of this product. They indeed should be asked to reconsider current authorizations and approvals of this product for children.

We are not naïve to the reality that after the FDA has fanatically promoted Pfizer's Covid-19 vaccine to the American people – which began before the FDA even approved the product – asking it to now admit it made a mistake as to this product and children is akin to asking the FDA's leadership to cut their own throats. It would take an incredible amount of selflessness to admit such a mistake. Hence, at the least, before even considering authorizing or licensing this product for any further age span of children, a thorough investigation of the clinical trial conduct and data for children is demanded, as well as an expanded trial in order to gather sufficient data to confirm safety.

Given that the actual severe harm to Maddie was not disclosed by Pfizer to the FDA, it must ask what other serious adverse events have been hidden from your view and ignored by regulators?

2. Identified Risks from Clinical Trials and Post-Authorization Use

Unfortunately, even putting aside the misrepresentations related to Maddie's serious harm, the Phase II/III clinical trial for Pfizer's vaccine in 12-15-year-olds[11] which led to the FDA's emergency use authorization of this product on May 10, 2021 was underpowered and inadequate to properly test efficacy or safety for the following reasons:

- 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.[12]

- The trial was underpowered. It included only 2,260 participants, half of who received the vaccine and half who received a placebo. Meaning, only 1,131 children were vaccinated. This is inadequate to identify any potential adverse events that may occur, nor the statistical significance of same. Without a clinical trial of sufficient size that reviews all potential serious adverse events, such as that experienced by Maddie, for a sufficient duration, this potentially catastrophic result will not be identified prior to licensure.

[11] *See* https://www.nejm.org/doi/10.1056/NEJMoa2107456?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed.

[12] As Dr. Woodcock and Dr. Marks have 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.

- The trial was not representative of most American children. It only included "healthy participants" and excluded those who previously were infected with SARS-CoV-2.[13] This results in excluding a large proportion of American children since at least 37% of children are estimated by the CDC to have been infected with SARS-CoV-2 as of May 2021[14] and 43% are estimated to have chronic health condition.[15] Moreover, the 12-15-year-olds in the trial were approximately 86% White and 12% Hispanic or Latinx, and only 567 boys were vaccinated in the trial.

- The trial did "not determine whether [the Pfizer] vaccination prevents asymptomatic infection or transmission of SARS-CoV-2."

- Safety data has only been 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."[16] From the limited data available, 6% of the participants reported adverse events within the trial, aside from reactogenicity. One participant discontinued vaccination because of a vaccine-related adverse event. Pfizer reported that "few participants in any cohort had serious adverse events, and none were considered by the [Pfizer] investigators to have been vaccine-related." That the trial was inadequate to detect adverse events was evidenced on June 23, 2021, when the CDC reported the alarming numbers of reported myocarditis and pericarditis cases occurring after COVID-19 vaccination.[17] This adverse event was not picked up in the clinical trial.

  As Dr. Woodcock and Dr. Marks have stated:

> 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** – and issues that may be addressed in pediatric vaccine trials can include whether there is a need for different doses or different strength formulations of vaccines already used for adults.[18]

Moreover, taking into account the FDA's guidance that clinical trials should "reflect the product and target condition,"[19] and a 2019 review, authored by researchers at the FDA and Duke University, which found that short-term pediatric studies may not provide complete safety data

[13] 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.

[14] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html.

[15] https://pubmed.ncbi.nlm.nih.gov/21570014/.

[16] https://www.nejm.org/doi/10.1056/NEJMoa2107456.

[17] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-06/03-COVID-Shimabukuro-508.pdf at p. 27.

[18] https://www.fda.gov/news-events/press-announcements/fda-will-follow-science-covid-19-vaccines-young-children.

[19] https://www.fda.gov/media/102332/download.

across all critical periods of growth and development,[20] the time frame for the safety review should be longer for minors. The FDA and Duke authors explained that, compared to licensing a drug for adults, "data on drug efficacy and safety in children may require an additional 6 years."[21] Since children have not been seriously affected by this virus, the risk of any vaccine must be fully understood in order to weigh it against any potential benefit.

Evidencing the need for longer trials, public health agencies have, over time, identified certain serious, and sometimes fatal, adverse events that are likely caused by COVID-19 vaccines that have not been identified in the trials. To date, these adverse events include anaphylaxis, TTS, and myocarditis. Myocarditis has been seen most frequently in younger people, more frequently in males, and following the second dose. The long-term effects of myocarditis are not fully understood but can be very serious.

And, while not yet acknowledged by the agencies, numerous additional serious side effects are being reported in alarming numbers in the Vaccine Adverse Events Reporting System ("**VAERS**") and by healthcare workers across the country with firsthand observations of same, including:

> deep vein thrombosis, pulmonary embolisms, new stroke, bleed, autoimmune hepatitis, sudden bilateral pneumonia or COVID-19 infection, syncope with head injury, STEMI, new arrhythmias, new seizure disorders, new chorea movement disorder, return of and new cancers, acute myeloid leukemia, appendicitis, tinnitus, death, and more.

Even if the risks from the COVID-19 vaccines are truly small, there is no reason to expose someone to any risk when their risk of the disease itself is negligible. These known and potential adverse events further demonstrate the inadequacy of the clinical trials.

Perhaps most alarming is Maddie's "adverse event" that, to date, does not appear at all in Pfizer's reported trial data. In this small cohort of just over 1,000 children vaccinated, and despite a complete lack of acknowledgement of same in the data, there was at least one severe adverse event to the vaccine. **If this has happened even once in such a small cohort, it is imperative that the manufacturer and the health agencies determine whether there are other similar cases and whether and how often this may happen again to other children.**

[20] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6526087/.

[21] *Id*.

C. Conclusion

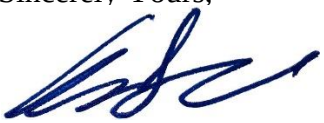
Since children are at extremely low risk of harm from SARS-CoV-2, and getting the infection actually provides sterilizing immunity, while the vaccine does not,[22] children in our country do not need a COVID-19 vaccine. Vaccinating them will not contribute to herd immunity since the vaccine, as you know, does not prevent infection and transmission of the virus.

To the extent a vaccine *is* authorized or approved for children, it must be properly tested and evaluated in a clinical trial that is adequate to determine safety and efficacy. It must further be mandated that those clinical trials accurately report, with full transparency and disclosure, any adverse events observed following vaccination. Vaccine manufacturers must not be allowed to get away with disguising serious adverse events like Maddie's.

The de Garay family ask that you properly respond forthwith to the data and concerns addressed above. In your response, please confirm whether you and your agencies acknowledge Maddie's vaccine injuries and whether you will properly address them both with the de Garay family and with Pfizer. If you deny that Maddie's ailments are injuries from Pfizer's COVID-19 vaccine, please provide your justification. If you admit that Maddie's ailments are vaccine injures, then we implore you to neither authorize nor approve this vaccine for children until you can properly address all issues and concerns raised by this letter.

If you do not provide a fulsome response that address all concerns raised above by close of business on Monday, October 25, 2021, we have been authorized to file a petition on behalf of the de Garay family regarding any contemplated authorization or licensure of the Pfizer vaccine and to withdraw any existing authorization or licensure of this vaccine for children.

Sincerely Yours,



Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.

CC: Patrick and Stephanie de Garay

[22] The clinical trial's primary endpoint for the Covid-19 vaccines is measuring effectiveness against disease – not against infection. https://pubmed.ncbi.nlm.nih.gov/33332292/. Once used in the real world, as Dr. Walensky has acknowledged, they do not "prevent transmission." https://twitter.com/CNNSitRoom/status/1423422301882748929 This is also confirmed by various studies, including, *inter alia*: https://pubmed.ncbi.nlm.nih.gov/34351882/; https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733; https://pubmed.ncbi.nlm.nih.gov/34176436/; https://pubmed.ncbi.nlm.nih.gov/34596015/; https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf; https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012240/Weekly_Flu_and_COVID-19_report_w33.pdf at 17-18; https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Briefing_22_21_09_02.pdf at 21.

Exhibit B

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October 25, 2021

VIA ELECTRONIC SUBMISSION
FDA-2021-N-1088

Re: VRBPAC Meeting on October 26, 2021

Dear VRBPAC Members:

We write on behalf of the Informed Consent Action Network ("**ICAN**") regarding one of the most important issues in this country right now: COVID-19 vaccination in the pediatric population. To date, the Pfizer-BioNTech COVID-19 vaccine, Comirnaty, is approved for children ages 16 and 17 and authorized for emergency use in children 12 through 15. On October 26, 2021, the Vaccines and Related Biological Products Advisory Committee ("**VRBPAC**") will meet to discuss Pfizer's request to grant Emergency Use Authorization ("**EUA**") for the Pfizer vaccine for children 5–11 years of age. We implore you to carefully consider the information in this letter before granting EUA for the Pfizer vaccine in the pediatric population.

A. COVID-19 in Children

There are nearly 73 million children living in the United States – accounting for approximately 22% of our nation's population.[1] From March through October of 2020, children ages 5-14 had a one in a million chance of dying with COVID-19.[2] Only 442 children between the ages of 5 and 18 died with a confirmed or presumed case of COVID-19 between January 4, 2021 and October 16, 2021.[3] For perspective, children in between the ages of 5 and 14 are nearly ten times more likely to die from suicide than with COVID-19.[4]

A White Paper written by 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

[1] https://www.childstats.gov/americaschildren/demo.asp

[2] https://jamanetwork.com/journals/jama/fullarticle/2774465

[3] https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3

[4] https://jamanetwork.com/journals/jama/fullarticle/2774465

children who did not have a pre-existing medical condition such as leukemia.[5] Neither the FDA nor the CDC have put forth data to dispute this, and the available data is for "deaths involving COVID-19" – not deaths caused by COVID-19.[6]

In the United States, for children 5-11 years old, the weekly rate of COVID-19-associated hospitalization has ranged from zero to a peak of 1.3 per 100,000.[7] 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."[8] At least one study that analyzed 117 pediatric hospitalizations with confirmed cases of COVID-19 found 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.[9]

Given these data and the extraordinarily low risk of hospitalization and mortality from COVID-19 in children ages 5-11, there is no justification for EUA approval of the Pfizer vaccine in the pediatric population.

B. Inadequate Clinical Trials

The clinical trials for the Pfizer vaccine are inadequate to support an EUA for this product for the pediatric population. According to Pfizer's own clinical trial data, there were no deaths or severe cases of COVID-19 reported in children ages 5-12 who received either the vaccine or the placebo, and none of the participants had more than 3 months of follow up after their second vaccine dose.

On the other hand, we now know that public health agencies have identified certain serious, and sometimes fatal, adverse events that are likely caused by COVID-19 vaccines, including myocarditis. Myocarditis has been seen most frequently in younger people and more frequently in males following the second dose.[10] The long-term effects of myocarditis are not fully understood but can be very serious. In its Benefit/Risk Assessment, Pfizer acknowledges that its clinical trial was "not large enough to detect any potential risks of myocarditis associated with vaccination."

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

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[5] https://s3.amazonaws.com/media2.fairhealth.org/whitepaper/asset/Risk%20Factors%20for%20COVID-19%20Mortality%20among%20Privately%20Insured%20Patients%20-%20A%20Claims%20Data%20Analysis%20-%20A%20FAIR%20Health%20White%20Paper.pdf.

[6] https://data.cdc.gov/NCHS/Provisional-COVID-19-Deaths-Focus-on-Ages-0-18-Yea/nr4s-juj3

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

[8] https://hosppeds.aappublications.org/content/11/8/e151.long

[9] *Id.*

[10] https://www.fda.gov/media/151707/download. A recent study examining COVID-19 mRNA vaccine-associated myocarditis found that among 12-15 year old boys, following the second dose of Pfizer's COVID-19 vaccine, there were 162 cardiac adverse events ("**CAE**") per million doses administered. https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1.full.pdf. Approximately 87% of these CAE's resulted in hospitalization. *Id.*

signals.'"[11] As of October 15, 2021, 19 deaths, 449 cases of myocarditis, and 126 cases of pericarditis involving children under 18 following a COVID-19 vaccine have been reported to VAERS.[12] And, according to a study funded by the United States Health and Human Services, "fewer than 1% of vaccine adverse events are reported."[13] Given these data, the clinical trials are inadequate because they were not large enough to adequately assess the risk of myocarditis following receipt of the Pfizer vaccine.

C. COVID-19 Vaccines Do Not Prevent Infection and Transmission

According to CDC Director Rochelle Walensky, individuals infected with SARS-CoV-2 have similar viral loads and can both transmit the virus.[14] The science agrees. 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.[15] These same scientists also concluded that fully vaccinated, asymptomatic individuals are also capable of shedding the virus.[16] In 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 percentage of population fully vaccinated have higher COVID-19 cases per 1 million people."[17]

The above research findings help explain why the state of Vermont, despite having the highest COVID-19 vaccination rate in the country,[18] is currently experiencing the highest number of active COVID-19 cases the state has seen since the beginning of the pandemic.[19]

Similarly, in the country of Singapore, 84% of the population is fully vaccinated against COVID-19,[20] but the country is currently experiencing their largest wave of COVID-19 cases and deaths since the beginning of the pandemic.[21]

Based on these data, the vaccine does not stop community spread of COVID-19, including in the pediatric population which is already low risk.

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[11] https://wonder.cdc.gov/vaers.html

[12] https://wonder.cdc.gov/controller/saved/D8/D241F920.

[13] https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

[14] https://www.cdc.gov/media/releases/2021/s0730-mmwr-covid-19.html

[15] https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf

[16] *Id.*

[17] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/pdf/10654_2021_Article_808.pdf

[18] *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.

[19] https://www.worldometers.info/coronavirus/usa/vermont/

[20] https://www.straitstimes.com/multimedia/graphics/2021/06/singapore-covid-vaccination-tracker/index.html?shell

[21] https://www.worldometers.info/coronavirus/country/singapore/

D. Natural Immunity

VRBPAC should also consider natural immunity to SARS-CoV-2 in its risk-benefit analysis. On May 29, 2021, the CDC estimated that nearly 27 million, or 36%, children in the United States had already been infected with SARS-CoV-2.[22] Nearly 60 studies prove that natural immunity to COVID-19 is superior to vaccine-induced immunity.[23] Therefore, for tens of millions of children in the United States, there is no benefit to be conferred by vaccination.

E. Conclusion

Healthy children in the United States are not at risk of dying or suffering from severe COVID-19. Therefore, there is no benefit to be achieved by vaccinating the entire pediatric population. This is especially true considering Pfizer's inadequate safety studies, the large number of serious adverse events reported to VAERS, and the high number of children who have already been infected with and recovered from COVID-19.

ICAN requests that you properly respond to its concerns and delay any granting of EUA for the Pfizer vaccine in children ages 5-11.

Sincerely Yours,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Gabrielle G. Palmer, Esq.

[22] https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html

[23] *See* 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.