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March 8, 2022

VIA EMAIL

Paul Richards, M.D.
Chief, Consumer Affairs Branch
Center for Biologics Evaluation and Research
Office of Communication, Outreach and Development
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re*: Madeline "Maddie" de Garay*

Dear Dr. Richards:

On behalf of our clients Patrick and Stephanie de Garay, we confirm receipt of the FDA's response regarding our communications to the agency concerning Madeline "Maddie" de Garay, the de Garays' daughter. These communications were dated October 22, 2021,[1] October 25, 2021,[2] January 3, 2022,[3] and January 14, 2022.[4] Each of these communications advised the FDA of Maddie's extensive injuries from Pfizer's Covid-19 vaccine which left her in a wheelchair and dependent upon a feeding tube, all of which appears to have been absurdly classified by Pfizer in its Emergency Use Authorization (EUA) Amendment for an Unapproved Product Review Memorandum as "functional abdominal pain."[5]

Despite the repeated requests from the de Garays and from us that these incredible injuries in a child who was part of the clinical trials be addressed by the FDA, the first response from the agency comes 128 days after our first contact and the advice given is that the de Garays should submit a VAERS report?! You cannot be serious.

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[1] Exhibit 1.

[2] Exhibit 2.

[3] Exhibit 3.

[4] Exhibit 4. Additionally, the de Garays submitted a comment themselves to the FDA's Vaccines and Related Biological Products Advisory Committee prior to its October 26, 2021 meeting. *See* Exhibit 5.

[5] *See* https://www.sirillp.com/wp-content/uploads/2022/03/nr_EUA-27034.132-Review-Memo-Pfizer-BioNTech-COVID-19-Vaccine_RE-4dc738480420dad83663dbb169bd3fd3.pdf at p. 30.

Your response on behalf of the FDA is shameful, at best. Maddie is now 13 years old but was 12 at the time of her vaccination. Before getting the Pfizer vaccine, Maddie used to dance in Tik Tok videos. She was happy and healthy and had her life in front of her. Since receiving her second shot, Maddie has ended up in the emergency room or admitted countless times with a cascade of medical issues that have destroyed her basic life functions and her quality of life. Pfizer has never reached out to her family. The FDA has never reached out to her family.

Now, after alerting the FDA to this situation for, at least, the fifth time, your only response is to simultaneously state that you are not aware whether the de Garays have submitted a VAERS report – something the de Garays have already done[6] – and that "FDA takes all reports of adverse events potentially related to vaccines seriously." Your words ring hollow. There is no indication that a single person at the FDA, yourself included, has taken Maddie's injuries seriously.

Maddie is only 1 of approximately 1,000 children in Pfizer's clinical trial of 12-15-year-olds that received this vaccine. Investigating her devastating and fundamentally life-altering injuries and the incomprehensible lack of acknowledgement of them by Pfizer should be at the very top of the FDA's list of priorities. The FDA has been in possession of Maddie's medical records since we sent them along with our very first letter of October 22, 2021. Additionally, Pfizer should also have provided every relevant medical record to you given that Maddie was part of the trial, rendering a VAERS report completely unnecessary for the agency's review of Maddie's injuries. Despite this, the FDA never responded to these urgent concerns.

Amazingly, prior to your recent tone-deaf response, the FDA never responded to anything we or the de Garays sent. Why should any American trust the FDA when it comes to making any important medical decision when a child who has ended up in a wheelchair with a feeding tube has been given the treatment you have afforded Maddie over the last 401 days? Clearly, there is something seriously broken in the FDA. If a child in a clinical trial suffers devastating injuries and is ignored by the federal health authorities while those authorities green light the experimental product, this speaks volumes about the agency's priorities.

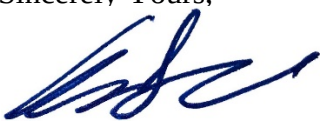
The FDA's shameful treatment of Maddie is no better than the treatment she has received from Pfizer whose interests the FDA is clearly seeking to protect. In just one of many examples of the sponsor's inexplicable behavior, Pfizer's principal investigator, Robert Frenck, Jr., M.D., refused to meet Maddie's urgent medical need for a wheelchair until we stepped in, despite the fact that Maddie's inability to walk was a direct result of her participation in the clinical trial he is conducting for Pfizer. The FDA's shameful treatment of the de Garays also mirrors the "care" she has received from Cincinnati's Children's Hospital since being injured in the trial. Had you read the January 14, 2022 letter we sent, which details the abhorrent standard of care Maddie has experienced, you likely would not have suggested that Maddie's doctors reach out to CDC's Clinical Immunization Safety Assessment ("**CISA**"). The doctors are not caring properly for Maddie. They have not reached out to CISA, nor should they have to; Maddie was a participant in a clinical trial for a biologic that your agency authorized for use. The FDA should be working with Maddie, her family, and doctors willing to treat her. We also note that a principal investigator of CISA, to whom you recommend the de Garays reach out, is Dr. Kathryn Edwards, who also sits

[6] See VAERS ID number 1400303-1, attached as Exhibit 6.

on Pfizer's Data Safety Monitoring Board overseeing its clinical trials, a conflict of interest that is jaw-dropping in itself.[7]

In order to retain any semblance of credibility, the agency must take immediate action. Please contact us forthwith to schedule a meeting during which we can discuss how to help Maddie de Garay as far too much time has passed already.

Sincerely Yours,



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

Enclosures
cc: Patrick and Stephanie de Garay

[7] *See* https://www.vumc.org/viiii/person/kathryn-m-edwards-md; https://lite.cnn.com/en/article/h_eb8046b112f9cc8976e19c3bf6935714.

Exhibit 1

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October 22, 2021

VIA EMAIL

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HHS Office of the Secretary
Secretary, Health & Human Services
200 Independence Ave., S.W.
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c/o Sean McCluskie
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Dr. Rochelle P. Walensky
Director, Centers for Disease Control and Prevention
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Dr. Janet Woodcock
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Dr. Peter Marks
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Dr. Tom Shimabukuro
CDC COVID-19 Vaccine Task Force
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Corporate Square, Bldg 12
Atlanta, GA 30329
ayv6@cdc.gov

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

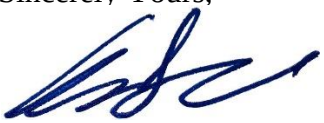
Since children are at extremely low risk of harm from SARS-CoV-2, and getting the infection actually provides sterilizing immunity, while the vaccine does not,[22] children in our country do not need a COVID-19 vaccine. Vaccinating them will not contribute to herd immunity since the vaccine, as you know,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

Siri | Glimstad

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October 25, 2021

VIA ELECTRONIC SUBMISSION
FDA-2021-N-1088

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

Re: *Emergency Use Authorization for Pfizer/BioNTech's COVID-19 Vaccine in Children Ages 5-11*

Dear Sir or Madam,

On behalf of our clients, we are submitting two letters for your careful review prior to the Vaccines and Related Biological Products Advisory Committee ("**VRBPAC**") meeting scheduled for October 26, 2021, where VRBPAC will discuss granting emergency use authorization ("**EUA**") for the Pfizer/BioNTech COVID-19 vaccine for use in children ages 5-11.

The first letter, which we submit on behalf of the Informed Consent Action Network ("**ICAN**"), summarizes the lack of benefit to COVID-19 vaccination in children and the absence of adequate safety data to support any recommendation for the use of Pfizer's COVID-19 vaccine in the pediatric population.

The second letter, which we submit on behalf of the de Garay family, outlines a serious adverse event suffered by a 12-year-old girl, Maddie de Garay, immediately following receipt of the second dose of Pfizer's COVID-19 vaccine, which Pfizer shockingly describes as "functional abdominal pain" even though Maddie's injuries have left her in debilitating pain, with an NG tube, and in a wheelchair.

We hope that each member of VRBPAC will carefully consider the information in these letters before making any regulatory recommendations for the use of Pfizer's COVID-19 vaccine in children.

Sincerely Yours,

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

Enclosures: (1) October 25, 2021 letter to VRBPAC; and (2) October 22, 2021 letter regarding Maddie de Garay

ATTACHMENT 1

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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.

ATTACHMENT 2

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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

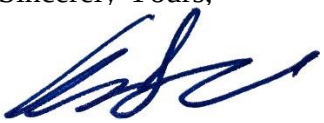
Since children are at extremely low risk of harm from SARS-CoV-2, and getting the infection actually provides sterilizing immunity, while the vaccine does not,[22] children in our country do not need a COVID-19 vaccine. Vaccinating them will not contribute to herd immunity since the vaccine, as you know, 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 3

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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

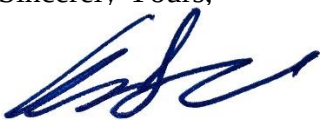
Since children are at extremely low risk of harm from SARS-CoV-2, and getting the infection actually provides sterilizing immunity, while the vaccine does not,[22] children in our country do not need a COVID-19 vaccine. Vaccinating them will not contribute to herd immunity since the vaccine, as you know,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

Exhibit 4

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January 14, 2022

VIA FEDEX AND ELECTRONIC MAIL

Dr Steve Davis
Chief Executive Officer
Cincinnati Children's Hospital Medical Center
Administrative Office
3333 Burnet Avenue
Cincinnati, Ohio 45229
c/o tina.cheng@cchmc.org

Dr. Tina Cheng
Chief Medical Officer
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Re: Madeline ("Maddie") de Garay's Medical Treatment

Dear Dr. Davis and Dr. Cheng:

We write on behalf of our clients Mr. Patrick de Garay and Mrs. Stephanie de Garay, parents of Madeline de Garay **("Maddie")** regarding violations of the standard of care in her treatment. Maddie received treatment at Cincinnati Children's Hospital starting January 21, 2021. Her presentations were for evaluation of side effects after receiving the Pfizer Covid-19 vaccination. Maddie was a participant in the vaccine trial. She was evaluated multiple times in the emergency department, and admitted to the hospital on three separate occasions (January 30, 2021, March 6, 2021, and April 9, 2021). She received specialty evaluations with neurology, allergy/immunology, gastroenterology, pain management, and behavioral medicine.

Upon review of Maddie's medical records, several breaches in standard of care were discovered. First, Maddie consistently had hematuria, and this issue was not addressed or it was simply ignored. The finding of hematuria is not a functional issue; an individual simply cannot make themselves have blood in their urine. Hematuria was found in one of her first emergency room presentations (January 21, 2021), and the finding continued in subsequent visits. It should be noted that blood would be present when Maddie was on her menstrual cycle, but there were several times when she was not on her cycle, and blood was still found in the urine. The diagnosis of hematuria was not listed in the medical records. More importantly, she did not have a work-up for this finding. A standard approach would start with repeating sample, sending urine cultures, and ordering clotting profile. If no obvious answers were provided with the aforementioned, proceeding with nephrology and urology consults would be appropriate. A kidney biopsy would also be a reasonable procedure if there was still no explanation for the hematuria. Considering the clinical picture with her recent vaccination, checking complement levels would be appropriate.

A second issue in Maddie's medical record is related to urinary retention. The medical record reflects that this issue was functional in nature. Prior to being given a functional diagnosis, Maddie did not appear to have any work-up for this issue. The symptom was simply being treated with a straight catheterization. The standard medical approach to urinary retention would be a urology consult, followed by tests including but not limited to checking post void residual urine volume, 24-hour urine creatinine clearance, and urodynamic evaluation. It is not clear that any of this was done.

One of the most obvious breaches in care occurred on March 5, 2021 when Maddie was evaluated by Dr. Amal Assa'ad from Allergy/Immunology. Maddie was referred to the specialist by Neurology (Dr. Wesselkamper) and by the pain doctor, Dr. Goldschneider. In Dr. Wesselkamper's note from March 3, 2021, he notes: "given the fact inflammatory responses have been seeing in Covid-19 disease, it should be assumed it could happen with the immune response from the vaccine. Madeline has a history of sensitivity and if she got the vaccine, she may have just been sensitive to it. That possibility needs to be evaluated before starting the functional treatment pathway." Thus, Maddie was being referred to Allergy/Immunology for a **work-up** given her history of sensitivities. Dr. Assa'ad, however, did not perform a work-up. She relied on a previous sedimentation rate and CRP to rule out an inflammatory disorder. She never mentioned the elevated CRP value of 2.90 on January 23, 2021 stating "her work-up for inflammatory disorder with sed rates and CRP are normal." She does not document that Maddie was on steroids and antihistamines, both of which could affect the inflammatory marker results. She relies on her physical examination to simply rule out rheumatologic or autoimmune disorder. She does not document a full and complete neurologic exam, yet notes in her chart that the neurologic exam is not with localizing lesion. Finally, she justifies no further testing with the following comment: "contacted in follow up Dr. Frenek, PI on Covid-19 vaccine trial, Madeline has functional impairment not organic in nature. Discourage further workup since this is usually detrimental in functional disorders because it drives the patient to thinking that there maybe something wrong that is indicating all this work-up. It also delays the necessary psychological intervention that is needed to help resolve the functional disorder." Obviously, Dr. Assa'ad did not read Dr. Wesselkamper's note indicating that a referral to Allergy/Immunology was being made to **work-up** Maddie's sensitivity to the vaccine.

Finally, Maddie had an EGD with biopsies performed on March 12, 2021 by Dr. Starva Xanthakos. The official pathology report from biopsies showed in several fragments of gastric fundic mucosa a subtle mild increase in mononuclear cells within the interstitium consisting of lymphocytes, occasional plasma cells, and very rare eosinophils. Rare lymphocyte invasion of glands is identified. No organisms or granulomas present. This finding was never addressed in the chart. No follow-up was recommended.

In conclusion, we have detailed several breaches in standard of care that occurred at the Cincinnati Children's Hospital Medical Center. This is not intended to be nor is a resuscitation of all such breaches. It is the legal responsibility of the ordering physician to follow up, and appropriately address abnormal findings on diagnostic tests they order. Therefore, we request that

you promptly respond by January 28, 2022 providing a detailed explanation with regard to **each** breach in Maddie's care detailed above.

Sincerely,

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

Exhibit 5

Docket No. FDA-2021-N-1088 for “Vaccines and Related Biological Products; Notice of Meeting

Our daughter Maddie was a healthy, energetic, 12-year-old social butterfly with an infectious sense of humor who loved school, trying new things, and hanging out with her friends. She wants to be a pediatric nurse when she grows up. She volunteered for the Pfizer Covid Vaccine Trial for 12-15-year-olds at Cincinnati Children’s with her 2 older brothers and was excited to be able to help other kids get out of this pandemic. She received her first dose on 12/30/21 and had the expected side effects which were no cause for concern. She got her second dose on 1/20/21 and less than 12 hours later she experienced severe abdominal pain, painful electric shocks on her spine and neck, swollen extremities, ice-cold hands and feet, chest pain, tachycardia, pins and needles in her feet that eventually led to the loss of feeling from her waist down. She had blood in her urine from 7 tests over 3 months, mysterious rashes, peeling feet, reflux, gastroparesis, vomiting, and eventually the inability to swallow liquids or food, dizziness, passing out, convulsions, the inability to sweat, swollen lymph nodes in her armpits, urinary retention, heavy periods with clots of blood, decreased vision, tinnitus, memory loss, mixing up words, extreme fatigue, and sadly more. She spent 64 days in the hospital, had 3 hospital stays, and 9 trips to the ER. We are 9 months into this, we have no real answers.

She is trapped in a body that doesn’t work remotely close to the way it did before. Her days now look like this...she is in a wheelchair with an ng tube and has to do 5 feeds, 4 water boluses and take multiple medications each day. She goes to school for 2 hours a day, which is all she can handle. She has 2 or more doctor’s appointments every week and needs help with simple things like showers, opening car doors, and lifting things. Somehow she still has her infectious sense of humor, hangs out with friends, and has more resilience than I ever had at her age.

We emailed and called many times to Cincinnati Children's Hospital Dr. Robert Frenck, the principal investigator for the Pfizer Trial for 12-15-year-olds, and asked what was reported to VAERS for Maddie’s reaction to the vaccine. After being dismissed and not responded to for

weeks, he then told us they do not report adverse reactions to VAERS during the trial, they report them to Pfizer who then reports to the FDA. When we asked him to tell us what was reported, the best answer he gave us was everything was reported. We asked for clarification on what symptoms/reactions had been reported so we didn't duplicate on our submission to VARES, but he refused to give any details other than they had been reported to their sponsor (Pfizer). The only adverse reactions disclosed in the EUA were functional abdominal pain and paresthesia. How do we know all of her adverse reactions were reported? Why weren't ALL of the other adverse reactions she had disclosed in the EUA? How can we find out specifically what was reported to Pfizer and then to the FDA? No one from the FDA, CDC, NIH, or Pfizer ever contacted us to discuss what happened to Maddie, NO ONE!

Maddie received all of her treatment at Cincinnati Children's Hospital, we thought and were assured she would receive the best care if we took her there. That was the biggest mistake we ever made. Why hasn't Maddie's case been researched by the NIH, like several other vaccine injured people that had almost identical reactions? Why wasn't she researched to determine why this happened to her so more healthy children weren't injured? Why was her diagnosis changed to Functional Neurological Disorder shortly after Dr. Frenck collaborated with another party who had only talked to her twice via televisit for less than two hours total and one day (4/8/21) before Pfizer submitted for the EUA for 12-15 year olds? Why did they say they would pay her medical bills related to the vaccine reactions, but instead led us on for months, and finally said this is not related and they would not pay? They ended up sending us paperwork to fill out for Medicaid which thank God she was finally approved for.

We trusted Pfizer and the government when they said the vaccine was safe and if Maddie was one of the rare cases that had a reaction, she would get the best care possible. There are thousands of adults and children experiencing the same adverse reactions as Maddie after getting the Pfizer

covid vaccine. Because she wasn't thoroughly researched and information was not provided in the EUA, people are not getting accurate informed consent when they get the vaccine and sadly are suffering the same consequences with no help from the medical community. I cannot even keep up with messages people send me saying this happened to them or their child, this isn't anything I would have ever imagined in a million years would happen to me or anyone in the United States.

We have been living a nightmare, Maddie's life was forever changed and she has been brushed aside as collateral damage. Let me repeat that, a 13 year old is collateral damage. Maddie volunteered to help get this vaccine approved, she did the right thing and she was excited to do it. Now it is time for you to do the right thing so she can get her life back and so more healthy children and adults don't have their lives ruined by this vaccine.

I am begging you to research why this happened to Maddie and to not approve the EUA for 5-11-year-olds until you figure out why. If it is something pre-existing then figure it out so anyone else that has it can be exempt from getting this vaccine. That was never done. You are putting healthy children like Maddie at risk for having life altering adverse reactions and in some cases even losing their lives.

I am attaching documentation to provide proof that she was in the Pfizer Trial for 12-15-year-olds at Cincinnati Children's Hospital and that she did get the vaccine and not the placebo. If you need documentation or proof for anything else, we will be happy to provide it to you. We have nothing to hide.

Sincerely,

Stephanie de Garay and Patrick de Garay
(Maddie de Garay's mother and father)

Exhibit 6

The Vaccine Adverse Event Reporting System (VAERS) Results

VAERS ID	Adverse Event Description	Lab Data	Current Illness	Adverse Events After Prior Vaccinations	Medications At Time Of Vaccination	History/Allergies
1400303-1	After the second dose she had immediate pain at the injection site and over the next 24 hours she developed: A fever of 101.4 severe abdominal pain and chest pain that made her feel like her heart was being pulled out painful electric shocks down her neck and spine that made her walk hunched over numbness and swelling in the arm she got the shot pain in her fingers and toes that turned white and were ice cold to the touch Over the next 2.5 months her abdominal, muscle and nerve pain became unbearable plus she developed new symptoms: Fatigue gastroparesis, nausea and vomiting Eventually she couldn?t even swallow food or liquids without immediately spitting it up. An itchy rash on her arms peeling skin on her feet Her menstrual cycle lasted a month with large clumps of blood She had unexplained painful cysts vision problems headaches erratic blood pressure and heart rate memory loss, mixing up words and brain fog Dizziness, fainting and then nonepileptic seizures that we suspect were from lyrica verbal and motor tics loss of feeling from the waist down, muscle weakness, abnormal gait and eventually she wasn?t able to walk at all urinary retention From the day she got her 2nd dose to today we took her to the ER nine (9) times and she was admitted to the hospital a total of 3 times totalling 2 months. The last time she was	Multiple blood tests, spine MRI, Upper GI, Endoscopy, x-ray and ultrasound of abdomen. Can provide test results, too much to type in here. Additional blood work done today and brain MRI/MRV scheduled for 6/22.	none	No prior vaccinations for this event.	Vyvanse 50mg	dermatographia,none before the vaccine, tape allergy after the vaccine

VAERS ID	Adverse Event Description	Lab Data	Current Illness	Adverse Events After Prior Vaccinations	Medications At Time Of Vaccination	History/Allergies
	admitted to the hospital she could not walk, was unable to feel or move below her waist, threw up anything she tried to eat or drink, had tachycardia and her blood sugar was at 47. Once she got an NG tube and was stable they transferred her to Inpatient Rehabilitation and she was just discharged on June 1st. Today she is able to walk with a walker and take care of herself but she still has little to no feeling below her waist. She still has an NG tube for nutrition and continues to have GI and urinary retention problems.					

Note: Submitting a report to VAERS does not mean that healthcare personnel or the vaccine caused or contributed to the adverse event (possible side effect).

Notes:

Caveats: VAERS accepts reports of adverse events and reactions that occur following vaccination. Healthcare providers, vaccine manufacturers, and the public can submit reports to VAERS. While very important in monitoring vaccine safety, VAERS reports alone cannot be used to determine if a vaccine caused or contributed to an adverse event or illness. The reports may contain information that is incomplete, inaccurate, coincidental, or unverifiable. Most reports to VAERS are voluntary, which means they are subject to biases. This creates specific limitations on how the data can be used scientifically. Data from VAERS reports should always be interpreted with these limitations in mind.

The strengths of VAERS are that it is national in scope and can quickly provide an early warning of a safety problem with a vaccine. As part of CDC and FDA's multi-system approach to post-licensure vaccine safety monitoring, VAERS is designed to rapidly detect unusual or unexpected patterns of adverse events, also known as "safety signals." If a safety signal is found in VAERS, further studies can be done in safety systems such as the CDC's Vaccine Safety Datalink (VSD) or the Clinical Immunization Safety Assessment (CISA) project. These systems do not have the same limitations as VAERS, and can better assess health risks and possible connections between adverse events and a vaccine.

Key considerations and limitations of VAERS data:

- Vaccine providers are encouraged to report any clinically significant health problem following vaccination to VAERS, whether or not they believe the vaccine was the cause.
- Reports may include incomplete, inaccurate, coincidental and unverified information.
- The number of reports alone cannot be interpreted or used to reach conclusions about the existence, severity, frequency, or rates of problems associated with vaccines.
- VAERS data are limited to vaccine adverse event reports received between 1990 and the most recent date for which data are available.
- VAERS data do not represent all known safety information for a vaccine and should be interpreted in the context of other scientific information.

Some items may have more than 1 occurrence in any single event report, such as Symptoms, Vaccine Products, Manufacturers, and Event Categories. If data are grouped by any of these items, then the number in the Events Reported column may exceed the total number of unique events. If percentages are shown, then the associated percentage of total unique event reports will exceed 100% in such cases. For example, the number of Symptoms mentioned is likely to exceed the number of events reported, because many reports include more than 1 Symptom. When more then 1 Symptom occurs in a single report, then the percentage of Symptoms to unique events is more than 100%. More information. (/wonder/help/vaers.html#Suppress)

Data contains VAERS reports processed as of 07/02/2021. The VAERS data in WONDER are updated weekly, yet the VAERS system receives continuous updates including revisions and new reports for preceding time periods. Duplicate event reports and/or reports determined to be false are removed from VAERS. More information. (/wonder/help/vaers.html#Reporting)

For more information on how many persons have been vaccinated in the US for COVID19 to date, see https://covid.cdc.gov/covid-data-tracker/#vaccinations/ (https://covid.cdc.gov/covid-data-tracker/#vaccinations/)

Help: See The Vaccine Adverse Event Reporting System (VAERS) Documentation (/wonder/help/vaers.html) for more information.

Query Date: Jul 13, 2021 10:19:25 PM

Suggested Citation:

United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 07/02/2021, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on Jul 13, 2021 10:19:25 PM

Query Criteria:

Age:	6-17 years
State / Territory:	Ohio
Vaccine Lot:	220395
Vaccine Manufacturer:	PFIZER\BIONTECH
Vaccine Products:	COVID19 VACCINE (COVID19)
VAERS ID:	All
Group By:	VAERS ID
Show Totals:	False
Show Zero Values:	False