

October 22, 2021

VIA EMAIL

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Secretary, Health & Human
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Dr. Tom Shimabukuro
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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

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

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.

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-olds¹¹ 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%20pubmed.

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 2021¹⁴ 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.