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# FDA Buries Data on Seriously Injured Child in Pfizer's COVID-19 Clinical Trial

## The FDA should not authorize the Pfizer jab for younger children until it conducts a proper trial

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*When Stephanie and Patrick de Garay enrolled their 12-year-old child Maddie and her two brothers in Pfizer's Covid-19 clinical trial, they believed they were doing the right thing.*

That decision has turned into a nightmare. Maddie, a previously healthy, energetic, full of life child, was within 24 hours of her second dose reduced to crippling, scream-inducing pain that landed her in the emergency room where she described feeling like someone was "ripping [her] heart out through [her] neck."

Over the next several months the nightmare continued, during which Maddie was hospitalized several times and suffered numerous systemic injuries, requires a tube through her nose that carries her food and medicine, and a wheelchair for assistance.

Ms. de Garay documented every detail of Maddie's injury and reported it to the principal investigator for the Pfizer trial at Cincinnati Children's Hospital where the vaccine clinical trial was occurring and where Maddie was treated and admitted. They first tried to treat Maddie as "a mental patient," telling the family it was psychological and in Maddie's imagination. Then they claimed it was unrelated to the vaccine (copy of recording with hospital below), and when that argument failed, Pfizer listed this traumatic adverse event as "functional abdominal pain" when reporting to the FDA.

Ms. de Garay reported what occurred to the CDC and FDA through VAERS in June 2021 but nobody from these agencies sought additional information or followed-up with the de Garays. Ms. de Garay also reached out to Dr. Nath, a Chief in the NIH's National Institute of Neurological Disorders and Stroke, responded by stating he was "Sorry to hear of your daughter's illness" and that "**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**." (Copy of this email is below.) Unfortunately, other than a call arranged by Maddie's

neurologist, there was no follow-up or response from NIH or any other federal health agency. Even after Ms. de Garay did a press event on June 28, 2021 with **Senator Ron Johnson**, neither Pfizer nor any health agency reached out in any manner to address Maddie's injury or obtain any additional information.

This story is extremely troubling. Pfizer's clinical trial for children aged 12-15 included only 1,131 children who were vaccinated and at least one of those children suffered a devastating, life-altering injury which, despite incontrovertible proof and the cries of both the victim and her parents, **has not been appropriately acknowledged by Pfizer or the FDA**. Putting aside that one serious injury in a small trial should alone raise blaring alarm bells, one must ask: what other serious adverse events have been hidden and ignored by regulators?

For a virus that rarely harms children, the need to assure safety of the Covid-19 vaccine is high. A study with only 1,131 children is underpowered. It will not pick up anything but the most common adverse events. If what Maddie suffered will occur in 1/1,000 children, that would result in 75,000 children in this country suffering this serious injury. If it happens 1/10,000 children, that is 7,500 suffering this serious injury. It could be that the cure is worse than the disease. But that will only be known if there is a properly powered (a.k.a., sized) clinical trial with children.

International scientists have declared that "inadequately powered studies should themselves be considered a breach of ethical standards." Without a clinical trial of sufficient size that reviews all potential adverse events, such as that experienced by Maddie, for a sufficient duration, this potentially catastrophic result will not be identified prior to authorization or licensure.

And as Dr. Woodcock and Dr. Marks have said, "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."

The de Garay family are truly brave to come forward with their story and are doing so in the hope of preventing other children from being injured like their Maddie. My firm has sent a letter to the FDA regarding Maddie, a copy of which is below. The de Garay family also released its communication with the NIH and recorded conversations with the trial's principal investigator – links to both are below.

Will the FDA require Pfizer to actually conduct a properly powered study? Unlikely. To do so would be for its leadership, and especially Dr. Janet Woodcock and Dr. Marks, to self-inflict a wound. It reflects the danger of placing safety in hands of government officials that have been promoting a product, because to admit a safety issue now requires them to effectively cut off their own hands.

**The real lesson is not that pharmaceutical companies, or the FDA should act better or do a better job. That just won't always be the case. The real lesson is that civil and individual rights should never be contingent upon a medical procedure. Never. Preserving those rights to choose whether to get a medical**

**product, without any government coercion, is the final and ultimate safeguard. Removing that right results in dangerous authoritarianism because just as the FDA will not admit to Maddie's serious injury after having promoted this vaccine, politicians that mandate the vaccine will not want to later admit a mistake by repealing the mandate.**

Click here to read the Letter to Federal Health Authorities Regarding Maddie.

Click here to read Stephanie de Garay's Email Exchange with NIH.

Click here to listen to Patrick and Stephanie de Garay's Phone Call with Pfizer trial Principal Investigator on May 17, 2021.

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