

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. French 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)

