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Rigged: Pfizer Trial Hid Injuries, Maddie's Story

Analysis by Dr. Joseph Mercola Fact Checked | September 10, 2022

STORY AT-A-GLANCE

- Maddie de Garay signed up for Pfizer's COVID-19 shot trial when she was 12; previously a healthy preteen, her life has been forever changed due to health problems caused by the shots
- Maddie suffered a severe systemic adverse reaction to her second dose of the shot and struggled through 11 ER visits and four hospital admissions in the year and a half that followed
- Injuries from the shot have left her unable to walk or eat — she receives her nutrition via a feeding tube — and suffering from constant pain, vision problems, tinnitus, allergic reactions and lack of neck control
- Maddie and her family were continually dismissed by the medical professionals put in place to help, ignored by the U.S. Food and Drug Administration and denied the care needed to help Maddie
- The medical professionals went so far as to label Maddie's health problems as psychological in nature, and they still haven't been contacted by anyone from Pfizer or the FDA — even after her true diagnosis was revealed and found to be related to the shots

When Stephanie de Garay allowed her three children to sign up for Pfizer's COVID-19 shot trial, she assumed the worst that could happen was anaphylactic shock — and in that case, they'd be treated with an EpiPen and be fine. From her daughter's perspective, the trial was a way to keep up with a close friend who had already signed up for the trial.

It also didn't hurt that the trial offered monetary compensation of $119 per visit.[1] This is what prompted all three of de Garay's children to ultimately sign up for the COVID-19 shot trial, which changed the life of de Garay's daughter Maddie. A healthy 12-year-old girl prior to the trial, Maddie loved to dance, play soccer and spend time with her friends.

She suffered a severe systemic adverse reaction to her second dose of the shot, however, and struggled through 11 ER visits and four hospital admissions in the year and a half that followed. Injuries from the shot have left her unable to walk or eat — she receives her nutrition via a feeding tube — and suffering from constant pain, vision problems, tinnitus, allergic reactions and lack of neck control.[2]

As though the physical trauma weren't enough, Maddie and her family were continually dismissed by the medical professionals put in place to help, ignored by the U.S. Food and Drug Administration and denied the care needed to help Maddie.

The medical professionals went so far as to label Maddie's health problems as psychological in nature, and they still haven't been contacted by anyone from Pfizer or the FDA — even after her true diagnosis was revealed and found to be related to the shots.

In the video above, Del Bigtree with "The Highwire" details Maddie's ordeal and the family's continued fight to not only get help for their daughter but get the word out so others aren't similarly harmed by COVID-19 injections.[3]

Adverse Reaction Started Within Hours of the Second Dose

After Maddie joined Pfizer's COVID-19 trial for 12- to 15-year-olds, she received her first dose of the experimental shot December 30, 2020. They were told it was just like a flu shot, "no big deal," de Garay said. The second dose was given three weeks later, blood drawn two weeks after that and immune responses compared.

Participants were given access to the TrialMax app to record side effects, like a swollen arm, but de Garay was surprised at the format it used. There wasn't space for open-

ended comments, only direct questions with "yes" or "no" options for answers, or check boxes to signify a set of predetermined potential effects.

With the first shot, Maddie had a fever and her arm swelled. She received the second dose January 20, 2021, which the children said hurt more than the first shot. At that point, de Garay started writing notes to make sure she was documenting what happened to the children; she thought it would be valuable for the trial.

The next day, January 21, 12 hours after Maddie's second COVID-19 shot, de Garay wrote, "Maddie came into our room around 4 a.m. and said she didn't feel right and asked if she could sleep with us. Not typical of her."[4]

The next day, she barely made it through the day at school, and when she walked in the door from the bus, she wasn't in good shape. De Garay's husband sent her a text at work saying Maddie was having a reaction to the shot. In the background, de Garay could hear her daughter screaming that her heart felt like it was going to be ripped out through her neck; she was in that much pain.

A trip to the ER was useless — they checked her out for appendicitis, ruled it out and sent her home, saying it was most likely an adverse reaction to the COVID-19 shot and would get better in time.

They recommended seeing a family doctor if there were any more issues — even though Maddie was part of a clinical trial, arguably the most high-profile clinical trial ongoing at the time, the whole purpose of which is to find out if the shots cause adverse reactions. Yet, Pfizer did not contact the family and Maddie's heart pain wasn't addressed.

Shot Reaction Labeled a Psychological Problem

January 23, 2021, de Garay recorded Maddie's continued symptoms, which included severe body pain, nausea, diarrhea and extreme fatigue. They visited an ER three times that week and Maddie was finally admitted on the third visit.

But instead of sending in medical specialists and doing extensive testing, they sent in psychologists and social workers, as they were focused on her mental health. They labeled Maddie with anxiety and suggested that her anxiety about the shot was causing all of the symptoms.[5] On Life Funder, a website where a fundraising effort has been started for Maddie, it's explained:[6]

> *"After reporting everything to the Pfizer clinical trial Principal Investigator [Dr. Robert Frenck] and being brushed aside, we started documenting every detail of Maddie's injury. Cincinnati Children's first tried to treat Maddie as "a mental patient," telling us it was anxiety and it was all in Maddie's head.*
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> *Pfizer listed her traumatic systemic adverse reaction as "functional abdominal pain" when reporting to the FDA. A day before Pfizer submitted their request for emergency approval for the covid vaccine for 12-15-year-olds and before necessary testing was done, they put Functional Neurological Disorder (FND) as a diagnosis in her chart."*

Maddie's symptoms continued into February, with old symptoms getting worse and new symptoms, including extreme bloating after eating, starting. Maddie was dizzy, nauseous and in pain. She felt like her heart was on fire and soon began throwing up when she ate, until she couldn't eat at all. Her ability to shower on her own became a thing of the past.[7]

It was Dr. Amal Assa'ad at Cincinnati Children's Hospital who, after spending just 15 minutes with Maddie, determined that her physical symptoms weren't the result of the shots but were due to a functional neurological disorder.

She put in her notes that she had discussed with another doctor, Robert Frenck, measuring an antibody titer to determine whether Maddie had received the shot or a placebo in the trial, but ultimately she said she thought it will be "irrelevant to the management of Madeline's functional disorder."[8] Assa'ad's notes went so far as to advise against any further investigation, even though Maddie was a participant in a clinical trial:[9]

"My assessment is that Madeline has a functional impairment that is not organic in nature … I also discourage further work up since this is usually detrimental in functional disorders because it drives the patient to thinking that there must be something wrong that is indicating all this work up. It also delays the necessary psychologic intervention that is needed to help resolve the functional disorder."

'It's Like We're Stuck in a Nightmare'

Frenck, director of the Vaccine Research Center at Cincinnati Children's Hospital, was principal investigator of the Pfizer COVID-19 trial, put there to act as an advocate for the people in the trial and making sure that they were safe, as well as determine if any reactions they experienced were due to the vaccine. He offered little help to the de Garays, even as Maddie's symptoms persisted and worsened.

February 19, 2021, de Garay wrote that Maddie fainted and, when she came to, couldn't remember her birthday or her friend's names. In response, the hospital gave her a different tape for her IV and said she may have a rubber allergy.

During her second hospital stay, Maddie woke up from an MRI of her brain and upper GI, fell to the ground and hasn't been able to walk since. Her father said, "It's like we're stuck in a nightmare," and they feel they've been abandoned.

When they signed Maddie up for the clinical trial, the de Garays assumed they'd have medical staff on hand and scientists there to support them. Any medical bills due to adverse events were also supposed to be covered, but Pfizer and the hospital were refusing to pay for Maddie's treatments, claiming they weren't research-related. De Garay's notes continued into March 2021:[10]

- March 24, blackout that lasted 20 minutes, pulse went up to 150
- March 28, 10 convulsions and seizures, can't walk, gets around by scooting on her butt

Previously, doctor's notes said Maddie had no anxiety, but then they changed their tune, writing that she "seems to have some anxiety which may be augmenting her pain." Even after 1.5 months in the hospital, the health care providers were treating Maddie's shot reaction as a psychological issue instead of a physical one.

After she didn't make any physical progress, the hospital transferred Maddie to a mental institution — but after seeing the harsh conditions used at the facility, the de Garays took Maddie home instead, with no support offered for her care.

"They've just basically pretended this didn't happen … I thought in a clinical trial that if anything happened, they were going to do everything they could to figure it out," de Garay said. "I thought that was the whole point. So that's why I wasn't worried. But they didn't do that. They just tried to make her look like she was crazy."[11]

Pfizer Reported Maddie's Severe Reaction as Abdominal Pain

If you're wondering how Pfizer got away with this, in Pfizer's April 2021 disclosure of Maddie's case to the FDA, it's stated:[12]

> *"One participant experienced an SAE [serious adverse event] 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."*

Bigtree stated, "That looks like fraud to me." Even as the de Garays tried to transfer Maddie's care to a different local hospital, they were met with bias and red tape; the health care providers who received all the digital records had already made their minds up about the diagnosis before Maddie was seen.

The de Garays feel they're blacklisted at major hospitals, and any doctor who's going to do the right thing is going to risk their career in doing so. And, as noted on Life Funder,

"Pfizer has zero financial obligation for Maddie's injury and they have not offered any assistance."[13]

After a year and a half, with the help of the Informed Consent Action Network (ICAN) and React19, a nonprofit that offers support for those suffering from long-term COVID-19 shot adverse events, they found doctors willing to conduct the proper tests, who diagnosed Maddie's vaccine reaction as follows:[14]

> *"The findings were consistent with severe distal chronic acquired demyelinating polyradiculoneuropathy, small fiber sensory neuropathy and orthostatic intolerance in the setting of COVID vaccination."*

Pfizer Classifies Severe Reactions as 'Not Related' to Shots

The FDA and Pfizer attempted to hide the COVID-19 shot clinical trial data for 75 years, but the FDA was ordered by the U.S. District Court for the Northern District of Texas to release redacted versions of trial documents on a much faster schedule. As part of the court order, 80,000 pages of documents related to the FDA's approval of Pfizer's COVID-19 shots were released June 1, 2022.[15]

Among those documents were case report forms (CRFs) revealing that deaths and severe adverse events took place during Phase 3 trials, but, as reported by Children's Health Defense, Pfizer had "a trend of classifying almost all adverse events — and in particular severe adverse events (SAEs) — as being 'not related' to the vaccine."[16]

Examples include a woman in her early 50s who died from a heart attack November 4, 2020, five days after she'd received the second dose of Pfizer's experimental COVID-19 shot. Her death was listed as "not related" to the shots. Two other heart attack deaths — one in a woman in her late 50s and the other in a man in his mid-60s — also occurred within two to three months of the shots, but were also listed as "not related."[17]

In other instances, a teenage girl suffered from deep vein thrombosis two months after the second dose of the shot, but it, too, was deemed "not related," as was the acute exacerbation of asthma experienced by a woman in her late 50s about two months after

the shots.[18] According to independent journalist Michael Nevradakis, for Children's Health Defense:[19]

> *"The many serious adverse events — and several deaths — recorded during the Phase 3 trials are also apparent in a separate, massive document exceeding 2,500 pages, cataloging such adverse events. This document lists a wide range of adverse events suffered by trial participants classified as toxicity level 4 — the highest and most serious such level.*
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> *However, not one of the level 4 (most severe) adverse events listed in this particular document is classified as being related to the vaccination … Similarly, only a small number of toxicity level 3 adverse events were indicated as having been "related" to vaccination."*

Even the instances that were attributed to the shots were downplayed, such as the report of "one younger participant with no past medical history [who] had a life-threatening SAE of myocardial infarction 71 days after Dose 2 that was assessed by the investigator as related to study intervention." The report then goes on to state that the SAE "lasted one day and resolved the same day."[20]

The FDA Ignored Maddie's Case

Just as it ignored the many red flags in Pfizer's clinical trial data, the FDA also ignored Maddie's case, even when attorneys got involved. In August 2021, the de Garays reached out to ICAN's legal team; ICAN's Aaron Siri is now representing them. According to Siri:[21]

> *"What happened to Maddie is not only the story of an injury to a child, which is heartbreaking in and of itself. But Maddie was in a clinical trial that only had 1,000 children in the age bracket of 12 to 15 years old that got the COVID-19 vaccine.*
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> *When she suffered that reaction, there should have been every medical expert at Cincinnati and at the FDA that should have descended to study what happened to Maddie, because if that could happen to one in 1,000 children, the*

repercussions could be really devastating, especially for an infection that doesn't harm children anywhere near that rate."

After ICAN's team got Maddie's medical records and reviewed them, they believe the causal connection to Pfizer's COVID-19 shot is extraordinarily strong. In October 2021, they sent a letter to the FDA, including all of Maddie's medical records and highlighting how Pfizer downplayed the condition in their disclosure, describing Pfizer's move as "at best dishonest. To regulators, it should be criminal."[22]

In February 2022, the FDA finally responded, incredulously by saying to file a VAERS report or send a letter to CISA — Clinical Immunization Safety Assessment Project — which is run by Dr. Kathryn Edwards, who sits on the data safety monitoring board for Pfizer's COVID-19 shot trials. In other words, they did nothing.[23]

Maddie's story is ongoing but, sadly, is only one of many cases of people being seriously injured or killed by COVID-19 shots and not being taken seriously — or outright discredited — by health care providers and health officials. However, there is hope — and it comes in the form of protecting your right to informed consent and the freedom to make your own medical choices. As Siri put it:[24]

"The hope is that we make sure that we always have the choice to say no. As long as we can say no, that is the safeguard. That is the stopgap to all of this bad conduct. It's not going to protect those who don't know better to say no in certain situations, but it will protect those who do … There should be a lot of hope out there because COVID vaccine mandates have receded all across this country …

Freedom of speech, the ability to have individual liberties. That is what will save us … The ability to become educated, to have access to information and to make informed decisions … the ability to say no about something, or a medical procedure, that we don't want to have on our bodies or our children's bodies."