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In 1996, Pfizer's drug, Trovan, was still in the clinical stage of development when the drugmaker tested it, without parents' consent, on about 200 children. Pfizer claimed Trovan was "safe," but 181 kids were gravely injured, and 11 died.

By <u>Chelli Stanley</u>, <u>The Defender</u> September 30, 2021

Pfizer last week <u>told</u> the public and the U.S. Food and Drug Administration (FDA) its new experimental COVID vaccine is safe for young children.

It's a familiar story, similar to one the vaccine maker told in the past about another drug it tested on children – a story that had a terrible outcome.

Both stories began with this simple claim: "These drugs are safe for your children."

In 1996, <u>Pfizer</u>, the transnational multi-billion-dollar pharmaceutical company, <u>was working</u> to bring a new drug – Trovan – to market. The drug was still in the clinical stage of development, when Pfizer made a decision that reportedly cost the lives of many children, and triggered an international firestorm.

Pfizer took its unlicensed Trovan to Kano, Nigeria, during a meningitis outbreak — though Trovan had never been tested in children or against meningitis.

According to <u>Pfizer whistleblower</u>, <u>Dr</u>. <u>Juan Walterspiel</u>, Pfizer sent unskilled doctors to Kano, who were unlicensed to practice medicine in Nigeria, and who had limited experience treating meningitis in children.

Walterspiel also reported the staff were so unskilled they could not place IV lines, and quickly resorted to orally administering the drug to children.

In the short two weeks Pfizer was in Kano, staff worked with 200 children, and gave 99 of the children unlicensed Trovan, despite the children's desperate state. Pfizer did this even though Doctors Without Borders was operating in the same Kano hospital, treating children for free, with medicine proven to work well against bacterial meningitis.

Doctors Without Borders realized what Pfizer was doing and in a <u>statement</u> said they "were shocked Pfizer continued the socalled scientific work in the middle of hell." They "<u>communicated their concerns</u> to both Pfizer and the local authorities."

Pfizer gave the other 101 children <u>ceftriaxone</u>, which is proven effective for meningitis. However, many children were "low-dosed," with only one-third of the recommended amount. Because Pfizer didn't have enough skilled medical personnel to administer ceftriaxone by IV, staff injected it directly into the children's butts or thighs.

But "<u>the shots were severely painful</u>, leading to 'great fear and sometimes dangerous struggles with children.'" So Pfizer lowered the dose significantly to ease the severe pain caused by the shots. <u>Pfizer said</u> available data indicated the dose remained more than sufficient, but the drug's manufacturer, Hoffmann-La Roche, said the reductions could have sapped the drug's strength.

"A high dose is essential," Mark Kunkel, Hoffmann-La Roche's medical director, told the Washington Post. "Clinical failures ... and perhaps deaths of children could have resulted from the low dosing."

According to a lawsuit against Pfizer, "five of the children who received Trovan and six of the children who were 'lowdosed' with ceftriaxone died, and others treated by Pfizer suffered very serious injuries, including paralysis, deafness and blindness."

Of the 200 children treated by Pfizer, <u>181 were gravely</u> <u>injured</u>, and 11 died.

The Washington Post investigated Pfizer's ethics, stating, "Some medical experts questioned why the company did not switch to the proven pills when it was clear the young patients were approaching death."

"It could be considered murder," <u>said Evariste Lodi</u>, the leading Doctors Without Borders physician in Kano, after <u>reading a report</u> that Pfizer kept a child solely on Trovan until the child died.

In a statement about the child's death, <u>a Pfizer</u> <u>spokeswoman</u> said "researchers had no reason to suspect the experimental medicine was not working." <u>Pfizer also</u> <u>said</u> Trovan was "at least as effective as the gold standard treatment," despite it having never been used in children, or for meningitis.

Pfizer designed the clinical trial in Kano "in six weeks, though the risks and complications of such a trial would typically require a year to adequately assess," <u>The Atlantic</u>

<u>reported</u>.

The parents in Kano have maintained they were not notified of an experiment, and that Pfizer did not have their consent to use their children in a drug trial in the middle of a health crisis. They organized to sue the drugmaker, while caring for children injured during the experiment.

Pfizer maintains the Nigerian parents gave full consent for their critically ill children to be used in an experiment, though even Pfizer admits no parent ever signed a consent form.

The lawsuits dragged on for years, as Pfizer refused to admit to any wrongdoing. "We are fed up with this case," <u>said a</u> <u>father</u> who lost his daughter. "Our children are dead and some are maimed."

Pfizer <u>said</u> "the trial was conducted appropriately, ethically and with the best interests of patients in mind; and it helped save lives."

However, even the approval letter Pfizer submitted to the FDA about the Kano trial was <u>exposed by a Nigerian doctor</u>, who "said that his office backdated an approval letter and this may have been written a year after the study had taken place."

The community of Kano has been profoundly affected – "<u>the</u> <u>experiment shaped public perception</u> of Western drugs in the region. Parents told their children about it. Teachers lectured about Pfizer in classrooms. Pundits spoke of Western physicians seeking human guinea pigs."

Pfizer acknowledged the severe nature of the meningitis outbreak to a Nigerian investigative committee, <u>then said</u>, "Pfizer's intervention was therefore strictly a humanitarian gesture aimed at saving lives. It was totally devoid of any commercial undertones." The company <u>called it</u> "the humanitarian trial." "If I had the power, I would take away their medical licenses," <u>said Lodi</u>.

Pfizer's Trovan history gets worse

In the initial development of Trovan, <u>Walterspiel</u> <u>reported</u> that Pfizer tried another study and:

" ... the study failed and several patients developed severe post-operative infections and one woman had her uterus removed. Pfizer dispatched risk managers and asked affected patients and relatives to fill out checks for whatever amount they felt right against their signature to keep the payments confidential."

Pfizer made no such offer in Kano. The families of Kano had to sue Pfizer repeatedly, and received no compensation until nearly 15 years after the incident occurred.

Pfizer did not let these mere setbacks of death, maiming and international scandals deter the company. Within a few short years, the drugmaker brought Trovan to market in both the United States and Europe.

Expecting to reap financial windfalls, Pfizer aggressively marketed Trovan — until it discovered the public in both the EU and U.S. was reeling from liver damage, liver failure and death as a result of taking Trovan.

Reports of adverse reactions grew until Europe took Trovan off the market completely, and the FDA severely restricted the public's access in the U.S.

A <u>New York Times article</u> detailed how Trovan's serious side effects became known only after it was given to the public. "The case showed how a new drug, marketed by an expert like Pfizer, could be swiftly prescribed to thousands of patients before all the side effects were known. Pfizer said its tests of Trovan had not revealed any serious problems." In 2000, William C. Steere Jr., then chairman of Pfizer, <u>acknowledged</u> some side effects only become known after a drug is approved, saying, "You put the drug in the general population, and then everyone is taking it. We just hold our breath and wait to see if there is something unique with the drug."

'If I had an enemy, I would not let him take their drugs'

Pfizer was repeatedly sued in Nigeria and the U.S. for its actions in Kano. In 2009, Pfizer agreed to pay \$75 million, despite initially being <u>sued for \$8.5 billion</u>.

The company got involved in several more scandals that exploded when <u>Wikileaks published</u> several U.S. Embassy cables detailing Pfizer's communications.

A Pfizer lawyer described in the cables that "Pfizer has worked closely with former Nigerian Head of State Yakubu Gowon. Gowan spoke with Kano State Governor Mallam Ibrahim Shekarau, who directed the Kano AG to reduce the settlement demand from \$150 million to \$75 million."

In another cable, a top Pfizer representative in Nigeria said:

"Pfizer had hired investigators to uncover corruption links to Federal Attorney General Michael Aondoakaa to expose him and put pressure on him to drop the federal cases. Pfizer's investigators were passing this information to local media. A series of damaging articles detailing Aondoakaa's 'alleged' corruption ties were published in February and March."

A cable showed a Pfizer representative commenting that "Doctors Without Borders administered Trovan to other children during the 1996 meningitis epidemic, and the Nigerian government has taken no action."

The accusation prompted Doctors Without Borders to publish a

<u>strongly worded press release</u> stating that they did not give anyone Trovan, and were in fact the first to speak out about Pfizer's unethical actions.

Finally, the cables showed that "Pfizer was not happy settling the case, but had come to the conclusion that the \$75 million figure was reasonable because the suits had been ongoing for many years, costing Pfizer more than \$15 million a year in legal and investigative fees."

The original lawsuit also sought <u>prison terms for Pfizer</u> <u>officials</u>.

Scandals continued even after the case was settled, when Pfizer demanded that anyone collecting the money give a sample of their DNA. Several people refused, <u>distrusting what Pfizer</u> may do with their DNA. They were not allowed to get compensation as a result.

<u>Pfizer said</u> it "always acted in the best interest of the children involved, using the best medical knowledge available."

Najib Ibrahim of Kano <u>said of Pfizer</u>, "If I had an enemy, I would not let him take their drugs." Abdul Murtala <u>said</u>, "Pfizer reminds me of recklessness with human lives."

The pattern continues, with 12-year-old injured during Pfizer COVID trial

Maddie de Garay was 12 when she voluntarily participated in Pfizer's COVID-19 vaccine trial for 12- to 15-year-olds in Ohio. After she took the second dose on January 20, 2021, her life changed.

Her mother, Stephanie de Garay, <u>spoke at press conference</u> in June, held by Sen. Ron Johnson (R-Wis.), during which she described the maiming of her child and Pfizer's disregard towards Maddie and the family – despite Maddie being part of the trial in order to determine whether Pfizer's covid vaccine is safe for children.

Stephanie said:

"All we want is for Maddie to be seen, heard, and believed, because she hasn't been. And we want her to get the care that she desperately needs so that she can go back to normal. She was totally fine before this. They're not helping her."

Stephanie <u>said</u> within 24 hours of the second dose, Maddie "developed severe abdominal and chest pain. She had painful electrical shocks down her neck and spine that forced her to walk hunched over. She had extreme pain in her fingers and toes."

Maddie went to the ER immediately, as instructed by Pfizer's vaccine trial administrator. After doctors ran few tests, she was sent home with a diagnosis: "Adverse effect of vaccine initial encounter."

In the first five months after getting her second dose, Maddie would return to the ER eight more times.

According to Stephanie:

"Over the next 2.5 months, her abdominal, muscle and nerve pain became unbearable. She developed additional symptoms that included gastroparesis, nausea and vomiting, erratic blood pressure and heart rate, memory loss, brain fog, headaches, dizziness, fainting, and then seizures.

"She developed verbal and motor tics, she had loss of feeling from the waist down and muscle weakness, drastic changes in her vision, urinary retention and loss of bladder control, severely irregular and heavy menstrual cycles, and eventually she had to have an NG tube put in to get nutrition. All of these symptoms are still here today. Some days are worse than others." Maddie's doctors began to suggest she had "functional neurological disorder due to anxiety" and even tried to admit her to a mental hospital. Her family fought it.

It took five months for Maddie to get an MRI of her brain and appropriate blood tests, which she got when her family went elsewhere for medical advice after talking to others who were adversely affected by the COVID vaccines.

Stephanie said:

"What I want to ask is: Maddie volunteered for the Pfizer trial. Why aren't they researching her to figure out why this happened so other people don't have to go through this? Instead, they're just saying it's 'mental.'"

The de Garay family has joined with <u>emerging grassroots</u> <u>advocacy groups</u> whose members' lives suddenly changed after they got a COVID vaccine. They are asking the CDC and FDA to <u>recognize their injuries</u>, the medical community to believe and help them, the media to share their stories, for the public to know about these injuries as part of informed consent, and for their injuries to be studied so that solutions can be found.

Since being injured by new vaccines still in phase 3 trials, they have been subjected to stonewalling, cover-ups, bullying, refusal to collect the data and blanket denials.

Pfizer has not commented publicly on Maddie's case.

At the September FDA advisory meeting on Pfizer COVID boosters in the U.S., Steve Kirsch, executive director of the COVID-19 Early Treatment Fund, <u>said Pfizer did not record Maddie's</u> <u>extensive injuries</u> in its clinical trial results. <u>Kirsch also</u> <u>noted</u> Pfizer marked the entirety of Maddie's injuries as "abdominal pain."

Kirsch reported Pfizer's fraud to FDA acting Commissioner Dr.

Janet Woodcock, but no investigation has been launched into Pfizer for allegedly erasing Maddie's extensive injuries from its trial data for children.

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