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## Pfizer Faces Criminal Charges in Nigeria

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Officials in [Nigeria](#) have brought criminal charges against pharmaceutical giant [Pfizer](#) for the company's alleged role in the deaths of children who received an unapproved drug during a meningitis epidemic.

Authorities in [Kano](#), the country's largest state, filed eight charges this month related to the 1996 clinical trial, including counts of criminal conspiracy and voluntarily causing grievous harm. They also filed a civil lawsuit seeking more than \$2 billion in damages and restitution from Pfizer, the world's largest drug company.

The move represents a rare -- perhaps unprecedented -- instance in which the developing world's anger at multinational drug companies has boiled over into criminal charges. It also represents the latest in a string of public-relations blows stemming from the decade-old clinical trial, in which Pfizer says it acted ethically.

The government alleges that Pfizer researchers selected 200 children and infants from crowds at a makeshift epidemic camp in Kano and gave about half of the group an untested antibiotic called Trovan. Researchers gave the other children what the lawsuit describes as a dangerously low dose of a comparison drug made by [Hoffmann-La Roche](#). Nigerian officials say Pfizer's actions resulted in the deaths of an unspecified number of children and left others deaf, paralyzed, blind or brain-damaged.

The lawsuit says that the researchers did not obtain consent from the children's families and that the researchers knew Trovan to be an experimental drug with life-threatening side effects that was "unfit for human use." Parents were banned from the ward where the drug trial occurred, the suit says, and the company left no medical records in Nigeria.

Pfizer and its doctors "agreed to do an illegal act," the criminal charges state, and behaved "in a manner so rash and negligent as to endanger human life."

Internal Pfizer records obtained by [The Washington Post](#) show that five children died after being treated with the experimental antibiotic, though there is no indication in the documents that the drug was responsible for the deaths. Six children died while taking the comparison drug.

Suspicion stirred by news of the drug trial has been so intense in Kano, the lawsuit says, that parents last year refused to allow their children to be immunized against polio, frustrating a program aimed at wiping out one of the disease's last refuges.

In a statement, Pfizer said it thinks it did nothing wrong and emphasized that children with meningitis have a high fatality rate.

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"It is indeed regrettable that, more than a decade after the meningitis epidemic in Kano, the Nigerian government has taken legal action against Pfizer and others for an effort that provided significant benefit to some of Nigeria's youngest citizens," the statement said.

"Pfizer continues to emphasize -- in the strongest terms -- that the 1996 Trovan clinical study was conducted with the full knowledge of the Nigerian government and in a responsible and ethical way consistent with the company's abiding commitment to patient safety. Any allegations in these lawsuits to the contrary are simply untrue -- they weren't valid when they were first raised years ago and they're not valid today."

The criminal charges also name Pfizer's Nigerian subsidiary and eight current or former executives and researchers. The charges could result in fines and prison sentences ranging from six months to seven years per count, according to Aliyu Umar, who served as Kano attorney general until earlier this month.

Umar said he filed the charges with the backing of federal and state authorities. He said it took 11 years to bring the action because officials only learned details in recent years, through a series of investigative reports in *The Post*. Three months ago, Umar's office obtained a six-year-old Nigerian government report that concluded Pfizer's actions violated international law.

"We realize we are the Third World and we need assistance," Umar said. "But we frown on people who think they can take advantage of us, especially if it's for profit. That's why we decided we needed to take action against Pfizer.

"Those people responsible should be punished, whether in Nigeria or in the [United States](#), for what they did to our people."

Pfizer's drug trial came to public attention in December 2000, when *The Post* published the results of a year-long investigation into pharmaceutical testing in the developing world. Nigerians met the news with street demonstrations and demands for reform.

Nigeria's health minister appointed a panel of experts to look into Pfizer's actions, but its final report was suppressed without explanation. Last year, *The Post* obtained a copy, which revealed that the panel had concluded Pfizer's actions violated Nigerian law, the international Declaration of [Helsinki](#) and the [U.N. Convention on the Rights](#) of the Child.

The panel said Pfizer administered an oral form of Trovan that apparently had never been given to children with meningitis. It said there were no records documenting that Pfizer told the children or their parents that they were part of a drug trial. And it said an approval letter from a Nigerian ethics committee, which Pfizer used to justify its actions, was a sham concocted long after the trial ended.

"The families of the children who [Pfizer] used as laboratory guinea pigs were led to believe and in fact understood that the Defendants were providing their children with volunteer relief, clearly focused humanitarian medical intervention and nothing more," the lawsuit says.

Parents were not told that alternative treatments were available, it adds.

The suit charges that parents were barred from Pfizer's ward and that the company's own lab tests had shown Trovan's life-threatening side effects. Researchers allegedly administered the comparison drug, Rocephin, in dangerously low doses to make Trovan look more effective.

The lawsuit contends that Pfizer researchers left the area during the epidemic, took all medical records and "obliterated any evidence" of the trial.

"Defendant's illegal conduct was deliberate and solely motivated by financial considerations," it says.

Every surviving child suffered one or more disabilities, the lawsuit says, adding that the state of Kano has incurred major costs caring for the children and otherwise dealing with the drug trial 's repercussions.

In its statement, Pfizer said the drug was in late-stage development and had been tested on 5,000 patients in a number of countries. "Pfizer's doctors had solid scientific evidence that it would provide a safe and effective treatment against the deadly disease," the statement said. The treatment "indisputably helped save the lives of almost 200 children," the company said.

The [U.S. Food and Drug Administration](#) never approved Trovan for use in treating American children. After being cleared for adult use in 1997, the drug quickly became one of the most prescribed antibiotics in the United States. But Trovan was later associated with reports of liver damage and deaths, leading the FDA to restrict its use in 1999. It remains available in the United States, but European regulators have banned it.

*Research editor Alice Crites contributed to this report.*

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