

Joe Stephens, *Panel Faults Pfizer in '96 Clinical Trial In Nigeria; Unapproved Drug Tested on Children*, Washington Post, May 7, 2006

A panel of Nigerian medical experts has concluded that Pfizer Inc. violated international law during a 1996 epidemic by testing an unapproved drug on children with brain infections at a field hospital.

That finding is detailed in a lengthy Nigerian government report that has remained unreleased for five years, despite inquiries from the children's attorneys and from the media. The Washington Post recently obtained a copy of the confidential report, which is attracting congressional interest. It was provided by a source who asked to remain anonymous because of personal safety concerns.

The report concludes that Pfizer never obtained authorization from the Nigerian government to give the unproven drug to nearly 100 children and infants. Pfizer selected the patients at a field hospital in the city of Kano, where the children had been taken to be treated for an often deadly strain of meningitis. At the time, Doctors Without Borders was dispensing approved antibiotics at the hospital.

Pfizer's experiment was "an illegal trial of an unregistered drug," the Nigerian panel concluded, and a "clear case of exploitation of the ignorant."

The test came to public attention in December 2000, when The Post published the results of a year-long investigation into overseas pharmaceutical testing. The news was met in Nigeria with street demonstrations, lawsuits and demands for reform.

Pfizer contended that its researchers traveled to Kano with a purely philanthropic motive, to help fight the epidemic, which ultimately killed more than 15,000 Africans. The committee rejected that explanation, pointing out that Pfizer physicians completed their trial and left while "the epidemic was still raging."

The panel said an oral form of Trovan, the Pfizer drug used in the test, had apparently never been given to children with meningitis. There are no records documenting that Pfizer told the children or their parents that they were part of an experiment, it said. An approval letter from a Nigerian ethics committee, which Pfizer used to justify its actions had been concocted and backdated by the company's lead researcher in Kano, the report said.

The panel concluded that the experiment violated Nigerian law, the international Declaration of Helsinki that governs ethical medical research and the U.N. Convention on the Rights of the Child.

Five children died after being treated with the experimental antibiotic and others showed signs of arthritis, although there is no evidence the drug played a part. Six children died while taking a comparison drug.

The panel recommended that Pfizer be "sanctioned appropriately" and directed to issue "an unreserved apology to the government and people of Nigeria." The company should also pay an unspecified amount of restitution, the report said. The panel recommended that Nigeria enact reforms to prevent a recurrence.

Aspects of the affair remain mysterious, such as why the report remains confidential. The head of the investigative panel, Abdulsalami Nasidi, said in a brief telephone conversation from Nigeria, "I don't really know myself" why the report was never released.

“I did my job as a civil servant,” said Nasidi, who is quoted in the report as saying he has been the target of unspecified death threats.

A New York City attorney for the families of the children, Elaine Kusel of Milberg Weiss Bershad & Schulman, said her firm had spent years looking for the report, of which they believed there were only three copies. They tracked one to a Nigerian government safe, but it was reported stolen, she said. Another copy was reported to have been held by an official who died.

“It sounds like a mystery novel here, like John le Carré,” Kusel said.

The current Nigerian health minister, Eytayo Lambo, did not respond to calls and e-mail messages from a reporter. Dora Akunyili, director of the Nigerian drug control agency, said she did not know why the report remained confidential but added that her agency had independently concluded that “these people did not have authority to conduct the trial.”

Executives at Pfizer, the world’s biggest drug company, said they had not seen the report. After reviewing a copy, they responded in a two-page statement:

“The Nigerian government has neither contacted Pfizer about any of the committee’s findings nor are we aware that the committee has approved a final report. Therefore it would be inappropriate for the company to respond to specific points in the document.

“However, as we have stated repeatedly over the past several years, Pfizer conducted this trial with the full knowledge of the Nigerian government and in a responsible way consistent with Nigerian law and Pfizer’s abiding commitment to patient safety.”

Pfizer said it had previously tested the drug in thousands of patients and found it effective. Local nurses explained the experiment to Nigerian parents, it added, and obtained their “verbal” consent. The company said that Trovan demonstrated the highest survival rate of any treatment at the hospital.

“Trovan unquestionably saved lives, and Pfizer strongly disagrees with any suggestion that the company conducted its study in an unethical manner,” the statement said.

At the time of the Nigerian experiment, Pfizer was developing Trovan for release in the United States, where it was expected to gross up to \$1 billion a year.

The FDA 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 severely restrict its use in 1999. European regulators banned the drug.

After The Post published its report, Nigeria’s health minister at the time, Tim Menakaya, appointed a blue-ribbon panel of medical experts to look into Pfizer’s actions, saying, “Let me assure you that my ministry will take all necessary steps to obtain details of this incident and make them known to the general public.” The committee collected hundreds of documents and interviewed at least 26 people.

Pfizer had told authorities that a Nigerian doctor directed the experiment. The committee, however, found that researchers from Pfizer’s U.S. office controlled the trial, and the inexperienced Kano doctor, Abdulhamid Isa Dutse, was the principal investigator “only by name.”

Publications listed Dutse as the lead author of articles on Trovan, but the committee found that depiction “did not sufficiently reflect his role.” Dutse indicated he was kept in the dark about the experiment’s results and said he did not see at least one publication until the committee showed it to him.

“He was shocked that Pfizer could publish such data without showing him or intimating him with details,” the report said, concluding that Dutse was “naive and exploited.”

The report quoted Dutse as saying that Pfizer’s motive was far from philanthropic.

“I have trusted people and am disappointed,” Dutse told the committee. “I regret this whole exercise, I wonder why on earth I did this.”

Dutse admitted that he created a letter after the experiment purporting to show that the test had been approved in advance by a Nigerian hospital’s ethics committee. He then backdated the letter to March 28, 1996 -- a week before Pfizer’s experiment began.

Pfizer used the letter as a key justification for the trial in discussions with reporters and submitted it to the FDA. U.S. regulations require the sponsors of foreign medical research seeking FDA approval to show that the tests have been reviewed in advance by an ethics committee.

The Post previously reported that the hospital had no ethics committee in March 1996 and that the letterhead stationery used was not created until months after the experiment’s conclusion.

In a statement last week, Pfizer said that after that article appeared, the company investigated and found that the letter was “incorrect.”

“Obviously this should not have occurred and the company very much regrets that it did,” the statement said. “It is important to point out, though, that Pfizer thought proper procedure had been followed at the time of the clinical study.”

The former director of Nigeria’s version of the FDA said the agency had been unaware of the experiment. He told the panel that he “viewed the conduct of the trial by Pfizer as an act of deception and misuse of privilege.”

The report said the treatment of two children during the experiment represented unspecified “serious deviations” from the trial’s protocol and concluded that those deviations compromised their care. One was a 10-year-old girl identified only as Patient No. 0069, who was given the experimental antibiotic for three days as her condition deteriorated. She died without receiving any other antibiotic.

Last week, Rep. Tom Lantos of California, the senior Democrat on the International Relations Committee, described the report’s findings as “absolutely appalling” and called on Pfizer to open its records.

“I think it borders on the criminal that the large pharmaceutical companies, both here and in Europe, are using these poor, illiterate and uninformed people as guinea pigs,” Lantos said.

Lantos said he expected to introduce a bill requiring U.S. researchers to give regulators details of tests they plan in developing countries.

“It’s the only ethical thing to do,” Lantos said. The bill is similar to one his committee approved in 2001 that did not make it out of the House. “There should be a lot of bipartisan support for it. This outrages people.”

The report's findings also breathe new life into a lawsuit against Pfizer, according to Kusel, who represents 30 Nigerian families. "It's great news, I'm very excited," she said when told of the committee's conclusions.

The families sued Pfizer in federal court in New York in 2001, alleging that the company had exposed the children to "cruel, inhuman and degrading treatment."

A U.S. judge dismissed the suit last summer, saying U.S. courts lacked jurisdiction. Kusel is appealing.

"A report like this does not get suppressed without someone high up being involved," she said.