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## Nigeria files criminal charges against Pfizer

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Officials in Nigeria have filed criminal and civil charges against Pfizer for its role in the deaths and disabilities of children who were treated with an experimental drug during a meningitis outbreak in Kano in 1996.

The charges, filed by government prosecutors in Nigeria, follow three attempts by families of the children to sue in US courts. All three attempts were denied after Pfizer successfully argued that the US courts were not an appropriate forum.

Four separate legal actions have been filed in Nigeria, including 31 criminal counts against 10 people, according to the *Washington Post* ([www.washingtonpost.com](http://www.washingtonpost.com), 2 Jun, “Pfizer faces new charges over Nigerian drug test”). The plaintiffs also seek a total of \$9bn (£4.5bn; €7bn) in civil suits.

The charges stem from Pfizer's test of its unlicensed drug, trovafloxacin (Trovan) to treat 100 children with meningitis. A comparator group of 100 children were treated with a low dose of ceftriaxone. Suits on appeal in US courts charge Pfizer with causing harm to the children in both arms of the trial, alleging that a number of the children either died or were left deaf, mute, or brain damaged.

The families allege that the company failed to tell them that their children were being enrolled in an experimental drug trial and that free, effective treatment was available from MÃ©decins Sans FrontiÃ©res at the same hospital. Five children in the trovafloxacin arm and six in the ceftriaxone arm died, according to Pfizer.

Pfizer issued a statement in response to the charges, saying “Pfizer continues to emphasise—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.”

Pfizer acknowledged to the *BMJ* that it used a low dose of ceftriaxone—33 mg/kg. When asked why a low dose was chosen, Pfizer's spokesperson, Bryant Haskins said that full dose shots were too “painful” for the children and made it hard for them to walk.

The US Food and Drug Administration responded to inquiries by the *BMJ* about whether the agency approved the unusually low dose of ceftriaxone saying, “Agency policy prohibits us from commenting on clinical trial correspondence between FDA and industry. Usually, such information concerning trial

details are submitted to FDA in the form of a protocol, as a part of an IND (investigational new drug) application. This information is not public.”

The FDA spokesperson acknowledged that the recommended daily dose of ceftriaxone for the treatment of meningitis is 100 mg/kg.

Curt Furberg, professor of public health science at Wake Forest University School of Medicine, observed, “This is very typical of comparative trials sponsored by industry. What many of the trials do is to use a suboptimal dose of the comparator so the test drug comes out looking good. It's possible that if they used an optimal dose [of ceftriaxone] that Trovan might have come out the loser,” said Professor Furberg.

Trovafloxacin was never approved by the FDA to treat meningitis. In June 1999 the FDA issued a warning that use of the drug could lead to serious liver toxicity and death and recommended that its use should be limited to institutionalised patients with serious infections.

The Nigerian charges are widely seen as part of a backlash against multinational drug companies. State prosecutor Aliyu Umar told the *WashingtonPost*, “We realise we are the third world and we need assistance. 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.”

Umar, according to the *WashingtonPost*, said in the court documents that the polio vaccine boycott in Kano was a “direct consequence of the 1996 actions” of Pfizer. Articles and editorials in the Nigerian press also allege that reaction against the Pfizer study was so fierce that parents have become fearful of vaccine efforts.

Abdulhamid Isa Dutse, the Nigerian principal investigator, told a Nigerian government inquiry panel in 2001 that he was misled about the nature of the study, saying, “I have trusted people and am disappointed,” adding, “I regret this whole exercise.”

The Nigerian government commissioned a report on the conduct of the study, which was concluded in 2001, but it was kept secret until it was leaked anonymously to the *Washington Post* in May 2006. The report concluded that Pfizer's conduct was illegal (*BMJ* 2006;332:1233 doi: [10.1136/bmj.332.7552.1233-a](https://doi.org/10.1136/bmj.332.7552.1233-a)).