

Pfizer Experiment Spurs Criminal Probe

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Federal regulators have opened a criminal inquiry into alleged improprieties in a 1996 medical experiment that Pfizer Inc. researchers conducted on perilously ill children in Nigeria, according to a source close to the investigation.

Martha B. Hughes, a special agent with the U.S. Food and Drug Administration's Office of Criminal Investigation, reportedly has been collecting information about Pfizer's trial of a then-unapproved antibiotic, known as Trovan. FDA criminal investigators develop cases and, when warranted, refer them to U.S. attorneys for possible prosecution.

The Nigerian experiment was first detailed in a Washington Post series last year that examined the rapid increase in the exportation of American drug trials to the developing world. Last week, lawyers filed a lawsuit in New York on behalf of 30 Nigerian families, charging that their children were unwitting participants in the "secret testing" and suffered injuries ranging from brain damage and paralysis to death.

The suit contends Pfizer's methods violated FDA regulations and international laws and that the researchers' actions constituted torture and inhuman punishment.

The lawsuit alleges that Pfizer used a falsified document to assure the FDA that the clinical trial, conducted at a squalid epidemic camp, had been approved by a Nigerian ethics committee. It also said Pfizer tested the children, some as young as a few months old, without getting the consent of parents or telling them alternative treatment was available.

A class action lawsuit pending in Nigeria levels similar charges and, according to media accounts there, has sparked street protests by as many as 2,000 Nigerians. The Nigerian government also is investigating.

Contacted Friday, Hughes referred a reporter to an FDA spokesman, who said that as a matter of practice the FDA does not confirm or deny the existence of investigations.

A Pfizer spokesman did not respond to a reporter's inquiry yesterday. Earlier, however, Pfizer said in a prepared release that its experiment was "well conceived, well executed and saved lives. The study was conducted with approval of the Nigerian federal and state governments and with consent from the families of treated patients."

Many U.S. companies are exporting their human medical experiments to the Third World, where costs are lower and regulations are lax. During the 1996 meningitis epidemic, Pfizer researchers hurriedly assembled a Trovan experiment in a sub-Saharan medical camp in Kano, Nigeria. Over two weeks, Pfizer researchers gave 100 children Trovan and another 100 children a comparison drug.

Eleven of the children died, and others suffered deafness, lameness and other permanent injuries. Pfizer has said none of the problems were related to its experiment.

In January, the Nigerian doctor who oversaw the experiment for Pfizer said in an interview that a key ethics approval document was created as long as a year after the trial concluded, and then backdated so it would appear to have been issued before the experiment began.

Trovan was never approved for sale to children in the United States. Shortly after its marketing release for adults, Trovan was associated with fatal liver failures and its use was severely restricted. The European Union banned Trovan altogether.

Earlier this year, the U.S. Department of Health and Human Services created an office to oversee experiments conducted on foreign patients by U.S. researchers. A presidential panel recently urged additional safeguards to prevent U.S. researchers from unethically testing medicines in developing nations.

In August, a House committee passed legislation that would bring foreign drug trials under tighter regulation, and bar U.S. researchers from shipping experimental medicines to developing nations unless they first provided U.S. regulators with details of their planned human experiments.

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