

Nigeria files new lawsuit against Pfizer

By BASHIR ADIGUN, Associated Press WriterFri Jul 20, 2:01 PM ET

Government lawyers filed a new \$7 billion civil lawsuit Friday against Pfizer Inc., adding a more serious fraud charge to their allegations that the U.S. drug maker did not properly obtain consent from families while testing an experimental drug on their children.

The government has accused Pfizer of taking advantage of a 1996 meningitis epidemic to test an experimental drug without authorization or the full understanding of the families involved — allegedly contributing to the deaths of some of the children and sickening others. Pfizer denies wrongdoing.

Government lawyer Babatunde Irukera said lawyers recently discovered material that suggested Pfizer committed fraud by bypassing company rules on obtaining consent from families. Based on that, they withdrew their original suit Friday and hours later filed a new one.

He said the new suit also clarifies some of the government's original arguments.

"Some of the materials we needed to establish that Pfizer was fraudulent only came out after we filed the suit," he said. Irukera said the earlier suit only levied a softer charge of "fraudulent representation."

The civil case is in addition to a federal criminal case and separate from civil and criminal cases launched at the state level in the northern state of Kano. All the cases stem from the same mid-1990s drug study in Kano's main city, also called Kano.

Pfizer treated 100 meningitis-infected children with an experimental antibiotic, Trovan. Another 100 children, who were control patients in the study, received an approved antibiotic, ceftriaxone — but the dose was lower than recommended, the families' lawyers alleged.

Eleven children died — five of those on Trovan and six in the control group, while others suffered physical disabilities and brain damage. Pfizer has always insisted its records show none of the deaths was linked to Trovan or substandard treatment, noting that the study showed a better survival rate for the patients on Trovan than those on the standard drug. Meningitis survivors sometimes sustain brain damage or other complications from the disease.

Pfizer, in a statement, said it is aware the federal civil case was withdrawn but has yet to receive a new complaint. The company also said it filed a "statement of defense" in the Kano state civil case, providing responses to allegations raised in both the state and federal cases.

"We stand by our previous statements on this issue," Pfizer said. "The Trovan study was approved in advance by the federal government of Nigeria, it was conducted in an ethical and appropriate manner, and it helped save lives. To our knowledge there is no additional information in the case. Any purported new facts more than 11 years after the study was conducted are simply rehashed allegations dressed up differently, and equally without merit."

Authorities in Kano state are blaming the Pfizer controversy for widespread suspicion of government public health policies, particularly the global effort to vaccinate children against polio.

Islamic leaders in largely Muslim Kano have seized on the Pfizer controversy as evidence of a U.S.-led conspiracy. Rumors that polio vaccines spread AIDS or infertility spurred Kano and another heavily Muslim state, Zamfara, to boycott a polio vaccination campaign.

Vaccination programs restarted in Nigeria in 2004, after an 11-month boycott, but the delay set back global eradication programs. The boycott was blamed for causing an outbreak that spread polio across Africa and into the Middle East.