

Pfizer vs. nigerian families: reality is more miserable than plot of fiction

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Medical experiments on children. Inhumane tests by a large American pharmaceutical company on a third world country. Sounds like the plot of a novel? It was.

The book is called “ The Constant Gardener.” and a movie of the same name followed in 2005. Nonetheless, the plots in both the novel and the movie were based on reality, on a case in which the pharmaceutical giant corporation Pfizer tested an illegal drug on Nigerian children and caused the deaths of 11 local kids. After the tragedy happened, Pfizer officially claimed that “ Pfizer stands by the results of the Trovan clinical trial, which was conducted with the approval of the Nigerian government, the informed consent of the study’s participants, and consistent with all applicable laws.

The results of the study in Nigeria demonstrated that Trovan helped save children’s lives.” “[1] However, with further investigation we discover that the claim made by Pfizer is invalid. The company didn’t receive the approval of the Nigerian government nor consent of the Nigerian families. Nor did the treatment obey relevant laws. The treatment conducted by the corporation on local children was illegal, inhumane, and unjustifiable.

Through the rest of this expose, I would like to disclose the hidden facts of the trial and give a further explanation of the three aspects mentioned above. Introduction of the Trovan Trial In 1996, during a meningitis outbreak in Nigeria, Pfizer tested a drug, Trovan, on children there. About 11 kids died. According to The Washington Post: “ Trovan was never approved for use by American children. The Food and Drug Administration approved it for adults

in 1998 but later severely restricted its use after reports of liver failure. The European Union banned the drug in 1999.

“[2] After the tragedy occurred, Rabi Abdullahi, the natural guardian and personal representative of her daughter Lubabatau Abdullahi, represented the families who suffered from the Trovan trial and sued Pfizer for making illegal experiment on the innocent Nigerian children. According to the court record, Plaintiffs, which were the Nigerian families, allege that instead of using safe and effective treatments, Pfizer embarked on a medical experiment involving the “ new, untested and unproven” antibiotic, trovaflozacin mesylate, better known by its brand name, Trovan.[3] Pfizer treated children ranging in age from one to thirteen years who exhibited symptoms of neck stiffness, joint stiffness and high fevers with headaches and divided them into two groups. One group was treated with Trovan, while the other was “ purposefully ‘ low-dosed”” with ceftriaxone, an FDA-approved drug shown to be effective in treating meningitis. To enhance the comparative results of Trovan, Pfizer administered only a third of ceftriaxone’s recommended dosage.

[4] After two weeks of testing, Pfizer’s team left Kano and never returned for follow-up evaluations. Five children who received Trovan and six children who were “ low-dosed” with ceftriaxone died, while others suffered paralysis, deafness and blindness. Approval of Nigerian Governments To conduct a medical experiment on people, especially on children, the Nigerian families contend that Pfizer engaged in “ bribery of judicial or law enforcement officials”: [W]hen Pfizer conducted the Trovan testing in Kano, a Pfizer

employee in Kano, Mike Dunn, suddenly contacted Pfizer headquarters and informed Dr. Scott Hopkins's secretary that the Nigerian government had halted the testing. According to Dr.

[Juan] Walterspiel, who in 1996 was a pediatric research physician in Pfizer's Groton, Conn., facility but was later dismissed by Pfizer, Dunn stated that it was imperative that Pfizer immediately supply him with cash, or else he and other members of the Pfizer team would go to jail. Ultimately, no Pfizer employees were jailed and the tests continued. The ex-employee of Pfizer, Juan Walterspiel, further confirmed that the company bribed the Nigerian government to continue the study of Trovan. According to the letter written by Walterspiel, the company put a courier on a KLM flight to Nigeria carrying bribes for local officials.

The letter also included 40 Pfizer executives, FDA officials as well as other witnesses who "allegedly have inside knowledge of the scandal". [5] In his letter, Walterspiel alleged that "a courier with cash was dispatched by intervention of (9) via KLM through Amsterdam. The study resumed about three days later." [6] According to Walterspiel's letter[7], Pfizer had not obtained the proper ethics committee approvals before the test began, since research on human subjects usually requires approval of an independent institutional review board before it can start. So the paperwork was faked: "(12) either by accident or not, placed a fax from (13) to (14) on (15's) desk.

The fax implored (14) to urgently send him an ethics committee approval from Kano. A falsified document was then presented to FDA inspector (11). (15), concerned about the imminent FDA inspection and Pfizer instructions to

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be truthful with answers to the FDA as well as to observe any orders and objections from a Pfizer representative who would be present, consulted a labor law attorney in CT. He was afraid to be forced to lie or be dismissed by Pfizer. He was advised to store a copy of the document.

Pfizer did not provide (15)'s name, labeling her/him as "not involved" to the inspector now, and it later lawsuits. (15) was not questioned but then personally debriefed by (16) saying, that the inspection found only minor infractions and was benign. " Consent of Study Participants In addition to the approval of local government, Pfizer also has to make sure parents of test participants allow the experiment to be tested on their children. On the Trovan trial, however, Pfizer failed to obtain consent from parents of the tested children. According to Rabi Abdullahi, mother of Lubabatau Abdullahi who is a victim in the Trovan trial, " Pfizer failed to explain to the children's parents that the proposed treatment was experimental, that they could refuse it, or that other organizations offered more conventional treatments at the same site free of charge." [8] The children's parents allege that despite knowing that Trovan could cause serious joint and liver damage, Pfizer failed to inform them of that risk or seek their informed consent, and neglected to evaluate the subjects subsequent to their treatment.

[9] Even considering the issue with common sense, we could easily figure out the real response of the parents. No parent would like to allow for his or her child to be a subject of a medical test, especially when the child's life is being threatened by a deadly infection. Therefore, no matter from what aspect, Pfizer's claim that it had the parents' consent for the trial was a lie

which could not be backed up by actual evidence. Consistent With All Applicable Laws Last but not the least, the experiment should comply with relevant laws which are based on all types of research, especially medical one. Nonetheless, Pfizer flagrantly treaded on laws in the case of Trovan trial. Pfizer violated international law, specifically, the Nuremberg Code, the Declaration of Helsinki, the guidelines authored by the Council for International Organizations of Medical Services (“ CIOMS”), article 7 of the ICCPR, the Universal Declaration of Human Rights and FDA regulations.

[10] Results Pfizer has attempted to make up its bad deeds by making payments of \$175, 000 to each of the four families which suffered from the Trovan trial. But one parent, who lost a daughter and did not wish to be named for legal reasons, said the process was still dogged by local factionalism and he had no idea when he would receive money. “ I talked to my attorney this week,” said the man, “ They are still in contact with Pfizer as to when I will get paid. We are just crossing our fingers.” [11] He added: “ We are fed up with this case. Our children are dead and some are maimed.

We want to end this matter now, but some people are being opportunist for riches.” [12] Conclusion The Trovan Trial conducted by Pfizer was eventually proved to lack official approval from the local government, the parents of the victims, and international laws. Unlike in the book *The Constant Gardener*, the pain brought by the experiment in reality was real and eternal. Even if the local families receive financial compensation after a 15-year legal battle over the drug trial, the damage they suffered was far beyond money. Their children died of the drug would never come back.

To curb such tragedies from occurring, flaws in the supervision treatments and national legal system should be carefully checked and corrected by the government. Moreover, anti-corruption mechanism should be further improved to prevent unfair practices, and illegal bribery in and out of the courts. References [1] By JIM EDWARDS. Pfizer Bribed Nigerian Officials in Fatal Drug Trial, Ex-Employee Claims. Retrieved February 9, 2011 [2] By JIM EDWARDS. Claim: LeCarre's "The Constant Gardener" Was Based on Pfizer Trovan Case.

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