Nigeria brings criminal charges against Pfizer over 1996 drug test

Robert Milkowski
4 June 2007

Nigerian government officials last week brought criminal charges against the Pfizer Pharmaceutical Company for the drug giant's role in the deaths of children who were treated with an unapproved drug during a meningitis epidemic.

This is the first time the Nigerian government has taken action concerning the tragedy. Numerous attempts by the relatives of the victims have been shot down in US courts. But, more than a decade after this tragic incident, there is growing public awareness and outcry over the greedy, unethical and often criminal conduct of multi-national drug companies.

According to a recent *Washington Post* article, "authorities in Kano, the country's largest state, filed eight charges related to the 1996 clinical trial, including counts of criminal conspiracy and voluntarily causing grievous harm. They also filed a civil lawsuit seeking more than $2 billion in damages and restitution from Pfizer, the world's largest drug company."

In addition to the multinational drug firm itself, the criminal indictment charges Pfizer's Nigerian subsidiary and eight current or former executives and researchers. If convicted those named could face up to seven years in prison.

Aliyu Umar, the Kano attorney general who filed the charges, said that the prosecution had the backing of the Nigerian government, which provided him with a six-year-old report concluding that Pfizer's conduct was in violation of both Nigerian and international law. The Nigerian government said that it never gave the corporation permission to dispense the untested drug.

"We realize we are the Third World and we need assistance," Umar told the *Post*. "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."

A description of the 1996 Nigerian event from the perspective of the plaintiffs who tried and failed several times over the years to bring civil charges against Pfizer is harrowing in its detail.

Not long after epidemics of bacterial meningitis, measles and cholera broke out in Kano, Nigeria, Pfizer established a treatment center at the Infectious Disease Hospital in Kano to treat meningitis victims. According to the indictment Pfizer, instead of using safe and effective bacterial meningitis treatments, seized upon the epidemic as an opportunity to conduct biomedical research experiments on Nigerian children involving the company's "new, untested and unproven" antibiotic, Trovan.

Pfizer is charged with failing 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. In addition, plaintiffs assert that half of the children who participated in Pfizer's treatment program were deliberately given inadequate doses of ceftriaxone—an FDA-approved drug shown to be effective in treating meningitis—so that Trovan would look more effective by comparison. Five of the children who received Trovan and six of the children who were "low-dosed" with ceftriaxone died and others treated by Pfizer suffered very serious injuries, including paralysis, deafness and blindness.

One of Pfizer's own researchers, child disease specialist Dr. Juan Walterspiel, protested in a letter to the company warning that it was improper to test a drug that had "not been tested for its sensitivity before the first child was exposed to a live-or-die experiment." He was fired by the company for speaking out and subsequently won a settlement in a wrongful dismissal lawsuit.

After the Pfizer test, suspicions ran so high in Kano about the potentially deadly practices of big drug companies that parents last year refused polio immunization for their children, fearing the worst. The program was meant to wipe out the disease in Nigeria, one of its last strongholds.

Pfizer's response to the case was predictable. The company "continues to emphasize—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."

But it is indisputable that Pfizer was in Nigeria to test drugs. Their activities there were driven by the profit motive. If they saved lives, it was a side result. It would provide them with a touching human interest story to tell at their next leadership conference in order to enable their managers to continue to delude themselves that at heart they are really there to help heal the world—and make a profit! Doctors without Borders, on the other hand, was set up outside at the same pathetically impoverished clinic. It was not treating patients with a new, unproven drug and also dispensing a competitor's drug (in less than adequate doses no less) in order to do comparisons. They were merely there to try to save lives.

An in-depth *Washington Post* investigative story in December 2000, inspired in part by the Nigerian tragedy, uncovered the vast use of unregulated corporate drug experiments in the oppressed countries of Africa and Latin America as well as in Eastern Europe. It revealed a "poorly regulated testing system that is dominated by private interests that far too often betrays its promises to patients and consumers."

"Experiments involving risky drugs proceed with little independent oversight. Impoverished, poorly educated patients are sometimes tested without understanding that they are guinea pigs. And pledges of quality medical care sometimes prove fatally hollow," the *Post* found.

"Drug makers hop borders with scant government review. Largely uninspected by the Food and Drug Administration—which has limited authority and few resources to police experiments overseas—US-based drug companies are paying doctors to test thousands of human subjects in the Third World and Eastern Europe."

It was the 2000 *Post* article, spelling out the enormity of the problem of drug companies' avaricious drive to test the potentially next best-selling drug, that led Aliyu Umar to initiate the legal prosecution in Nigeria. But it was the corruption of the Nigerian courts that led the children's parents to pursue their case in the US in 1997. So it is far from certain that there will be any justice for these impoverished villagers this time around either.

The political power of the big pharmaceuticals in the US itself has served to protect their activities. When California's Democratic Representative Tom Lantos, in response at least in part to the Nigerian case, introduced a bill called "Safe Overseas Human Testing Act," which would have supposedly demanded that companies provide US authorities with details of planned overseas drug tests and get approval from an ethics committee for the research, the legislation found only one co-sponsor and quietly died in committee at the end of the 2006 congressional session.

Public awareness of—and outrage over—the practices of the big pharmaceutical corporations in the oppressed countries has grow in part as a result of the success of John le Carré's novel and the 2006 film *The Constant Gardener*. The popular Cold War spy novelist's fictional account of a young woman who is murdered when she uncovers crimes committed by a drug company testing a new tuberculosis vaccine in Kenya is based in large part on the Nigerian tragedy. In "Criminals of Capitalism," an article he published just before the release of his novel, le Carré condemned "the conviction that, whatever profit-driven corporations do in the short term, they are ultimately motivated by ethical concerns, and their influence on the world is therefore beneficial, and so God help us all."

In the meantime, Pfizer reported late last year that its third-quarter earnings had more than doubled from a year earlier. The drug giant's former CEO, Henry McKinnell, retired last year with a compensation package worth $200 million. He was the company's executive vice president and chief financial officer at the time that 11 children died while unwittingly participating in the Trovan test in Nigeria.