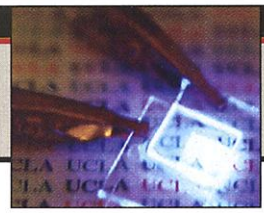

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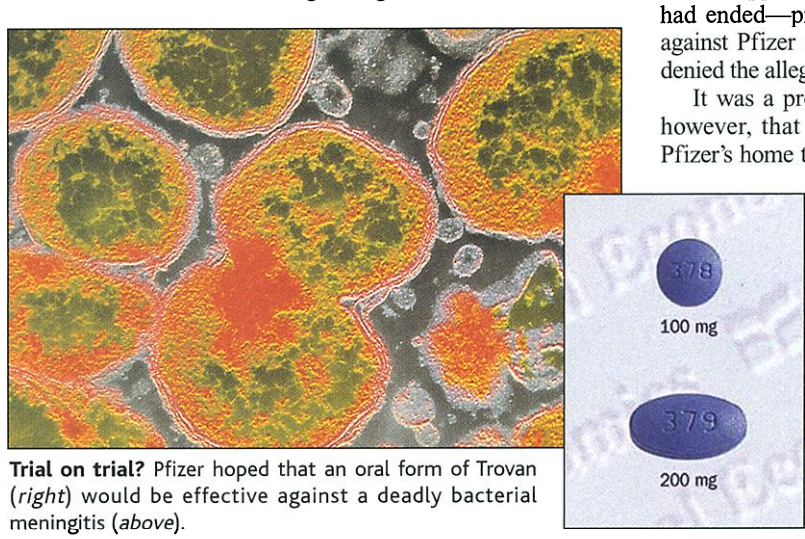
HUMAN RESEARCH

Nigerian Families Sue Pfizer, Testing the Reach of U.S. Law

In a case that could create new liabilities for U.S. research conducted abroad, 30 Nigerian families have sued pharmaceutical giant Pfizer Inc., alleging that the company unethically tested an antibiotic on their children during a 1996 meningitis outbreak. The unusual suit—filed by foreign citizens in a U.S. court under a 210-year-old U.S. law originally designed to combat pirates—seeks to recover unspecified damages from the company for death and serious disabilities.

The complaint, filed on 29 August in a federal district court in New York City, alleges that Pfizer researchers violated international law by failing to obtain informed consent from the families of about 200 Nigerian children, aged 1 to 13, enrolled in a trial that took place at a rudimentary hospital in the northern city of Kano. The study tested the effectiveness of the oral antibiotic Trovan against epidemic meningococcal meningitis, a deadly bacterial infection of the developing world. Eleven of the enrolled children—including both treated and control patients—died, and others became paralyzed or deaf, according to the complaint.



Trial on trial? Pfizer hoped that an oral form of Trovan (*right*) would be effective against a deadly bacterial meningitis (*above*).

The families allege that Pfizer increased the risk of death and injury by failing to provide a proven existing treatment to patients who did not improve after ingesting Trovan, and by giving control patients a weakened version of the standard therapy. "Pfizer took the opportunity presented by the chaos caused by the civil and medical crises in Kano to accomplish what the company could not do elsewhere—to quickly conduct on young children a test of [a] potentially dangerous antibiotic," claims the suit.

The New York City–based Pfizer rejects the charges, saying in a 30 August statement that it is "proud of the way the study was conducted" and that it was "well conceived, well executed, and saved lives." The company says it obtained prior consent from both the Nigerian government and patients' families.

The lawsuit is the latest development in a 5-year-old controversy. According to Pfizer, the idea for the trial arose when Scott Hopkins, a physician working at the company's research center in Groton, Connecticut, noticed an Internet news item about the outbreak of bacterial meningitis, a brain and spinal cord infection that eventually claimed an estimated 15,000 lives in Nigeria. Within 6 weeks, Pfizer had obtained permission from the Nigerian government and the U.S. Food and Drug Administration (FDA) to test the then-experimental oral form of Trovan (the trade name for trovafloxacin) in Kano, where the company already had an outpost.

Hopkins and Pfizer's medical team, composed of both U.S. and Nigerian doctors, gave Trovan in 1996 to about 100 children selected from long lines of patients awaiting help. They administered the proven drug ceftriaxone, manufactured by competitor Hoffmann–La Roche, to an equal number of control patients. Pfizer completed the trial in about 2 weeks and submitted results later to regulatory agencies, seeking approval for a wide variety of uses. (The drug was approved for many adult uses in 1997, but those approvals were sharply curtailed in 1999 due to liver-damaging side effects.)

Even before the trial ended, doctors within and outside Pfizer raised concerns about the study. Juan Walterspiel, a former Pfizer infectious disease specialist, has claimed that he was fired in 1997 after repeatedly warning company officials that the trial was both legally and scientifically flawed. He has filed a wrongful dismissal lawsuit. The same year, Pfizer withdrew its U.S. application to use Trovan against epidemic meningitis in children, in part because an FDA audit had raised questions about the Kano study. Then, last December, *The Washington Post* highlighted the Kano controversy in a high-profile series examining the growing use of overseas drug trials. The press coverage—including allegations that Pfizer gave control patients one-third of the recommended dose of the standard drug, and that Nigerian doctors fabricated trial approval letters years after the study had ended—prompted a flurry of lawsuits against Pfizer in Nigerian courts. Pfizer has denied the allegations.

It was a prominent New York law firm, however, that took the Nigerians' case to Pfizer's home turf, using a novel legal strategy. Lawyers at Milberg Weiss Bershad Hynes & Lerach argue that Pfizer is vulnerable under the 1789 Alien Tort Claims Act, which allows foreign nationals to use U.S. courts to go after individuals and companies that have broken international laws on foreign soil. In this case, the Nigerian families charge that Pfizer has violated ethical research rules, including the Nuremberg Code of 1947.

Created in part to allow ship owners to sue pirates, the law has been used by human rights, labor, and environmental groups to win damages or out-of-court settlements from torturers and corporate miscreants. Now, foreign research subjects have a good chance of being added to the list of those allowed to sue, says Ralph Steinhardt, an alien tort claims expert at George Washington University Law School in Washington, D.C. But it will be at least a year, other lawyers predict, before researchers find out whether the court agrees that the ancient piracy law can be used to press such claims.

–DAVID MALAKOFF

CREDIT: (LEFT) CNRI/PHOTO RESEARCHERS