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Commentary

The Trovan Experiment: Killing Nigerian Children

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[Editor's Note: Zoe Littlepage of Littlepage & Associates in Houston represents plaintiffs injured by defective medical products and drugs. She currently handles cases nationally including Propulsid, Rezulin, phenylpropanolamine (PPA), Sulzer hip implants, Fen-Phen/Redux, Duract and Trovan. Littlepage & Associates currently has Trovan cases for liver damage on file across the country. Littlepage graduated from Rice University and completed her law degree at the University of Houston Law School. Rainey Booth of Levin, Middlebrooks, Thomas, Mitchell, Echsner, Proctor & Papantonio in Pensacola, Fla., limits his practice to mass tort litigation focusing on pharmaceutical cases. He received his B.A. from Washington & Lee University and his J.D. from the University of Florida. Copyright 2001 by the authors. Replies to this commentary are welcome.]

In 1998, Wall Street forecasted that Pfizer would reap profits in excess of $1 billion per year for Trovan, their newly approved powerful antibiotic. Sales were tremendous in the first few months. Then the adverse event reports started pouring in — confirming the drug's serious liver toxicity. Trovan is now "black box" restricted for treatment of only five specific life-or-limb threatening infections or where Trovan therapy starts in an inpatient hospital setting. Sales are minimal and limited to situations that justify that type of medical risk. The blockbuster drug is a bust . . . and new evidence now exposes Pfizer to punitive damages for their conduct during the Trovan clinical trials.

In 1996, an epidemic of meningitis broke out in Nigerian children. Pfizer officials saw a unique opportunity to test their drug without the restrictions of FDA clinical study protocols. Within days, a DC-10 of Trovan and Pfizer researchers arrived in Kano, Nigeria, and set up a clinic within yards of a Doctors Without Borders facility. The Nigerian healthcare professionals in the hospital at Kano were paid almost double their usual salary for participation in the study. Naturally, many signed on to work for Pfizer and abandoned their regular duties at the hospital. For weeks, Pfizer dispensed Trovan to Nigerian children and babies with complete disregard for all scientific research protocols such as:

(a) Trovan had never been tested on children before and Pfizer had no idea whether it would even be effective on epidemic meningitis. Yet it was dispensed to more than a hundred gravely ill children.

(b) Pfizer did not receive written consent from the families of the sick children. Pfizer explains this oversight as due to the language difficulties and illiteracy. However, many families now report that they were not even

aware that the treatment was experimental or that they had the option of getting approved and tested medical care at the Doctors Without Borders facility, just a short step away.

(c) Standard treatment for epidemic meningitis is IV antibiotics. This permits the medication to rapidly enter the body and impact the disease. Pfizer tested oral Trovan on the children in an attempt to prove their hypothesis that oral Trovan had the same potency as IV antibiotics.

(d) Because epidemic meningitis can be quickly fatal in children, physicians change medications within hours if the child does not show any improvement with the original drug. Pfizer researchers kept children on Trovan for days, despite clear signs that the children were getting worse, until the children died.

(e) Trovan is from a category of drugs called quinolones. This class of drugs has been shown to cause joint damage in young animals. Pfizer's own records confirm that more children in the Trovan treated group complained of joint pain than other test groups. However, Pfizer took no medical equipment to Nigeria to monitor for such symptoms.

(f) Trovan is liver toxic. The current package insert requires liver enzyme testing to document the drug's impact on the liver. Pfizer did no blood testing on the children in Nigeria.

(g) After five weeks, Pfizer packed up and went home. Pfizer did no long-term follow up and made no real effort to contact patients who did not return for their scheduled check-ups. Pfizer left Nigeria without any significant information about the final health impact of Trovan on this group of children.

FDA rules require that before foreign country studies begin, an ethical committee in the foreign country must approve the study. Long after the Nigerian epidemic, Pfizer produced a letter to the FDA that purported to be such an ethics board approval. Now, Dr. Abdulhamid Isa Dutse (a Nigerian physician) admits that Pfizer asked him to backdate the ethics approval document for submission to the FDA. According to Dr. Dutse, the letter was written more than a year after Pfizer left Nigeria because Pfizer never obtained approval before the start of the study.

Sadly, among the 200 stricken children enrolled in the experimental testing, 11 died and many others seriously suffered. One child — Patient No. 0069 — was given 56 milligrams of Trovan. The next day, the child's eyes froze in place. Her medication was not changed despite the clear worsening of symptoms. The third day, Pfizer's records indicate that her "Dose continued unchanged" and the outcome was noted as "Death."

When Trovan got FDA approval in the United States, it was not approved for either the treatment of epidemic meningitis or for use on children. Patient No. 0069 died within sight of a Doctors Without Borders mobile hospital that was dispensing accepted meningitis medications. Patient No. 0069 died in vain — not even in the name of science. ■