

Doc Claims Bayer Falsified Cipro Data

By MARIMER MATOS



INDIANAPOLIS (CN) - A doctor claims in court that Bayer got an extension on an exclusive government contract by hiding data that its Cipro antibiotic can cause tendon and cartilage damage in children.

The United States ex rel. Dr. Juan Walterspiel sued Bayer A.G., of Germany, and Quintiles Transnational Corp. under the False Claims Act, in Federal Court.

The complaint states: "The FDA, based on bioterrorism concerns, gave emergency use permission for ciprofloxacin in children for prophylaxis and treatment of pediatric inhalation [of] anthrax in August of 2000.

"This conditional emergency approval was based on a risk/benefit analysis. It states: 'However, because inhalational anthrax is lethal, the risk-benefit assessment indicates that use of Cipro for this indication in pediatric patients is appropriate. Studies are currently under way to evaluate long-term safety, including effects on cartilage, in pediatric patients.' This emergency approval was conditional on further acquisition of reliable cartilage safety data from studies such as the two studies performed by Bayer."

Walterspiel says he worked as an independent contract for Bayer in 2002.

"His contractual obligations were to retrieve from electronic study databases, that were patient identifier free, information on selected adverse events (AE)," the complaint states. "This information was presented by Dr. Walterspiel as short and medically meaningful narratives to Bayer's Independent Pediatric Safety Committee."

Walterspiel claims he has "direct, independent and personal knowledge that the false claims presented by defendant herein were knowingly presented."

Defendant Quintiles collected pediatric data for Bayer "for the two studies at issue in this complaint which Bayer used in support of Bayer's application for a 6-month market exclusivity extension for Cipro," according to the complaint.

Walterspiel says the FDA in 2003 granted Bayer a 6-month extension on its exclusive contract to provide Cipro for anthrax inhalation. In December 2003, Walterspiel says, Bayer got a 6-month market exclusivity for pediatric use of Cipro to treat a urinary tract infection.

He claims Bayer provided falsified data to get the exclusive contracts, and hid Cipro's harmful effects on children.

He says he found data provided in the Cipro study "improbable," and told Bayer's chief clinical research associate that he had "doubts about the integrity of the data."

He claims the first signs of falsification he noticed were "only the tip of the iceberg," and that his doubts "were further increased when (he) noticed a lack of variability from measurement to measurement ... and noticed a lack of an analysis to flag any suspect data".

The complaint states: "The false data and statements submitted by defendants to the FDA, which hid adverse effects of Ciprofloxacin in children, were material to the FDA's decision to approve the six month patent market exclusivity extension for Bayer for Cipro."

Walterspiel claims that "long rows" of data in one study "were obviously just 'filled in.'" These numbers repeated themselves in endless fashion," and some, he says, "were scientifically impossible, i.e., joint angles indicating a range of movement for which the human limbs in question are not capable. ...

"The fraudulent data should have been clearly noticeable to Quintiles Transnational source verification personnel.

"Both Quintiles Transnational and Bayer AG elected to take the option of knowingly submitting the Bayer Cipro pediatric study to the FDA without disclosure of the false and fraudulent data, so as to not jeopardize Bayer's \$0.5 + billion in Cipro sales and Quintiles Transnational's current and future contracts with Bayer and other drug companies."

Walterspiel says Bayer was selling more than \$1.1 billion of Cipro a year before its 6-month extension in December 2003, about 30 percent of it in the United States. About 10 percent of U.S. sales are to the federal government, and states also buy it, Walterspiel says.

Therefore, Walterspiel says, "The loss to the US government from defendant's false claims relating to Cipro during the six month market exclusivity extension is estimated at \$14.85 million.

He claims that Cipro is just the latest in a string of Bayer's ethical breaches.

"Defendant Bayer AG has engaged in a continuing pattern of deception that has led to the avoidable deaths of U.S. citizens, a pattern that combined with the fraud regarding the Cipro market exclusivity extension would support a decision by the U.S. to impose the debarment sanction," the complaint states. "This pattern of misconduct includes the deaths of children from AIDS through Factor VIII (1980s), the deaths of adults from kidney failure through Cerivastatin (2001), and most recently (2008), the deaths of adults from cardiac complications through Aprotinin."

Walterspiel seeks treble damages and costs.

He is represented by Mick Harrison from Bloomington. 

<http://www.courthousenews.com/2012/07/30/48809.htm>