

Glaxo Executive's Memo Suggested Burying Drug Studies (Update4)

By Jef Feeley and Margaret Cronin Fisk

Sept. 15 (Bloomberg) -- An executive of **GlaxoSmithKline Plc**, the world's second-biggest drugmaker, talked about burying negative studies linking its antidepressant drug Paxil to birth defects, according to a company memo introduced at a trial.

"If neg, results can bury," Glaxo executive Bonnie Rossello wrote in a 1997 memo on what the company would do if forced to conduct animal studies on the drug. The memo was read during opening statements in the trial of a lawsuit brought by the family of a child born with heart defects.

The Philadelphia trial is the first of more than 600 cases alleging that London-based Glaxo knew Paxil caused birth defects and hid those risks to pump up profits. The drug, approved for U.S. use in 1992, generated about \$942 million in **sales** last year, 2.1 percent of Glaxo's total revenue.

The family of Lyam Kilker claims Glaxo withheld information from consumers and regulators about the risk of birth defects and failed to properly test Paxil. Kilker's mother, Michelle David, blames Paxil for causing life-threatening heart defects in her 3-year-old son.

Glaxo officials urged scientists to withhold information about Paxil's risks from a paper laying out the company's "core safety philosophy" for the drug, said Sean Tracey, a lawyer for Kilker and David, in his opening statement in the trial.

"They said if there's any doubt, take it out," Tracey told jurors. "They do not want to scare anybody. It's a very competitive marketplace. It's a multibillion-dollar industry."

'Rare Thing'

Glaxo executives contend that the boy's heart defect wasn't caused by Paxil, **Chilton Varner**, one of the company's lawyers, told jurors today in her opening statement. In court filings, Glaxo has said it appropriately tested and marketed the antidepressant drug.

"When Lyam Kilker was born in 2005, GSK had not received notice" of his specific type of heart defect in connection with Paxil use, Varner said. "The numbers will tell you the defect is a rare thing."

The Paxil label at that time reported about animal studies, "including the rate of deaths," she said.

Glaxo didn't target pregnant women and its sales force didn't use strong-arm tactics to push prescriptions, Varner said. "Whatever the marketing was, it played no role in Ms. David's doctors' decision to prescribe Paxil or Ms. David's decision"

to take the drug, she said.

Rat Studies

Glaxo officials purchased the compound sold as Paxil from a Danish company that had done animal studies showing young rats died after taking low doses of the drug, Tracey said in his opening statement.

One of the company's scientists noted in internal documents in 1980 that information in the rat studies suggested Paxil "could be" a cause of birth defects, Tracey said. Still, the drugmaker refused for almost 20 years to do studies on why the young rats died, he added.

Tracey told jurors they would see documents in the trial that the company hadn't turned over to regulators or congressional investigators. "You are going to see docs that have never seen light of day before," he said.

For example, Tracey pointed to a 1998 internal review by Glaxo of all reports of side effects tied to Paxil and officials found "an alarmingly high number" of birth-defect reports. Even with those concerns, the report was never turned over to the U.S. Food and Drug Administration and "the alarming language" was deleted from it, the lawyer said.

In 2001, the company received a letter from a woman who used Paxil during her pregnancy and decided to abort her fetus after tests showed it had birth defects, Tracey said.

Internal Report

In analyzing the woman's case, Glaxo officials concluded in an internal report that it was "almost certain" the fetus's birth defects were caused by his mother's Paxil use, the family's lawyer added. Still, the company didn't turn over its analysis to the FDA or beef up the drug's warning label, Tracey said.

It wasn't until after the FDA ordered Glaxo and other makers of antidepressants in 2003 to do more safety studies on their products that Glaxo officials publicly acknowledged that Paxil increased the risk of birth defects, Tracey said.

The lawyer for David, a college nursing student who was a former cheerleader for the National Basketball Association's Philadelphia 76ers, told jurors that Glaxo hid Paxil's problems to protect its profits.

Paxil is "the No. 1 asset to this day this company has ever owned," the attorney said.

'Quite Different'

Varner said she will present "quite different" evidence on animal tests tied to Paxil.

"The animal testing did not suggest Paxil caused birth defects," Varner said. The FDA considered the tests when it approved the drug for use by U.S. consumers in 1992, she said.

When Glaxo officials considered offering Paxil for sale in Japan, internal records show executives worried in 1994 they might have to do more safety testing on the antidepressant, said Dr. David Healy, an Irish psychiatrist testifying as an expert for Kilker's family in the case.

It may be the "type of study we wish to avoid," Jenny Greenhorn, an official in Glaxo's international regulatory affairs unit, said in a memo.

Glaxo also is fighting suits in the U.S., Canada and the U.K. over claims that Paxil, also known by the generic name paroxetine, causes homicidal and suicidal behavior. The company has settled some suicide claims, though terms of the settlements haven't been released.

New York Settlement

In 2004, the drugmaker agreed to pay the state of New York \$2.5 million to resolve claims that officials suppressed research showing Paxil may increase suicide risk in young people. The settlement also required Glaxo to publicly disclose the studies.

The company's provision for legal and other non-tax disputes as of June 30 was 1.7 billion pounds (\$2.8 billion), the company said in a July 22 regulatory filing that didn't mention the Paxil litigation.

"We do not disclose our legal reserves for any specific litigation matter," Glaxo spokesman **Kevin Colgan** said earlier this month.

Glaxo American depositary receipts, each representing two ordinary shares, fell 68 cents, or 1.7 percent, to \$38.76 in New York Stock Exchange composite trading today. Glaxo fell 14 pence, or 1.2 percent, to 1,175.5 pence in London.

The case is *Kilker v. SmithKline Beecham Corp. dba GlaxoSmithKline*, 2007-001813, Court of Common Pleas, Philadelphia County, Pennsylvania.

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