

## Glaxo Said to Have Paid \$1 Billion in Paxil Suits (Update2)

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By Jef Feeley and Margaret Cronin Fisk

Dec. 14 (Bloomberg) -- **GlaxoSmithKline Plc** has paid almost \$1 billion to resolve lawsuits over Paxil since it introduced the antidepressant in 1993, including about \$390 million for suicides or attempted suicides said to be linked to the drug, according to court records and people familiar with the cases.

As part of the total, Glaxo, the U.K.'s largest drugmaker, so far has paid \$200 million to settle Paxil addiction and birth-defect cases and \$400 million to end antitrust, fraud and design claims, according to the people and court records.

The \$1 billion "would be worse than many people are expecting," said **Navid Malik**, an analyst at Matrix Corporate Capital in London. "I don't think this is within the boundaries of current assumptions for **analysts**."

The London-based company hasn't disclosed the settlement total in company filings. It has made public some accords. Glaxo's provision for legal and other non-tax disputes as of the end of 2008 was 1.9 billion pounds (\$3.09 billion), according to its latest annual report. This included all legal matters, not just Paxil. The company said 112 million pounds of this sum would be "reimbursed by third-party issuers."

The drugmaker has reduced its insurance coverage to contain costs, "accepting a greater degree of uninsured exposure," the annual report states. "Recent insurance loss experience, including pharmaceutical product-liability exposures, has increased the cost of, and narrowed the coverage afforded by, insurance for pharmaceutical companies generally," Glaxo said.

### Glaxo Comment

Glaxo declined to confirm the \$1 billion figure. "Paxil has been on the market in the U.S. since 1993. Like many other pharmaceutical products, it has been the subject of different kinds of litigation over the years," **Sarah Alspach**, a spokeswoman for Glaxo, said in an e-mailed statement. "It would be inappropriate and potentially misleading to aggregate payments in these various types of litigation."

Chief Executive Officer **Andrew Witty** has moved to replace revenue lost to generic versions of drugs such as Paxil. Worldwide, Paxil generated about 514 million pounds in sales last year, or 2.1 percent of the total.

Glaxo rose 21 pence to 1,324 pence in London **trading** after falling 4 pence earlier today. Shares have risen 12 percent in the past year.

About 450 suicide-related Paxil cases were settled. Only about a dozen haven't been, the people said. The \$1 billion total doesn't include more than 600 claims that Paxil caused birth defects.

### Philadelphia Trial

A Philadelphia jury on Oct. 13 found the drugmaker should pay \$2.5 million to the family of Lyam Kilker, a 3-year-old boy born with a heart defect after his mother took Paxil while pregnant. Based on that outcome, an analyst estimated the company may potentially face additional verdicts in birth-defect cases waiting to be tried in Pennsylvania.

"A liability totaling \$1.5 billion is possible," **Savvas Neophytou**, a Panmure Gordon analyst in London, wrote in a note to investors the day after the Kilker verdict. He still recommended buying Glaxo shares because a likely appeal may reduce the amount paid by the company.

In comparison, Pfizer Inc., parent of Wyeth, the maker of diet-drug combination fen-phen, has had to set aside about \$21 billion to resolve about 200,000 personal-injury claims over that medicine. Merck & Co. agreed to pay \$4.85 billion to resolve more than 48,000 claims over the withdrawn painkiller.

**Harris Pogust**, an attorney for Paxil plaintiffs, couldn't confirm the total. He said the amounts are confidential.

#### Paxil Is Different

"Paxil's been different from most drugs," said Pogust, a lawyer from Conshohocken, Pennsylvania, who is handling suicide and withdrawal cases. "You've had three major personal injury litigations over one drug -- the suicide, the birth defect and the withdrawal cases. To have three significant problems with one drug is really unusual."

The company had \$11.7 billion in U.S. Paxil sales for nine years starting in 1997, according to documents made public this year in a Pennsylvania trial. In 2002, the year before Paxil faced generic competition in the U.S., sales of the drug there were \$2.12 billion. Last year, U.S. sales had fallen to \$129 million. Through September of this year, sales were \$52 million, down 52 percent from the same period in 2008.

Since at least 2003, Glaxo has faced claims in U.S. courts that some Paxil users were subjected to an undisclosed, higher risk for suicide and birth defects.

#### A Suicide Settlement

The suicide settlements included a suit over the death of a 14-year-old boy who had been taking Paxil for two months. The parents of Scott Cunningham, of Valparaiso, Indiana, sued after the boy hanged himself in 2001. They alleged Glaxo suppressed evidence that Paxil use was linked to the risk of suicide attempts by adolescents. Glaxo denied the allegations, according to court papers.

The family settled its suit in May, according to court filings. Family attorney **Bijan Esfandiari** confirmed the settlement, saying the amount was confidential.

About 150 cases over suicides by Paxil users were settled for an average of about \$2 million, and about 300 over suicide attempts settled for an average of \$300,000, they said. Some of the claims were resolved before suits were filed, according to the people familiar with the matter.

Glaxo has settled about 10 birth-defect cases, Sean Tracey, a Houston-based lawyer who represented the family of a child victim, said in court Dec. 2. The settlements averaged about \$4 million, the people familiar with the cases said.

#### Unspecified Totals

The company hasn't specified in regulatory filings the number of suicide, birth-defect and addiction cases settled.

"It's important to disclose such settlements because it raises the red flag for both doctors and patients that there might be a problem," said Dan Carlat, a psychiatrist at Tufts University School of Medicine in Boston who writes and edits a **blog** and a monthly **Psychiatry Report**. "It would motivate doctors to dig into the literature even more before prescribing these drugs."

Glaxo paid an average of about \$50,000 per case to resolve about 3,200 claims linking Paxil to addiction problems, the people familiar with the cases said.

In its 2008 annual report, company officials said they had reached a "conditional settlement agreement" in January 2006 with Paxil users who alleged they suffered withdrawal symptoms after taking the drug. The case, filed in Los Angeles federal court, was marked closed in court records in February.

#### No Liability Admission

“Glaxo did not admit liability” in the addiction settlements, the company’s officials said in a March 2009 filing with the U.S. Securities and Exchange Commission.

In one of eight accords unrelated to individual suicide, addiction or birth-defect claims, Glaxo agreed in 2003 to pay \$87.6 million to the U.S. and 49 states over claims it repackaged and privately labeled Paxil and another drug, Flonase, to a health maintenance organization at discounted prices.

Glaxo, denying liability, agreed in 2004 to pay \$165 million to settle two antitrust suits over allegations it engaged in sham patent infringement litigation to stall approval of generic versions of the drug, court records show.

Of that total, \$100 million was for direct purchasers of Paxil, such as drug wholesalers, and \$65 million was for indirect buyers, the records show.

New York

In the same year, Glaxo agreed to pay \$2.5 million to New York to resolve accusations the company withheld safety data about the antidepressant. The company, calling the claims unfounded, agreed to release safety studies on the medicine’s effect on children.

In 2005, the company added a black-box warning to its Paxil label that the drug increased the risk of suicidal thoughts among adolescents, following a request by the U.S. Food and Drug Administration to do so.

The drugmaker agreed last year to pay \$40 million to settle suits by so-called third-party payers, primarily insurance companies that reimbursed parents for their children’s Paxil.

Insurers said Glaxo knew the drug “was neither safe nor effective for the treatment of depression in persons under the age of 18,” U.S. District Judge **Michael Davis** in Minneapolis said in a September 2008 order approving the accord.

Glaxo “denies any liability,” company spokeswoman Alspach said at the time. “GSK has agreed to the settlement to avoid the costs, burdens and uncertainties of ongoing litigation.”

Reimbursing Parents

In 2006, the company resolved similar claims by consumers for about \$64 million, reimbursing parents of patients for money spent on Paxil prescriptions, in an Illinois class-action suit.

Glaxo “denies any liability” in those cases, the company said in its annual report.

In 2001, a jury in Cheyenne, Wyoming, ordered Glaxo to pay \$6.4 million to the relatives of a man who shot his family to death and then turned the gun on himself after taking Paxil. The case was settled on confidential terms while on appeal, according to Kevin Colgan, a Glaxo spokesman.

The Philadelphia case is *Kilker v. SmithKline Beecham Corp. dba GlaxoSmithKline*, 07-001813, Court of Common Pleas, Philadelphia County, Pennsylvania (Philadelphia).

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