

**Guardian**  
UnlimitedFinancial services designed for people  
living and working abroad. **Click here** ▶**HSBC**   
The world's local bank[Sign in](#) | [Register](#)

Go to:

**Guardian**Unlimited **The Guardian**

Home	UK	Business	Online	World dispatch	The Wrap	Weblog	Talk	Search
The Guardian	World	News guide	Arts	Special reports	Columnists	Audio	Help	Quiz



Search this site

## Glaxo faces drug fraud lawsuit

Firm accused of keeping back negative trial results

**David Teather in New York and Sarah Boseley**

**Thursday June 3, 2004**

[The Guardian](#)

Britain's biggest drug company, GlaxoSmithKline, is facing fraud charges in the United States for allegedly concealing information that its leading antidepressant caused suicidal behaviour among children and teenagers during clinical trials.

The civil lawsuit, filed by the combative and popular New York State attorney general Eliot Spitzer, claims that the company suppressed the results of at least four different studies that showed the drug, called Paxil in the US and Seroxat in the UK, at best was no more effective than a placebo and at worst was harmful. At the same time the company was said to be promoting the drug heavily to American doctors boasting of its efficacy and safety.

Mr Spitzer, who has successfully taken on big financial institutions, said the company had "engaged in repeated and persistent fraud".

On both sides of the Atlantic Seroxat has been accused of causing some children and adults to become violent and suicidal. In 2002, more than 2m prescriptions for Paxil were written for American children and adolescents to treat mood disorders and depression, equivalent to \$55m (£32.5m) in sales.

The lawsuit alleges that five studies conducted by GSK between 1998 and 2002 raised serious questions about the efficacy of Paxil and in some cases increased the likelihood of suicidal behaviour.

In two of the studies, Paxil was no more effective than a placebo, or dummy pill, when treating depression in young people. In fact, in one of the studies, the placebo outperformed Paxil. Most worryingly, the incidence of suicidal tendencies doubled among users in three of the trials. In one case, 6.5% of the sample taking Paxil developed suicidal tendencies compared to 1.1% in the placebo group.





In this section

An internal GSK document from 1998, cited in the lawsuit, said the company would have to "effectively manage the dissemination of these data in order to minimise any potential negative impact".

In the UK, public pressure led the drug regulator, the Medicines and Healthcare Regulatory Agency (MHRA) to set up a review of Seroxat and the other antidepressants in its class, which include Prozac.

GSK carried out trials of Seroxat on children from the late 1990s at the request of the American drug regulator, the Food and Drug Administration (FDA).

But the results were kept secret because they showed that the drug had no more effect than a placebo, while there were some worrying side-effects. Of those on Seroxat, 3.2% suffered mood changes including thoughts of suicide, attempted suicide and trying to harm themselves - compared to 1.5% on placebo.

A document revealed in the Guardian earlier this year showed that GSK was determined to bury the bad news as long ago as 1998. An internal strategy document proposed that GSK should not hand the data from two trials to the regulators.

To admit the drug did not work in children would be "commercially unacceptable ... as this would undermine the profile of paroxetine (Seroxat/Paxil)".

The lawsuit says GSK submitted the unpublished results to regulators in 2002, four years after the first negative results appeared, when it hoped to win approval for the treatment of obsessive-compulsive disorder with Paxil.

The MHRA was finally given the full trial data on May 27 last year. Two weeks later it announced it was banning the use of Seroxat in children. Following further investigations by the expert group, every other drug in the SSRI (selective serotonin reuptake inhibitor) class except Prozac has also been banned from use in children.

Shortly after the British authorities took action, the Food and Drug Administration (FDA) in the US also recommended that Paxil not be prescribed for children or adolescents but has so far stopped short of an outright ban.

Mr Spitzer said: "By concealing critically important scientific studies on Paxil, GSK impaired doctors' ability to make the appropriate prescribing decision for their patients and may have jeopardised their health and safety.

David Healy, the consultant psychiatrist who first brought the safety of the SS RIs under scrutiny, said yesterday that the suppression of data in children was matched by the suppression of data in adult trials. "The original data sent to the regulators for this drug showed an eight time greater rate of suicidal acts on paroxetine compared to placebo in adults." Yet the published data suggests there is no difference.

[Fertility clinic planned for lesbian couples](#)

A GSK spokesman said the firm had not had a chance to examine the lawsuit in detail. But he denied there had been a cover-up.

[Naked pictures force closure of gallery](#)

"We have acted responsibly in the conduct of clinical studies in paediatric patients and the dissemination of the results. The paediatric studies have been made available to the FDA and regulatory agencies worldwide."

[Equitable directors snub report](#)

[PCs: the latest waste mountain](#)

He said data had been published in medical journals and presented at scientific conferences.

[Shadow cast over boom in online betting](#)

**Special reports**  
[Medicine and health](#)

[OS maps out the future](#)

**Useful links**

[Footballers to be told charges they face](#)

[British Medical Association](#)  
[Department of Health](#)  
[General Medical Council](#)  
[Health on the Net Foundation](#)  
[Institute of Cancer Research](#)  
[Medical Research Council](#)  
[NHS Direct](#)  
[World Health Organisation](#)

[Test could cut exam stress for 7-year-olds](#)

[Glaxo faces drug fraud lawsuit](#)

[It was 37 years ago today - and Sgt Pepper cover has still failed to pay](#)

---

[Printable version](#) | [Send it to a friend](#) | [Save story](#)

[Met PC wins £500,000 to settle race and sex abuse claim](#)

[Lambeth Palace quashes royal marriage rumours](#)

[Olympic torch songs at Mall concert](#)



[Art market 'a cultural obscenity'](#)

[Greyhound streaks ahead of racehorse](#)

[Convicts flee in search of stricter prison](#)

[Tube strike to hit mayor's election](#)

[Pianist jailed in Sri Lanka  
abuse case](#)

[In brief](#)

[Rejoyce ... Irish MPs save  
festival](#)

[Cover-up alleged over  
Bollywood death](#)

['Anti-white' bias in awards  
coverage](#)

[Inquest hears of Porton gas  
test](#)

[Books of labels are the fruit  
of a strange hobby](#)

[Fear of 'toxins' leads to brain  
drain](#)

[BBC urged to appoint  
complaints monitor](#)

[Man Booker launches  
international prize](#)

[Author takes swipe at  
scientific elite](#)

[Smoke alarm is Britons'  
most popular invention](#)

[Cameras 'block' criminals  
from Bradford city centre](#)

[Airline fraudster jailed](#)

[Boy sees father's suicide](#)

[Falconio suspect 'altered his  
looks'](#)

[Shipman play to be staged  
near inquiry](#)

[BSE outbreak in sheep  
could lead to cull of 25m  
animals](#)

[NHS wins national ban on patient](#)

[Treasures of age of exploration on show](#)

[Back to Normandy, this time by bus](#)

Guardian Unlimited © Guardian Newspapers Limited 2004