

GlaxoSmithKline faces US lawsuit over concealment of trial results

Owen Dyer *London*

The British pharmaceutical giant GlaxoSmithKline (GSK) is facing a major lawsuit in the United States over alleged concealment of negative trial results involving its antidepressant paroxetine (marketed there as Paxil and in Britain as Seroxat).

The civil suit, filed by New York state's attorney general, Eliot Spitzer, charges the drug company with "repeated and persistent fraud" in concealing the results of studies that suggested that paroxetine was ineffective in treating depression in adolescents. It is the first time a US public authority has pursued a drug company for misreporting trial data.

Five studies have attracted particular attention. Two of these showed no benefit from paroxetine compared with

placebo in depressed adolescents. Three showed evidence of an increase in suicidal thoughts and behaviour, though there were no actual suicides.

Mr Spitzer has an internal SmithKline Beecham memo from 1998 which stated that it would be "commercially unacceptable" to admit that paroxetine did not work in children. It went on to say that the company would have to "effectively manage the dissemination of these data in order to minimise any potential negative impact."

The document was published by the journal of the Canadian Medical Association, *CMAJ*, in February and reported in the *BMJ* that month (21 February, p 422).

The negative trial data came out when one of the participat-

ing researchers, Dr Robert Milin, presented results at the 1999 meeting of the American Academy of Child and Adolescent Psychiatry. He said the company did not try to stop him.

In a statement, GSK said: "GlaxoSmithKline has acted responsibly in conducting clinical studies in paediatric patients and disseminating data from those studies. All paediatric studies have been made available to the FDA [US Food and Drug Administration] and regulatory agencies worldwide. We have publicly communicated data from all paediatric studies. As for the 1998 memo, it is inconsistent with the facts and does not reflect the company position."

The company's share price fell sharply last Wednesday when the suit was announced, but recovered somewhat as analysts predicted that potential damages would be unlikely to surpass \$250m (£136m; €203m). Mr Spitzer said off-label prescribing of paroxetine to under 18s had

accounted for about \$55m in sales in the United States in 2002.

The case has reignited debate in the United States about a national trials registry that would record all clinical trials from the outset. GlaxoWellcome was considering setting up a company trials registry when it merged with SmithKline Beecham in 1998, but it never implemented the plan.

David Fassler, a Vermont psychiatrist who is on the council of the American Academy of Child and Adolescent Psychiatry, said he believed that a national registry would probably be set up in the next few years. "This case is a healthy development."

● GSK's treatment of paroxetine data has also come under scrutiny in Britain, where the Medicines and Healthcare products Regulatory Agency has been investigating the case for nine months. The MHRA has not yet decided whether to take action against GSK, but expects the investigation to conclude in the next few weeks. □

Report shows strong sex differences in teenage health behaviour

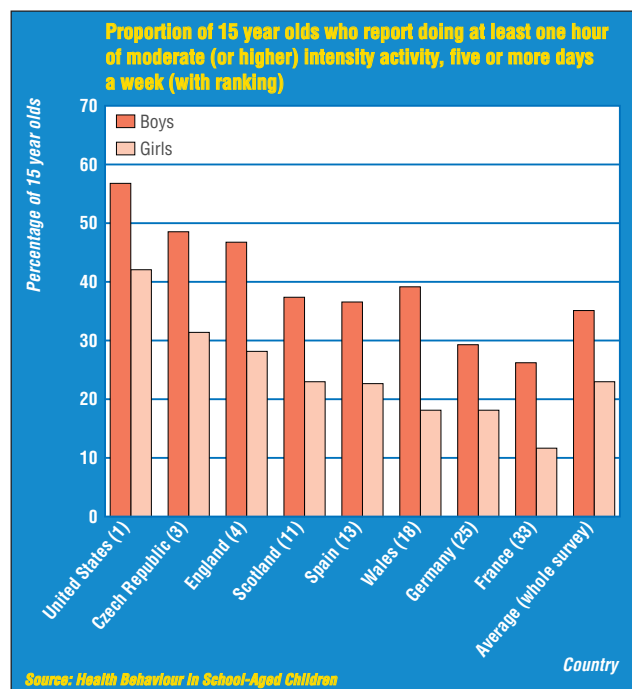
Bryan Christie *Edinburgh*

Strong sex differences have been found in the health behaviours of school age children across Europe and North America in one of the largest surveys ever carried out into young people's health.

The study, funded by the World Health Organization, is based on interviews with 162 000 young people, aged 11, 13, and 15 in 35 countries. It found that girls are more concerned about their body size, yet boys are more likely to be overweight.

Girls in all countries reported a poorer health status than boys did. Boys drink more regularly and are more likely to use cannabis and less likely to eat fruit.

When it comes to smoking, 11 year old boys are more likely than girls to have ever smoked, but this changes by age 15: in



more than half the countries studied, more 15 year old girls reported ever having smoked, particularly in western Europe.

The survey found common patterns across all countries but also uncovered huge extremes. Some of the main findings are: Only 35% of 15 year old boys and 22% of girls are participating in recommended levels of

physical activity (at least one hour of moderate (or higher) intensity activity, five or more days a week). The highest proportions are in United States, Canada, the Czech Republic, and England.

Two thirds of 15 year olds and more than a third of 13 year olds have experimented with tobacco. The highest pro-

portions of regular smokers are in Greenland, Germany, Ukraine, and Slovenia. Cannabis use is common—19% of 15 year olds reported using it in the past year.

Young people who are happy at school and get on well with their parents have the best health and are least likely to engage in risky behaviour.

Dr Erio Ziglio, the head of the WHO European Office for Investment in Health and Development, said the report provided a wealth of information, much of which was not previously available in some countries. He said the WHO European Office is planning to establish a forum to bring together young people, parents, policy makers, and researchers to learn lessons from the report.

This is the fourth and by far the most detailed report in a series that began in 1983. The international coordinator of the study, Dr Candace Currie of the University of Edinburgh, said it showed important information such as widespread sex differences in health behaviours and attitudes that need to be better understood. □

Young People's Health in Context: Health Behaviour in School-aged Children is at www.euro.who.int