

GlaxoSmithKline faces US scrutiny over Paxil suicide link

- [Elana Schor](#) in Washington
- guardian.co.uk,
- Thursday June 12 2008

GlaxoSmithKline (GSK), the UK's largest drug maker, is facing new scrutiny in America in the wake of a British government inquiry that found the company withheld data on the suicide risk of an antidepressant.

A US senator today asked the food and drug administration (FDA), the agency that regulates American pharmaceuticals, to follow its UK counterpart in probing whether GSK concealed clinical trial evidence.

"If the company engaged in this behaviour in the UK, then I want to make sure that the same didn't happen here in the US," Grassley said.

"The FDA should investigate this question thoroughly and be forthcoming about its findings."

The drug in question - Paxil, marketed in the UK as Seroxat - has been the subject of suicide warnings since 2003, when the British government told doctors not to prescribe it to young adults. A warning to that effect was added to its US labels in 2006.

In responding to the UK conclusion that GSK failed to inform authorities of Paxil's suicide risk, Grassley quoted the Guardian's report on imminent British legislation requiring drug companies to promptly publicise clinical trial data.

The senator also pointed to a report recently unsealed by a US court that found GSK knew as early as 1989 that Paxil carried a heightened suicide risk in adults as well as children.

The report, by Harvard University psychiatrist Joseph Glenmullen, was based on internal GSK documents and intended for use in ongoing US court cases against the company.

Glenmullen found that GSK inappropriately inflated the suicide risk of a placebo during clinical trials of the antidepressant, obscuring the increased danger associated with Paxil.

"It is my opinion, based on a reasonable degree of medical probability ... that Paxil increases the risk of suicidality in adults," Glenmullen wrote. "In addition, GlaxoSmithKline was aware of this risk, but hid it."

GSK has challenged the Glenmullen report since it was first unsealed in February and defended its use of so-called "washout" data in analysing suicide attempts made by patients taking Paxil during clinical trials.

Asked for comment on the senator's request for an FDA inquiry, a GSK spokeswoman pointed to comments the company made earlier this year responding to Grassley's concerns about the Glenmullen report.

"Dr Glenmullen has carefully selected excerpts from GlaxoSmithKline documents and made his own interpretations without looking at the totality of the data," GSK said in February.

- guardian.co.uk © Guardian News and Media Limited 2008
-