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Glaxo in a soup over Avandia

A leading doctor had voiced concerns about the heart risks of GlaxoSmithKline Plc's diabetes drug Avandia in a letter to the US Food and Drug Administration in 2000, years before Monday's high-profile study questioning its safety. One year later the FDA criticised the firm for minimising safety concerns, according to documents posted on the agency's Web site.

John Buse, president-elect of the American Diabetes Association and faculty member at the University of North Carolina in Chapel Hill, cited "a worrisome trend in cardiovascular deaths and severe adverse events" among patients using the drug in a letter to the agency in March 2000.

He also accused the drugmaker of "rampant abuse of clinical trial data".

The FDA sent Glaxo a warning letter in July 2001 after its own monitoring, saying the company's sales representatives had played down safety concerns and asking the company to send out a letter to doctors warning them of the risks

The news comes after a pooled analysis of dozens of trials, published in the New England Journal of Medicine this week, concluded that Avandia increased the risk of heart attack by 43 per cent and cardiac-related death by 64 per cent.

Glaxo has disagreed with the study findings. But shares in Europe's biggest drugmaker have fallen 8 per cent in the past three days on fears for sales, profits and the risk of lawsuits that could potentially reach billions of dollars.

A Glaxo spokesman in London, said both the company and the FDA had consistently monitored for adverse events since Avandia's approval in 1999.

"In doing so, the product labelling for Avandia has been updated several times to reflect new data, including with new cardiovascular safety information," he added.

"The totality of the data show that Avandia has a comparable cardiovascular profile to other oral anti-diabetic treatments."

The United States and European regulators have given a measured response to the new analysis, advising patients to talk to their doctors but not taking any immediate action to restrict Avandia use. The FDA will hold an expert advisory meeting at a later date.

Plaintiff lawyers, however, are expected to latch onto the warnings from years ago as they seek to build a case for bringing product liability lawsuits against Glaxo.

Lawyers said on Wednesday they were already fielding calls from Avandia users, with one predicting lawsuits could run into tens of billions of dollars.

Avandia sales were 1.6 billion pounds (\$3.16 billion) and accounted for 7 per cent of group revenues and significantly more of profits -in 2006.

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