BMJ 2017;357:j2050 doi: 10.1136/bmj.j2050 (Published 2017 April 25)

NEWS

US drug regulators should consider adding adults to SSRI suicide warning, says campaigner

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A British doctor who campaigned for the public to be warned about increased suicide risk in young people taking antidepressants has said that US drug regulators should consider including adults in warnings.

David Healy, a psychiatry professor at Bangor University, called for the warnings after GlaxoSmithKline (GSK) was ordered to pay $3m (£2.34m; €2.75m) to the widow of a US man who killed himself shortly after starting generic paroxetine.

The jury in the case of Stewart Dolin, a 57 year old attorney, concluded that GSK had failed to properly warn the public about the increased risk of suicide when taking paroxetine. The jury reached its verdict after lawyers for Dolin's widow, Wendy, presented evidence in the Chicago federal court suggesting that GSK knew that paroxetine posed a risk to adults but had concealed or manipulated data.

Dolin stepped in front of a train in July 2010 shortly after starting a generic version of paroxetine that was sold by Mylan Pharmaceuticals. Mylan was originally named in the lawsuit but was later dismissed because of regulations and a Supreme Court ruling that a generic company cannot be sued if the brand name company does not first change product labelling.

Warnings about the increased risk of suicidal thoughts and behaviour in children and young adults were added to the labels of antidepressants in the US and Europe more than a decade ago.[1] In the US, however, labels do not warn of these risks for anyone over 24 years old.

Many consumers have tried to hold drug makers responsible for suicides in adults without success. But the legal team representing Wendy Dolin argued that GSK had artificially inflated the number of suicides and suicide attempts that occurred among people who were given a placebo during clinical trials of paroxetine. They said that this alleged move made the antidepressant look better by comparison, since it appeared to minimise the risk of suicide associated with the drug.

The lawyers also argued that GSK had used averages for all selective serotonin reuptake inhibitors (SSRIs) to demonstrate that paroxetine did not raise the risk of suicide in adults aged over 24. Court documents also indicated that paroxetine displayed a much higher risk than all but one of the SSRI drugs.

Wendy Dolin declared the verdict "a great day for consumers." After the verdict she told the *Chicago Tribune*, "This for me has not just been about the money. This has always been about awareness [of] a health issue, and the public has to be aware of this."

Healy, who spearheaded the campaign to upgrade suicide warnings on antidepressants and testified as an expert witness on behalf of Wendy Dolin, said that the findings in the case should prompt the US drug regulator to review the evidence on SSRIs and suicide risk in adults.

"When it becomes so clear cut that a jury finds there is a problem, it suggests the evidence is strong enough to look at the issue," Healy told *The BMJ*. "If it's that clear to the average man on the street, and the FDA [the US Food and Drug Administration] doesn't do something about it, we have an odd situation."

GSK, which markets paroxetine under the brand name Paxil in the US, has said that it will appeal the verdict. "GSK maintains that because it did not manufacture or market the medicine ingested by Mr Dolin, it should not be liable," it said in a statement. "Additionally, the Paxil label provided complete and adequate warnings during the time period relevant to this lawsuit."

GSK added, "The scientific evidence does not establish that paroxetine causes suicide, suicide attempts, self-harm, or suicidal thinking in adult patients. In 2007, FDA revised the labelling for the entire class of SSRI drugs (including generic paroxetine and Paxil). The label includes statements that studies did not show an increased risk of suicidality (attempts or ideation) in adults over the age of 24, and that there appeared to be a protective effect in adults over 64."

1 Eaton L. Regulator restricts use of SSRIs in children. *BMJ* 2005. www.bmj.com/content/330/7498/984.2.

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