

Seroxat to blame for baby's heart defects, American jury rules

- British maker of Seroxat told to pay £1.6m damages
- GlaxoSmithKline denies drug harms fetuses
- [Sarah Boseley](#), health editor
- [guardian.co.uk](#), Wednesday 14 October 2009 20.40 BST



Drug regulators warned in 2005 that Seroxat could be linked to heart defects. Photograph: Rex Features

A family has been awarded \$2.5m (£1.6m) in damages after a jury in Philadelphia decided that the British-made antidepressant Seroxat was responsible for their three-year-old son's heart defects.

[GlaxoSmithKline](#), the British manufacturer of Seroxat, known as Paxil in the US, said it would appeal against the verdict. Although drug regulators in the US and UK warned in 2005 that Seroxat could be linked to heart defects, GSK does not accept its drug is the cause.

Thousands of women worldwide have taken antidepressants such as Seroxat in [pregnancy](#), assured by manufacturers and doctors that they are safe. The case is one of a number in the US and the first to end in a verdict against the company.

Michelle David, 24, was prescribed Paxil in the US after panic attacks. Around mid-February 2005, she discovered she was pregnant. According to her lawyer, Sean Tracey of Houston, Texas, her obstetrician gave her the standard advice at the time: that Paxil was safe. David later stopped taking it because of side-effects that might have been attributable to the pregnancy.

Her son, Lyam Kilker, was born in October 2005. A couple of weeks later he stopped feeding and doctors found he had two holes in the heart and a very rare congenital defect called an

interrupted aortic arch. "The hospital put in a stent to keep him alive," said Tracey. "He had acquired an infection – the heart condition made him more susceptible."

Soon afterwards, Lyam had the first of two open heart operations and spent five months in hospital. He will need more major heart surgery in five to 10 years.

A number of studies have suggested that rates of congenital heart defects are higher among women taking Paxil and other [drugs](#) of the SSRI (selective serotonin reuptake inhibitor) class. David Healy, professor of psychiatry in Bangor, Wales, who gave evidence in the Kilker case, said that at 4%, the rate of birth defects was double the normal rate, while the rate of major defects was 2% compared with 1%. The general rate of miscarriages is 8%, but 16% of women on Seroxat miscarry.

GSK denied that its drug was responsible for harm to babies in the womb. "While we sympathise with Lyam Kilker and his family, the scientific evidence does not establish that exposure to Paxil during pregnancy caused his condition," said the company in a statement. "Very unfortunately, birth defects occur in 3-5% of all live births, whether or not the mother was taking medication during pregnancy.

"GlaxoSmithKline acted properly and responsibly in conducting its clinical trial programme for Paxil, including sharing documentation and submitting results from studies on Paxil to regulators. Once approved for use, the company acted properly in marketing the medicine, including monitoring its safety, updating pregnancy information in the medicine's labelling as new information became available, and in communicating important safety information to regulatory agencies, the scientific community and the public."

Lawyers for women in the US allege that GSK knew of the problem earlier than it admits. Internal documents produced at the Kilker trial suggest that it was investigating complaints as early as 2001, when a woman emailed GSK to ask whether Paxil could be the reason for her baby developing severe heart defects in the womb. The pregnancy was terminated.

GSK replied with a formal letter telling her to consult her doctor. But an internal report recorded that the link between her baby's defects and Paxil was "almost certain". In court, GSK officials said the report was a mistake and that somebody had filled in the form wrongly.