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BREAKING NEWS

# GSK's litigation woes for selling harmful drugs continue

BY RHODA WILSON ON MAY 31, 2024 • ( 5 COMMENTS )



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**5** Drugmakers GlaxoSmithKline (“GSK”) and Boehringer Ingelheim have managed to persuade a Chicago jury to reject a woman’s claim that the heartburn drug Zantac caused her cancer. Although the companies won this case, it is the first of thousands of such lawsuits to go to trial in the USA.

As Professor Carl Heneghan and Dr. Tom Jefferson explain, this is not the first time GSK has been mired in litigation.

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## The Real Winners

By Prof. Carl Heneghan (<https://substack.com/@trusttheevidence>) and Dr. Tom Jefferson (<https://substack.com/profile/96340933-tom-jefferson>)

This week, GSK won (<https://fortune.com/europe/2024/05/24/victory-drugmakers-gsk-boehringer-640-million-zantac-cancer-lawsuit-thousands-still-to-come/>) a much-needed victory in a \$640 million cancer lawsuit over the heartburn drug Zantac. However, thousands of lawsuits are still due to go to trial in the US. And there are thousands more to come.

Zantac became available in the 1980s before becoming an over-the-counter product. At one point, it was the world's top-selling medicine, with more than \$1 billion in annual sales. Its ownership has changed hands. Sanofi, Zantac's current owner, has paid over \$100 million to settle Zantac cancer lawsuits (<https://www.bloomberg.com/news/articles/2024-04-22/sanofi-to-pay-100-million-to-settle-zantac-cancer-lawsuits?embedded-checkout=true>).

In 2019, GSK recalled (<https://www.gov.uk/drug-device-alerts/class-2-medicines-recall-zantac-injection-50mg-2ml-zantac-syrup-150mg-10ml-zantac-tablets-150mg-zantac-tablets-300mg-el-19-a-24#:~:text=Download%20document-,Product%20information,has%20genotoxic%20and%20carcinogenic%20potential.>) Zantac stocks “due to possible contamination with an impurity NDMA, which has genotoxic and carcinogenic potential.” Having already settled some cases before going to trial and facing over 70,000 field Zantac cases, GSK went on the offensive to dismiss claims the drug caused colorectal cancer.

Recent cohort evidence reports (<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2809671#:~:text=The%20findings%20of%20this%20large,with%20increased%20risk%20of%20cancer.>) use was not associated with an increased risk of cancer but with a caveat that further research is needed on the long-term association. Inconsistent results across different countries prevented ruling out a potential association with cancer.

The lawsuits claim that GSK knew about the dangers of NDMA but failed to adequately warn the public. This is not the first time GSK has been mired in litigation: it has previously faced allegations of unethical and unsafe business practices (<https://www.drugwatch.com/manufacturers/glaxosmithkline/>).

Zofran (ondansetron) was prescribed for morning sickness even though the US Food and Drug Administration (“FDA”) had never approved it for this indication. Families who suffered congenital disabilities after taking Zofran while pregnant sued GSK as it marketed the drug during pregnancy without FDA approval. In 2021, GSK “scored a big win” in litigation (<https://www.fiercepharma.com/pharma/glaxosmithkline-scores-a-big-win-its-zofran-litigation-after-fda-repeatedly-rejects>). It argued that the FDA had repeatedly rejected pregnancy warnings. Further attempts to the US appeals court were thwarted as in 2023, it stated (<https://www.reuters.com/legal/litigation/us-appeals-court-wont-revive-zofran-birth-defect-cases-against-gsk-2023-01-09/>) it won't revive Zofran congenital disability cases.

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In 2010, Avandia (Rosiglitazone) was recalled. GSK had long known about the increased risk of heart disease, but it “used its power (<https://www.ucsusa.org/resources/glaxosmithkline-tried-silence-scientist-who-exposed-dangers-its-drug-avandia>) to silence scientists rather than protecting its customers by bringing the harm to light.”

As we have often said, not much gets by the *Trust the Evidence* (<https://trusttheevidence.substack.com/>) office. In 2006, writing in the *BMJ* Prof. Heneghan pointed out (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1602003/>) that “despite the population being at low risk of heart failure (10-year risk 0.33%), a significant increase (0.4%) in heart failure was seen in the rosiglitazone group compared with placebo (7.03, 1.60 to 30.9, number needed to harm at three years 250).” Yet it took until 2010 to ask questions about what went wrong (<https://www.bmj.com/content/341/bmj.c4848>).

Perhaps the most egregious example of bad behaviour is GSK’s withholding of trial data for the drug Paroxetine, known as Paxil in North America and Seroxat in the UK.

As part of the largest healthcare fraud settlement (<https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report>) in US History, GSK was fined for unlawfully promoting the product to under-18s, data withholding, and misbranding the product, among other illegal practices.

**Paxil:** In the criminal information, the government alleges that, from April 1998 to August 2003, GSK unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use. The United States alleges that, among other things, GSK participated in preparing, publishing and distributing a misleading medical journal article that misrepresented that a clinical trial of Paxil demonstrated efficacy in the treatment of depression in patients under age 18, when the study failed to demonstrate efficacy. At the same time, the United States alleges, GSK did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under 18. The United States further alleges that GSK sponsored dinner programs, lunch programs, spa programs and similar activities to promote the use of Paxil in children and adolescents. GSK paid a speaker to talk to an audience of doctors and paid for the meal or spa treatment for the doctors who attended. Since 2004, Paxil, like other antidepressants, included on its label a “black box warning” stating that antidepressants may increase the risk of suicidal thinking and behavior in short-term studies in patients under age 18. GSK agreed to plead guilty to misbranding Paxil in that its labeling was false and misleading regarding the use of Paxil for patients under 18.

Source: GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data, Office of Public Affairs, US Department of Justice, 2 July 2012

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products.

Sir (Sir) Patrick Vallance (<https://www.gov.uk/government/people/patrick-vallance>) (Sir squared) joined the company in 2006 as head of drug discovery and was president of Research and Development at GSK from 2012 to 2018. Everyone knows where he went next.

The latest news is that GSK has sold its remaining stake in Haleo, the maker of Panadol painkillers and Sensodyne toothpaste, raising £1.25bn. (<https://www.reuters.com/markets/deals/gsk-raises-15-bln-offloading-haleo-stake-discount-2024-05-17/>) This underlines GSK's strategy to focus (<https://www.ft.com/content/557b7f43-da17-46b6-aa1c-740c1859fa96>) on the most profitable drugs.

Profits on newer drugs are excessive; they distort the development market and ensure the focus is on blockbuster sales. In the US, the price of prescription drugs increased (<https://www.globaljustice.org.uk/wp-content/uploads/2023/07/Bitter-Pills-Why-the-NHS-cant-swallow-big-pharmas-profiteering.pdf>) from roughly \$1,400 a year in 2008 to over \$150,000 a year in 2021. The UK's NHS spent £13 billion on just ten medicines in the decade up to 2022. *Global Justice Now* estimated drug companies made up to £12.6 billion through “extreme profiteering.” Their report (<https://inews.co.uk/news/health/big-drug-firms-accused-ripping-off-nhs-excess-profits-2471226>) estimated the cost of these ten drugs to the NHS was “well below 10 per cent of the price charged.”

The fines, though, are insignificant in the context of GSK revenues (<https://www.macrotrends.net/stocks/charts/GSK/gsk/revenue#:~:text=GSK%20revenue%20for%20the%20twelve,a%2022.68%25%20decline%20from%202021.>) – for the twelve months ending March 2024, revenues were \$38.7 billion, a 22% increase year on year as vaccine and cancer drug sales soared.

The reputational damage to GSK has done little to the careers of those who have overseen these woes: when it comes to drug companies, it seems that crime really does pay.

This post was written by two geezers who may be awarded the Order of the Squared Golden Boot.

## About the Authors

Carl Heneghan (<https://www.phc.ox.ac.uk/team/carl-heneghan>) is a professor of Evidence-based Medicine at the University of Oxford, Director of the Centre for Evidence-Based Medicine (<https://www.cebm.net/>) (“CEBM”) and NHS Urgent Care general practitioner who regularly appears in the media. Tom Jefferson (<https://drtomjefferson.com/>) is a clinical epidemiologist and a Senior Associate Tutor at the University of Oxford. Together they publish articles on a Substack page titled '[Trust the Evidence](https://trusttheevidence.substack.com/)' (<https://trusttheevidence.substack.com/>).