

\$3 Billion in Fines for Illegal Marketing of Paxil, Wellbutrin and Other Drugs

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In the last few years in a series of civil and criminal suits, the federal government has been hitting the pharmaceutical industry with billions in fines, often for false or misleading marketing practices. Many of these suits have involved psychiatric drugs.

In January 2009, the [Department of Justice](#) announced:

American pharmaceutical giant Eli Lilly and Company today agreed to plead guilty and pay \$1.415 billion for promoting its drug Zyprexa for uses not approved by the Food and Drug Administration (FDA), the Department of Justice announced today. This resolution includes a criminal fine of \$515 million, the largest ever in a health care case, and the largest criminal fine for an individual corporation ever imposed in a United States criminal prosecution of any kind. Eli Lilly will also pay up to \$800 million in a civil settlement with the federal government and the states.

In recent months, Abbott Laboratories settled for \$1.6 billion in regard to false marketing of the antiepileptic and mood-stabilizing drug Depakote and an agreement with Johnson & Johnson that "could result in a fine of as much as \$2 billion is said to be imminent over its off-label promotion of another antipsychotic drug, Risperdal," according to the [New York Times](#).

The states have also been [suing drug manufacturers](#), often in regard to psychiatric drugs, and winning huge verdicts. In April, an Arkansas judge ordered Johnson & Johnson and a subsidiary to pay more than \$1.2 billion in fines after a jury found that the companies had minimized or concealed the dangers associated with the antipsychotic drug Risperdal.

Now the [federal government has announced](#) the largest settlement of all involving civil and criminal fines of \$3 billion against GlaxoSmithKline (GSK). Criminal fines of \$1 billion were levied in regard to the marketing of the antidepressants Paxil and Wellbutrin, and withholding negative information about the diabetes drug Avandia. Another \$2 billion in fines involved sales and marketing practices surrounding the asthma drug Advair and several other drugs.

"GSK's sales force bribed physicians to prescribe GSK products using every imaginable form of high priced entertainment, from Hawaiian vacations to paying doctors millions of dollars to go on speaking tours to a European pheasant hunt to tickets to Madonna concerts, and this is just to name a few," according to [Carmin M. Ortiz](#), the U.S. attorney in Massachusetts.

GSK admitted wrongdoing in the criminal action but not in the civil settlement.

[According to](#) the *New York Times*:

Despite the large amount, \$3 billion represents only a portion of what Glaxo made on the drugs. Avandia, for example, racked up \$10.4 billion in sales, Paxil brought in \$11.6 billion, and Wellbutrin sales were \$5.9 billion during the years covered by the settlement, according to IMS Health, a data group that consults for drugmakers.

In one of the [most egregious examples](#) of fraudulent marketing, "In the case of Paxil, prosecutors claim GlaxoSmithKline employed several tactics aimed at promoting the use of the drug in children, including helping to publish a medical journal article that misreported data from a clinical trial."

Extreme tactics have also been used by [other drug companies](#) in regard to marketing psychiatric drugs for children. Drug companies allegedly [paid seven figures](#) to three Harvard professors of psychiatry -- Joseph Biederman, Thomas Spencer, and Timothy Wilens -- who then went on to encourage [diagnosing children](#) with bipolar disorder and medicating them with antipsychotic drugs.

I have been involved as a medical expert in a number of product liability suits against drug companies. In a case against GSK regarding Paxil as an alleged cause of violence and suicide, a judge made public my report, leading to my publication of [three articles here](#), [here](#), and [here](#), concerning the drug company's practices in the development and marketing of Paxil, and in particular its alleged withholding or manipulation of information about the drug's dangerousness. (The case had been resolved without the drug company admitting any wrongdoing.) My observations are also published in [*Medication Madness: The Role of Psychiatric Drugs in Cases of Violence, Suicide and Crime*](#).

Although it is encouraging to see the legal system to some degree catching up with drug company malfeasance, there are a number of problems with the criminal and civil cases brought by the Department of Justice against drug companies.

As in the case of the recent settlements with GSK, the company makes so much money from the drugs that they are little affected by paying out even \$3 billion. Its stock rose significantly after the announcement.

Individuals within the companies, including the CEOs, rarely have to face individual charges or fines.

None of the money goes to the victims of the civil and criminal offenses, including the many children injured by the fraudulent off-label marketing of drugs like Risperdal and Paxil.

There is little or no public examination and reform of many of the promotional and marketing practices that have contributed to such egregious behavior on the part of drug companies. Reforms might include requiring public, internet-accessible reporting of any payments from drug companies to doctors, researchers and institutions such as universities.

There is no requirement for drug companies to disclose all research programs and their results, for example, making available the data from failed and negative research studies, as well as all adverse drug reaction data before it is combed and manicured.

Genuine reform will begin when these problems are addressed by making the fines so large that the companies cannot do business as usual, by holding corporate executives personally responsible, by compensating the victims and their families and by fully disclosing manipulative sales and marketing techniques and underlying "spun science" that invalidates many claims for safety and efficacy. Above all else, the health professions and the public need to view medications of all kinds with much more skepticism in regard to drug-company claims for their safety and efficacy. In my field of psychiatry, nothing would contribute more to public health than cutting back on psychiatric drug prescriptions and encouraging patients, whenever possible, to carefully [withdraw from psychiatric medications](#) with professional supervision, while turning to non-drug, psychosocial support and counseling.

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Disclosure: Peter Breggin, M.D. was the plaintiff's medical expert in the Paxil/GSK suit referenced above.