CHRONOLOGY OF PSYCHOTROPIC DRUG LAWSUITS



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With the risks of psychotropic drugs being exposed, lawsuits seeking damages have commensurately increased. The following lawsuits were successfully prosecuted resulting in judgments against and/or known payments by pharmaceutical companies totaling \$4.96 billion (€3.3 billion) in criminal and civil fines and settlements.

2001, May

Justice Barry O'Keefe of the New South Wales Supreme Court, Australia, found the antidepressant Lustral (Zoloft) in part responsible for turning David Hawkins, a peaceful, law-abiding man, into a violent killer. Judge O'Keefe stated that had Hawkins not taken Lustral, "it is overwhelmingly probable that Mrs. Hawkins would not have been killed ..." 1

2001, June

Tobin vs. GlaxoSmithKline (GSK): A U.S. District Court jury in Wyoming returned a verdict against DSK awarding \$6.5 million (€4.4 million) to relatives of Donald Schell, who shot and killed his wife, daughter, granddaughter and himself after taking Glaxo's antidepressant Paxil for two days for insomnia.2

2002, November

Eli Lilly settled a lawsuit filed by Diane Cassidy of Pennsylvania who became suicidal after taking Prozac for weight loss. Following a suicide attempt, Ms. Cassidy was partially paralyzed and mentally impaired from injuries sustained. Settlement figure not released.

2003, April

USA vs. GSK: The drug maker agreed to pay \$87.6 million (€59.7 million) to settle civil charges brought by the United States Department of Justice (US DOJ), alleging the company overcharged the U.S. Medicaid (government insurance for the poor and disabled) for the antidepressant Paxil and a medical drug.3

2003, June

William & Lisa Van Syckel of New Jersey filed a lawsuit against several psychiatrists (Joseph Donnalan, Ileana Bernal and Robert Bransfield) and the University Behavioral Health Care psychiatric hospital after their 15-year-old daughter, Michelle, who had suddenly lost her appetite and was losing weight, was misdiagnosed as depressed and prescribed Zoloft. Michelle subsequently became violent and suicidal and was admitted to a psychiatric facility. When it became obvious the drug was harming her daughter, Mrs. Van Syckel, had her taken off it. It was later determined that Michelle was really suffering from Lyme Disease. The case settled with an undisclosed amount.4

2004, April

Law firms Parker & Waichman and Douglas & London filed the first nationwide class action lawsuit against Eli Lilly & Co., (Lilly) on behalf of Americans who had taken the antipsychotic drug Zyprexa. The suit, filed in New York District Court, named three people who developed diabetes after taking the drug.5

2004, May

Mrs. Kim Witczak filed a wrongful death lawsuit against Pfizer in the County of Hennepin District Court, Fourth Judicial District, in Minneapolis, Minnesota claiming that Zoloft caused her husband, "Woody," to experience severe side effects that caused him to commit suicide. He had been prescribed Zoloft to help him sleep and had no history of depression. Key to the case was whether Pfizer gave adequate warning that use of Zoloft could lead to suicidal tendencies.6 In July 2004, Pfizer unsuccessfully attempted to dismiss Witczak's suit arguing the FDA had not required it to add a warning for suicidality for adults taking the drug.7 On July 21, U.S. District Judge James Rosenbaum denied Pfizer's application and ruled that FDA warnings were minimum standards.8 The case settled February 24, 2006 and terms are confidential.9

2004, June

State of New York vs. GSK: GSK paid \$2.5 million (€1.7 million) to settle the lawsuit that alleged "persistent fraud" in suppressing research on Paxil that had shown increased risk of suicidal thoughts and actions in children taking the antidepressant.10

2004, October

Remeron Antitrust Litigation: Netherlands-based pharmaceutical maker Akzo Nobel and its subsidiary, Organon USA, paid \$59.8 million (€40.7 million) to several U.S. pharmacy chains, attorneys general and insurance companies to settle a lawsuit alleging that the company engaged in various acts calculated to suppress competition by companies that market low-cost generic equivalents of prescription drugs, resulting in a monopoly on its antidepressant Remeron.11

2005, April

Organon and Akzo Nobel also paid \$36 million (€24.5 million) to all 50 United States to settle similar charges, the proceeds of which were distributed to consumers that purchased Remeron.12

2005, June

U.S. Zyprexa Class Action Lawsuit: Lilly agreed to pay \$690 million (€470 million) to settle product liability claims by 8,000 plaintiffs who alleged Zyprexa caused diabetic and hyperglycemic (high level of sugar in the blood) side effects.13 In January 2007, the company agreed to pay a further \$500 million (€340 million) to settle 18,000 more Zyprexa suits.14

2005, October

A Virginia jury delivered a \$1.6 million verdict in a tardive dyskinesia (uncontrollable shaking) suit. Sylvia Jones was 21 when in 1982 she was prescribed a neuroleptic [nerve seizing] psychiatric drug and an antidepressant for anxiety. Although the symptoms abated, she was kept on the neuroleptic until 1997, and has been completely disabled by TD (tardive dyskinesia), the known side effect of the drug.

2005, November

U.S. District Judge Samuel Der-Yeghiayan found against Pfizer in a lawsuit about Zoloft. The widow of Donald Zikis, a man who committed suicide while taking Zoloft, argued that Pfizer had failed to properly warn users of the drug's dangerous side effects. Pfizer asserted that if it had added such warnings to its label, "it might mislead physicians about the risks entailed in prescribing a drug, thereby over-deterring its use." The court rejected the assertion, stating that the company could add any warning, precaution or notice of adverse reactions without prior FDA approval.15

2006, June

Faith Myers vs. Alaska Psychiatric Institute: Faith Myers challenged the constitutionality of the Alaska Psychiatric Institute (API) to force her to take psychotropic drugs when she was committed to the facility on February 3, 2003. The Alaska Supreme Court found in her favor, recognizing the dangers of psychiatric drugs, stating, "Given the nature and potentially devastating impact of psychotropic medications...we now similarly hold that the right to refuse to take psychotropic drugs is fundamental." Further, "Psychotropic drugs 'affect the mind, behavior, intellectual functions, perception, moods, and emotion' and are known to cause a number of potentially devastating side effects... Courts have observed that 'the likelihood [that psychotropic drugs will cause] at least some temporary side effects appears to be undisputed." Therefore, informed consent applies and includes: "information about the proposed medication, its purpose, the method of its administration, the recommended ranges of dosages, possible side effects and benefits, ways to treat side effects, and risks of other conditions...." They are to be told "information about alternative treatments." 16

2006, December

U.S. vs. Bristol-Myers Squibb: The company entered into agreement with the U.S. DOJ to pay the \$499 million (€340 million) to settle a federal investigation for illegally marketing its antipsychotic drug Abilify to physicians for uses exceeding its FDA approval.17

2007, April

The national consumer protection group, Public Citizen, secured an improved settlement for the parents of thousands of children prescribed the antidepressant Paxil. The class action against GSK had sought economic damages, alleging the company misled parents by not disclosing that the drug was dangerous and ineffective when taken by children younger than 18. GSK agreed to put \$63.8 million (€43.4 million) into a settlement fund for victims and attorneys' fees.18

2007, June

U.S. Zyprexa Class Action Lawsuit: Lilly settled another 900 Zyprexa product liability lawsuits but declined to release the settlement amount.19

2008, March

State of Alaska vs. Eli Lilly & Co.: The company paid \$15 million (€10 million) to settle the state's civil suit (filed in 2006), alleging that it illegally marketed Zyprexa for conditions for which it was not approved to treat and for downplaying the known diabetic and hyperglycemic side effects of the drug.20

2008, April

USA vs. Otsuka Pharmaceuticals: Otsuka, maker of the antipsychotic drug Abilify, entered into an agreement with the U.S. DOJ to pay \$4 million (€2.7 million) to resolve allegations it unlawfully marketed the drug for use in children and for dementia-related psychosis in the elderly, uses for which it did not have approval. (The company developed the drug in Japan and marketed it in the U.S. with Bristol-Myers Squibb, which settled similar allegations in December 2006).

2008, October

Paxil U.S. class action suit: GSK paid \$40 million (€27.2 million) to settle a long-standing class action lawsuit alleging that it suppressed studies that showed Paxil was ineffective and might increase the risk of suicidal thoughts and actions in children. The settlement reimburses health insurance companies that paid for the drug.

2008, October

State of Texas vs. Eli Lilly & Co.: An 18-month-long investigation of Lilly by 33 states, under the Texas Consumer Protection Act, ended in a judgment and injunction calling for Lilly to pay \$62 million (€42 million) and agree to numerous restrictions and reforms for the ensuing six years regarding its promotion, marketing, medical communications and other aspects of business relating to Zyprexa.21

2009, January

USA vs. Eli Lilly & Co.: Lilly entered into an agreement with the U.S. DOJ to plead guilty to a criminal charge of unlawful promotion of Zyprexa for non-Food and Drug Administration (FDA)-approved uses, specifically as a treatment for dementia in the elderly. It paid a penalty fine of \$515 million (€351 million). The company also settled a concurrent federal civil investigation, paying \$800 million (€545 million), to be split between the federal government and the states.22

2009, March

West Virginia vs. Johnson & Johnson: Brook County Circuit Court Judge Martin Gaughan ordered J&J to pay the state \$4.4 million (€2.9 million) for false advertising to physicians about two of its products, one of which was the antipsychotic drug Risperdal.23

2009, April

State of Georgia vs. Eli Lilly & Co.: Lilly paid \$15 million (€10 million) to the state of Georgia to settle the state Attorney General's civil suit over the company's unlawful promotion of Zyprexa for non-FDA-approved uses.24

2009, August

West Virginia vs. Lilly: Lilly agreed to pay \$22.5 million (€15.3 million) to the state of West Virginia to settle a similar Attorney General-filed suit regarding its Zyprexa activities.25

2009, September

USA vs. Pfizer: The U.S. Department of Justice ordered Pfizer to pay a record-breaking \$2.3 billion (€1.5 billion) in criminal and civil fines for illegal promotions to induce doctors to use four of its products, including the antipsychotic Geodon. To prevent future occurrences of illegal promotion, the company was placed under the monitoring of the federal Department of Health and Human Services Office of Inspector General for five years.26

2009, September

Maryland vs. Pfizer: The company also paid \$33 million (€22.4 million) to 43 states to settle consumer protection claims against them regarding Geodon. The suit, filed by the Attorneys General of Maryland and Delaware, was filed on behalf of all the AGs involved. It alleged that Pfizer engaged in unfair and deceptive practices when it marketed Geodon.27

2009, October

In Kilker vs. GSK, the first of more than 800 Paxil birth defect suits to go to trial, a Pennsylvania jury found in favor of the plaintiff, awarding \$2.5 million (€1.9 million) in compensatory damages Lyam Kilker, age 3, was born with heart defects his mother attributed to her use of Paxil while pregnant. The jury found that GSK failed to adequately warn doctors and pregnant users of the antidepressant's risks. 28

2010, August

Astrazeneca paid approximately \$198 million (€153 million) to settle 17,500 cases alleging that its antipsychotic drug Seroquel caused diabetes in some users.29

Endnotes:

- 1 Sarah Boseley, "Prozac class drug blamed for killing," The Guardian, 26 May, 2001.
- 2 StarNews.com, "Antidepressant maker held liable," June 7, 2001 and "Paxil maker held liable in murder/suicide," Lawyers Weekly USA, 9 July 2001.
- 3 "Rx drugs: Bayer, Glaxo announce settlement for overcharging," American Health Line, 17 Apr. 2003.
- 4 Van Syckel vs. Somerset Medical Center et al., Docket No. L-000106-03, Superior Court of New Jersey, filed
- 5 "Class action filed over Zyprexa side effects," Pharma Marketletter, 19 Apr. 2004 and "Parker & Waichman and Douglas & London file first nationwide class
- action...," PR Newswire, 19 Apr., 2004.
- 6 David Phelps, "Judge denies Pfizer's motion to dismiss Zoloft lawsuit," Star Tribune, 21 July 2005.
- 7 Anna Wilde Mathews, "FDA Plan Would Aid Drug Makers in Liability Suits," The Wall Street Journal, 14 Jan. 2006.
- 8 David Phelps, "Judge denies Pfizer's motion to dismiss Zoloft lawsuit," Star Tribune, 21 July 2005.
- 9 Witczak vs. Pfizer, Court file No. WD 04-6680, State of Minnesota County of Hennepin, District Court, Fourth Judicial District, May 20, 2004 and Agreement
- and Consent to Distribution of Settlement Proceed and Waiver of Notice of Hearing, File No. 04-CV-2819 JMR/FLN, Feb. 24, 2006.
- 10 David B. Caruso, "GlaxoSmithKline begins releasing data on drug trials," Associated Press, 2 Sept. 2004; The People of the State of New York, by Eliot Spitzer, Attorney General of the State of New York vs. GlaxoSmithKline.
- 11 "Akzo Nobel settles additional Remeron court cases," Medical News Today, 1 Oct., 2004.
- 12 "Organon settles with states in antitrust case," Generic Line, 3 Nov. 2004 and "Remeron refund procedure announced, consumeraffairs.com, 18 Mar., 2005.

- 13 Carolyn Pritchard, "Eli Lilly agrees to Zyprexa settlement," MarketWatch, 9 June 2005 and U.S. Securities and Exchange Commission, Washington, D.C. 20549, Form 10-Q, Quarterly Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarter ended 30 June 2009 Commission File Number 001-6351 Eli Lilly and Company.
- 14 "Lilly to Pay Up to \$500 Million to Settle Claims," New York Times, 4 Jan. 2007.
- 15 Robert A. Clifford, "Battle brews over new FDA rule preempting state law," Chicago Lawyer, Mar. 2006.
- 16 Faith Myers vs. Alaska Psychiatric Institute, Supreme Court, 2-11021, Superior Court No. 3AN-03-00277, Opinion, No. 6021, 30 June 2006.
- 17 Julie Schmit, "Bristol's \$499M drug-pricing settlement among biggest," USA Today, 21 Dec. 2006.
- 18 "Bigger Settlement for Paxil Parents," consumeraffairs.com, 26 Apr. 2007.
- 19 "Lilly settles Zyprexa lawsuits," Forbes, 12 June 2007.
- 20 Alex Berenson, "Alaska Suit Against Lilly Is Settled, New York Times, 27 Mar. 2008.
- 21 Final Judgment and Agreed Permanent Injunction, State of Texas vs. Eli Lilly and Company, Cause No. 08-12714, 7 Oct., 2008 and "Texas, 33 States Reach

Landmark \$62 Million Settlement with Eli Lilly & Company," press release of Texas Attorney General, 7 Oct. 2008.

- 22 "Eli Lilly to pay \$1.4 billion to settle Zyprexa suits," CNNMoney, 15 Jan. 2009.
- 23 "Court orders Johnson & Johnson to pay millions for misleading WV doctors; Attorney General McGraw states false advertising," West Virginia Attorney General Press Release, 2 Mar. 2009.
- 24 "Georgia settles with drug company for \$6M," Atlanta Journal Constitution, 29 Apr. 2009.
- 25 "State settles lawsuit against Eli Lilly," Charleston Gazette, 21 Aug. 2009.
- 26 "Pfizer to pay record \$2.3B penalty over promotions," Miami Herald, 2 Sept. 2009.
- 27 "Attorney General Gansler leads settlement of consumer protection claims against Pfizer, Company to pay \$33 million as part of settlement," press release of the Maryland Attorney General, 2 Sept. 2009.
- 28 Jef Feeley and Sophia Pearson, "Glaxo Ordered to Pay \$2.5 Million for Paxil Defects (Update4)," Bloomberg.com, 13 Oct. 2009.
- 29 Jef Feeley and Trista Kelley, "AstraZeneca to Pay \$198 Million for Seroquel Lawsuits," Bloomberg.com, 9 Aug. 2010.