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GlaxoSmithKline Corporate Rap Sheet: Lethal Side Effects, Law Suits, Marketing Controversies

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London-based GlaxoSmithKline is the product of the 2000 merger of two drug giants: Glaxo—which had its origins in the infant formula business and then jumped to the top ranks of the pharmaceutical industry on the basis of the extraordinarily popular ulcer drug Zantac—and SmithKline Beecham, which was itself the product of a merger of a U.S. and a British drugmaker and had a broader portfolio of drugs, including the competing ulcer medication Tagamet and the ill-fated diabetes drug Avandia.

In recent years, GlaxoSmithKline has become known as the company that pays massive amounts to resolve wide-ranging charges brought by U.S. regulators and prosecutors. These included a $750 million payment relating to the sale of adulterated products from a facility in Puerto Rico and a record $3 billion in connection with charges relating to illegal marketing, suppression of adverse safety research results and overcharging government customers. The company also set a record for the largest tax avoidance settlement with the U.S. Internal Revenue Service.

Product Safety

In 1984 the U.S. Food and Drug Administration (FDA) brought charges under the little used criminal provisions of federal drug laws against what was then known as SmithKline Beckman, alleging that the company failed to warn regulators and the public about potentially lethal side effects associated with its blood pressure medication Selacryn. Several company officials were also charged with misdemeanor offenses. The company later pleaded guilty, and three officials pleaded no contest. The judge in the case ordered SmithKline to give $100,000 to an organization working to prevent child abuse; the officials were each sentenced to five years of probation and 200 hours of community service.

In 2003 regulators in Britain warned that use of GlaxoSmithKline's antidepressant Seroxat (the UK name for Paxil) by children could increase suicidal thoughts and should not be prescribed for them. The FDA followed with a similar recommendation and subsequently ordered that a "black box warning" be added to the drug's packaging. In 2004 New York Attorney General Eliot Spitzer filed suit against the company, accusing it of suppressing research that reached negative conclusions on the efficacy of Paxil. The case was later settled, with GlaxoSmithKlineagreeing to take the unusual step of disclosing the results of its clinical trials for Paxil and other drugs.

The company later came to regret that agreement. In a review of the data posted by the

company on clinical trials involving its diabetes drug Avandia, researchers at the Cleveland Clinic concluded that the medication posed a heightened risk of heart attacks. The *New York Times* discovered that the FDA had been warned of such risks years earlier. Over the following months and years, more and more information came to light questioning the safety of Avandia, prompting actions such as a move by the U.S. Department of Veterans Affairs to sharply curtain use of the drug.

In 2010 an FDA reviewer issued a scathing critique of the clinical trial GlaxoSmithKline had used to argue for the safety of Avandia, concluding that the company had excluded information about numerous instances in which users experienced severe medical complications. It was thenreported that the company had spent more than a decade covering up research results showing that Avandia performed no better a competing medication.

Also in 2010, an FDA advisory panel recommended that Avandia either be withdrawn from the market or severely restricted in its use. A European panel later did the same. In July 2010 GlaxoSmithKline announced it would take a $2.4 billion charge against earnings to cover legal liabilities related to Avandia. (Six months later, the company took another charge of $3.4 billion.)

In October 2010 GlaxoSmithKline agreed to pay a total of $750 million—$150 million in connection with federal False Claims Act charges and $600 million for state claims—to settle civil and criminal complaints that it knowingly sold adulterated drugs produced at a subsidiary's troubled plant in Puerto Rico. Among the products were Avandia, Paxil and the baby ointment Bactroban.

In 2011 the U.S. law firm Hagens Berman filed suit against GlaxoSmithKline, charging that its predecessor company Smith, Kline and French conducted a trial of Thalidomide in the 1950s and buried evidence of the dangers of the German drug, which ended up causing thousands of horrific cases of deformities in children.

In July 2012 the U.S. Justice Department announced that GlaxoSmithKline would pay $3 billion to settle various criminal and civil charges, among which were allegations that the company withheld crucial safety data on Avandia from the FDA. Those charges accounted for $899 million of the total: $242 million in criminal fines and $657 million in civil payments ($508 million to the federal government and $149 million to states).

The company's commitment to Avandia paid off in mid-2013, when an FDA advisory panel called for easing restrictions on the drug.

Pricing and False Claim Controversies

In 1996 SmithKline Beecham was one of 15 drug companies that together agreed to pay more than $408 million to settle a class action lawsuit charging them with conspiring to fix prices they charged to thousands of independent pharmacies. In addition to contributing $30 million to the financial settlement, SmithKline agreed to supply the plaintiffs with a quantity of the generic version of its Tagamet ulcer medication worth $20 million.

In 1997, following an investigation dubbed Operation LabScam by federal investigators, SmithKline Beecham Clinical Laboratories agreed to pay $325 million to settle charges that it had overcharged Medicare by billing for millions of laboratory tests that were not

medically necessary, were not ordered by a physician or were not performed. At the time, the amount set a record for a healthcare-related civil settlement.

In 2000, after Maine passed a law allowing price controls on prescription drugs, SmithKline Beecham responded by warning it would no longer ship its products to wholesalers in the state.

In 2001 GlaxoSmithKline and other major pharmaceutical companies dropped a lawsuit they had filed to block a plan by the South African government to import relatively inexpensive drugs to deal with the country's AIDS epidemic.

In 2003 GlaxoSmithKline agreed to pay $87.6 million to the federal government to resolve charges that it sold its antidepressant Paxil and its allergy spray Flonase to the Medicaid program at inflated prices.

In 2004 GlaxoSmithKline announced that it would pay $175 million to settle a lawsuit brought by drug wholesalers contending that it violated antitrust laws by blocking cheaper generic forms of its Relafen arthritis medication.

In 2005 GlaxoSmithKline agreed to pay $150 million to resolve federal government allegations that the company violated the False Claims Act through fraudulent pricing and marketing of two anti-nausea drugs sold to the Medicare and Medicaid programs for use primarily by cancer patients. The following year, the company agreed to pay $70 million to settle related suits brought by state governments.

In 2006 GlaxoSmithKline agreed to pay $14 million to settle allegations by state governments that it inflated prices for Paxil by engaging in patent fraud, antitrust violations and frivolous litigation to maintain a monopoly and block generic versions of the medication from entering the market.

The $3 billion settlement GlaxoSmithKline reached with the federal government in 2012 included a payment of $300 million to resolve charges that the company reported false drug prices, allowing it to underpay rebates it owed under the Medicaid Drug Rebate Program and to overcharge certain Public Health Entities. Of the $300 million, $161 million was to go to the federal government, $119 million to the states and $20 million to Public Health Service entities.

In April 2013 the UK Office of Fair Trading charged GlaxoSmithKline with violating competition laws by paying other companies to delay the introduction of generic versions of its antidepressant Seroxat (sold in the U.S. as Paxil).

Marketing and Advertising Controversies

In 1993 the FDA ordered Glaxo to stop making what the agency called false and misleading statements about the effectiveness of the company's best-selling anti-ulcer drug Zantac.

In 2004 the FDA sent a warning letter to GlaxoSmithKline charging that a TV advertisement for Paxil was false and misleading. That same year, the FDA sent a warning letter to the company alleging that promotional materials for three hepatitis drugs contained false or misleading statements.

In 2008 the FDA sent a warning letter to GlaxoSmithKline alleging that materials the

company was sending health practitioners to promote its breast cancer drug Tykerb were misleading because they omitted serious risks.

Among the charges covered by the $3 billion settlement that the U.S. Justice Department reached with GlaxoSmithKline in 2012 were criminal and civil allegations relating to the unlawful marketing of Paxil, the antidepressant Wellbutrin and other drugs for unapproved purposes. That marketing allegedly included kickbacks paid to doctors and other health professionals to get them to prescribe and promote the drugs for those unauthorized uses. Payments also went to people such as radio personality Drew Pinsky, who was paid $275,000 by the company to promote Wellbutrin on his program.

The settlement included $757 million in criminal fines and forfeitures as well as $1.04 billion in connection with the civil charges—$832 million to the federal government and $210 million to state governments. GlaxoSmithKline was also compelled to sign a 122-page Corporate Integrity Agreement with the Office of Inspector General of the U.S. Department of Health and Human Services that lists numerous measures the company had to adopt to make it more likely to comply with federal laws and regulations.

In July 2013 the Chinese government accused Glaxo of using bribes, kickbacks and other fraudulent methods to increase its drug sales in China. The company was said to have laundered the payments through travel agencies. Glaxo was later fined $500 million in the matter.

Human Rights

Before Glaxo's infant formula business was sold off in the late 1980s, that operation was the subject of controversy. Like many other formula producers, Glaxo had been accused of violating World Health Organization standards for the marketing of formula in poor countries. Religious and public health advocates had pressured the World Health Organization to adopt guidelines to discourage aggressive marketing of the formula in situations where mothers were often compelled to mix the powder with impure water or dilute the formula to the extent that it became much less nutritional than breast milk.

Environmental

In 2008 the U.S. Justice Department announced that GlaxoSmithKline and two other companies would pay a $500,000 civil penalty in connection with the release of trichloroethylene (TCE) into the public drinking water system of Scottsdale, Arizona.

Executive Compensation

In 2003 shareholders in GlaxoSmithKline were the first to make use of a new investor-protection law enacted in Britain that year when they voted to reject a lucrative pay packages proposed for chief executive Jean-Pierre Garnier and other top executives.

Taxes

In 2006 GlaxoSmithKline said it would pay $3.1 billion to the U.S. Internal Revenue Service to resolve a 17-year dispute over the tax treatment of transactions between the company's U.S. operation and the parent company. The settlement, the largest in IRS history, focused on the issue of transfer pricing—a method by which transnational corporations artificially reduce their tax liabilities.

Employment Issues

In 1999 SmithKline Beecham agreed to pay $19,000 to settle allegations that the company retaliated against an employee who reported to management apparent violations of the anti-discrimination provisions of the Immigration and Nationality Act.

Watchdog Groups and Campaign

AIDS Healthcare Foundation

Center for Science in the Public Interest

Community Catalyst

Consumers International

Doctors Without Borders

Families USA

Interfaith Center on Corporate Responsibility

Oxfam International

Prescription Access Litigation (PAL) Project

Public Citizen Health Research Group

The Paxil Protest

Treatment Action Campaign

Key Books and Reports

A Healthy Business? World Health and the Pharmaceutical Industry by Andrew Chetley (1990).

Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients by Ben Goldacre (2012).

Benchmarking AIDS: Evaluating Pharmaceutical Company Responses to the Public Health Crisis in Emerging Markets (Interfaith Center on Corporate Responsibility, 2006).

Branding the Cure: A Consumer Perspective on Corporate Social Responsibility, Drug Promotion and the Pharmaceutical Industry in Europe (Consumers International, 2006).

Dare to Lead: Public Health and Company Wealth (Oxfam International, January 2001).

Glaxo: A History to 1962 by R.P.T. Davenport-Hines and Judy Slinn (1993).

GlaxoSmithKline: A Company Profile (Corporate Watch, November 2002).

GlaxoSmithKline Company Profile (SOMO, October 2004).

Investing for Life: Meeting Poor People's Needs for Access to Medicines through Responsible Business Practices (Oxfam International, 2007).

Merck v Glaxo: The Billion Dollar Battle by Matthew Lynn (1991).

Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Health: Mission to GlaxoSmithKline (United Nations Human Rights Council, May 5, 2009).

Side Effects: A Prosecutor, a Whistleblower, and a Bestselling Antidepressant on Trial by Alison Bass (2008).

Staff Report on GlaxoSmithKline and the Diabetes Drug Avandia (U.S. Senate Finance Committee, January 2010).

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