



Department of Justice

GLAXOSMITHKLINE SETTLEMENT

FACT SHEET

- GSK has agreed to plead guilty and pay \$3 billion as part of this criminal and civil resolution.
- Largest combined federal and state health care fraud recovery in a single global resolution in the history of the United States.

CRIMINAL RESOLUTION

- GSK has agreed to plead guilty to three misdemeanor violations of the Food, Drug and Cosmetic Act:
 - Regarding Paxil, GSK will plead guilty to distribution of a misbranded drug due to false and misleading labeling, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) & 352(a).
 - Regarding Wellbutrin, GSK will plead guilty to distribution of a misbranded drug due to inadequate directions for use, in violation of 21 U.S.C. §§ 331(a), 333(a)(1) & 352(f)(1).
 - Regarding Avandia, GSK will plead guilty to failure to report data to the FDA, in violation of 21 U.S.C. §§ 331(e), 333(a)(1) & 355(k)(1).
- The information, filed in the District of Massachusetts, alleges that:
 - **Paxil**
 - The FDA has never approved Paxil for any purpose for treating patients under age 18.
 - From 1999 to 2003, during sales calls, dinner meetings, spa programs, lavish weekend conferences to places such as Puerto Rico and Hawaii, through a false and misleading medical journal article, and through the distribution of free samples for patient use, GSK promoted Paxil to doctors for the treatment of depression and, to a lesser extent, obsessive-

compulsive disorder in patients under age 18.

- GSK conducted three placebo-controlled clinical studies to study Paxil's safety and efficacy in treating depression in patients under age 18. In all three studies, GSK failed to demonstrate efficacy on the endpoints identified in the study protocols.

- Nevertheless, GSK hired a contractor to write an article on one of the studies that was published in July 2001 in the Journal of the American Academy of Child and Adolescent Psychiatry (JAACAP). The article stated that Paxil "is generally well tolerated and effective for major depression in adolescents." The article did not explicitly state that the study failed to demonstrate efficacy on either of its two primary endpoints or on any of the secondary endpoints that had been identified in the study protocol.

- GSK's marketing team distributed the JAACAP article to all of the Paxil sales representatives with a cover memo that stated that Paxil had demonstrated "REMARKABLE Efficacy and Safety in the treatment of adolescent depression." Some GSK sales representatives used the article to urge doctors to prescribe Paxil to treat patients under age 18.

- GSK did not write a medical journal article about the other two unfavorable studies nor did it inform its sales representatives about the results of those studies.

o **Wellbutrin**

- At the time of the conduct relating to Wellbutrin at issue in this settlement, the only approved use of Wellbutrin was for Major Depressive Disorder, commonly known as depression.

- GSK promoted Wellbutrin for a variety of unapproved uses and with unapproved claims. For example, GSK promoted Wellbutrin for:
 - weight loss and obesity;
 - sexual dysfunction;
 - Attention Deficit Hyperactivity Disorder (ADHD), ADD (Attention Deficit Disorder), bipolar disease and anxiety;
 - addictions, including to drugs, alcohol and gambling;
 - patients under age 18, including children;
 - use as an add-on or in combination with other drugs;
 - use as an antidote for the side effects of other antidepressant medications; and
 - use in dosages contrary to that recommended in the label, with safety claims greater than those justified in the label.

- GSK targeted the promotion of Wellbutrin for unapproved uses especially in quality of life areas, e.g., enhancing sex life, losing weight, addressing substance addictions and attention issues. GSK promoted Wellbutrin as what some sales representatives referred to as “the happy, horny, skinny pill.”
 - GSK paid doctors to attend lavish meetings in places such as Jamaica and Bermuda during which GSK provided off-label information to encourage doctors to write Wellbutrin prescriptions for unapproved uses of the drug.
 - GSK called these frequent meetings “advisory board” or “consultant” meetings to create the pretense that GSK was gathering information and feedback from the doctors. In fact, there generally was little consulting provided by the doctors during these meetings and GSK made no real effort to capture and disseminate the advice it supposedly obtained.
 - GSK also sponsored extensive continuing medical education (CME) programs for doctors during which off-label information about Wellbutrin was disseminated. Although CME programs were ostensibly independent, providing doctors with objective medical information as opposed to pharmaceutical company marketing, in certain CME programs, GSK influenced the content, selected the location and the speakers, invited many of the attendees, and sometimes determined how much the speaker was paid.
- **Avandia**
- At the time of the conduct at issue, Avandia was FDA approved as an antidiabetic agent, that is, a drug which helps diabetes patients – whose bodies cannot control their blood sugar (called glucose) – a process known as glycemic control. Specifically, the FDA has approved Avandia as safe and effective for use in addition to diet and exercise to improve glycemic control in adults with type 2 diabetes.
 - Over time, the FDA added two black box warnings to the Avandia label – the strongest warning the FDA can require – to alert physicians to the potential for increased risk of congestive heart failure, and myocardial infarction (heart attack).
 - Drug manufacturers are required to include certain data relating to clinical experience in periodic reports to the FDA to allow the FDA to determine if a drug continues to be safe for its approved indications. Those periodic

reports provide a collection of data in such a way as to facilitate the FDA's ability to spot drug safety trends.

- Between 2001 and 2007, GSK failed to include certain required information in periodic reports to the FDA. The missing information included data regarding certain post-marketing studies, as well as data regarding two studies undertaken in response to European regulators' concerns about the cardiovascular safety of Avandia.
- GSK has agreed to pay \$1 billion in criminal penalties, which is the second-largest penalty for a drug company in a single criminal plea:
 - \$159,768,000 criminal fine for the misbranding of Paxil.
 - \$554,433,600 criminal fine for the misbranding of Wellbutrin.
 - \$43,185,600 criminal forfeiture related to Paxil and Wellbutrin.
 - \$242,612,800 criminal fine related to Avandia.
- The criminal plea includes an Addendum designed to ensure GSK's future compliance with the law.
 - GSK will be required to report to DOJ any probable violations of the Food, Drug and Cosmetic Act.
 - The board of directors and GSK's U.S. president will be required to annually certify that GSK has maintained appropriate compliance measures.
 - GSK will maintain certain compliance programs including the abolishment of incentive-based compensation for its sales representatives; full, fair and accurate reporting of scientific data; policies requiring appropriate contracting practices with payers; abolishment of any sales or marketing role by GSK in physician continuing independent medical education; and a requirement for confirmation that physician requests for off-label information about GSK drugs are truly unsolicited by GSK as opposed to driven by GSK marketing.
 - If GSK fails to maintain any of these policies or fails to provide the required reporting and certifications, the plea agreement includes a liquidated damages clause whereby GSK will pay to the United States \$20,000 for each day it is in violation of any provision.
- GSK has not yet entered a guilty plea. While the parties have agreed to the

disposition discussed above, it is subject to acceptance by the court.

CIVIL SETTLEMENT

- GSK will pay \$2 billion in civil damages to federal and state health care programs, which is the largest civil recovery from a drug company in a single global resolution:
 - \$1,043,000,000 in civil damages to resolve allegations relating to false claims arising from the off-label promotion and kickback allegations relating to Paxil, Wellbutrin, Advair, Lamictal, Zofran, Flovent, Imitrex, Lotronex and Valtrex.
 - \$657,000,000 in civil damages to resolve allegations relating to misrepresentations about Avandia.
 - \$300,000,000 in civil damages to resolve allegations relating to false reporting of best prices.
- The \$2 billion civil settlement is allocated as follows:
 - Federal Recovery: \$1,501,618,568.
 - State and Public Health Service (PHS) recovery: \$498,381,432.
- The federal portion of the settlement will be distributed among the following programs: Medicare, Medicaid, Department of Defense (TRICARE), Office of Personnel Management (Federal Employee Health Benefits Plan), Department of Veterans Affairs, U.S. Postal Service and Department of Labor (Office of Workers' Compensation Programs).
- There are three civil settlements:
 - One settlement resolves allegations relating to false claims to federal health care programs resulting from marketing and promotion practices, including off-label marketing. The United States alleges that:
 - GSK promoted Paxil, Wellbutrin, Advair, Lamictal and Zofran for uses that were not approved as safe and effective by the Food and Drug Administration.
 - GSK paid kickbacks to doctors to induce them to prescribe Advair, Flovent, Imitrex, Lotronex, Paxil, Wellbutrin, and Valtrex and other drugs, critically undermining the doctors' independent clinical judgment.

- A second settlement resolves allegations that GSK promoted Avandia to physicians and other health care providers with false and misleading representations, causing false claims to be submitted to federal health care programs. The United States alleges that:
 - GSK misleadingly represented that Avandia had a positive lipid, or cholesterol, profile despite having no well-controlled studies sufficient to support that message and despite information on the FDA-approved label stating that Avandia was associated with statistically significant increases in LDL and HDL cholesterol.
 - GSK sponsored programs which suggested cardiovascular benefits from Avandia therapy, despite warnings on the FDA-approved label regarding congestive heart failure and other cardiovascular issues.
- A third settlement resolves allegations that GSK reported false best prices to the Department of Health and Human Services and as a result underpaid quarterly rebates owed under the Medicaid Drug Rebate Program.
 - Under federal law, pharmaceutical companies are required to give Medicaid the best price on medications that they offer to any customer.
 - The United States contends that GSK had “bundled sales” arrangements that included steep discounts known as “nominal prices” and yet failed to take such contingent arrangements into account when calculating and reporting its best prices to HHS.

QUI TAM ACTIONS

- The off-label civil settlement also resolves allegations set forth in the following lawsuits filed against GSK under the qui tam, or whistleblower, provisions of the federal False Claims Act, 31 U.S.C. § 3730.
 - U.S. ex rel. Thorpe et al. v. Smith Kline Beecham Inc. and GlaxoSmithKline plc d/b/a GlaxoSmithKline, Civil Action No. 11-10398 (D. Mass, transferred from D. Colo.) (filed 1/1/03);
 - U.S. ex rel. Gerahty et al. v. GlaxoSmithKline PLC and SmithKline Beecham Corp. d/b/a GlaxoSmithKline, (D. Mass.), Civil Action Number 03-10641 (D. Mass.) (filed 4/7/03);
 - U.S. ex rel. Graydon v. GlaxoSmithKline plc, Civil Action No. 11-10741 (D. Mass.) (filed 6/5/09);

- U.S. ex rel. LaFauci v. GlaxoSmithKline plc, Civil Action No. 11-10921 (D. Mass.) (filed 8/7/09).
- There were no whistleblowers in the Avandia or pricing investigations.

ADMINISTRATIVE RESOLUTION

- As part of the settlement, GSK entered into a five-year Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services. The agreement requires enhanced accountability, increased transparency and wide-ranging monitoring activities conducted by both internal and independent external reviewers. Specifically, among other things, the agreement requires:
 - that GSK's board of directors annually review the company's compliance program and certify as to its effectiveness;
 - that GSK's president and key managers annually certify about compliance;
 - that GSK maintain its new sales compensation policy, which pays sales representatives based on product knowledge and quality of customer service rather than sales volume in the representative's territory;
 - that GSK change its executive compensation program to permit the company to recoup annual bonuses and long-term incentives from covered executives if they, or their subordinates, engage in significant misconduct. Under this program, GSK may recoup monies from executives who are current employees and those who have left the company;
 - that GSK notify health care payers about the settlement and follow specified policies in its contracts with health care payers so as not to reduce or alter rebates based upon appropriate formulary or prior authorization provisions consistent with the label;
 - that GSK implement a centralized process to identify and mitigate risks associated with promotional activities.
- If GSK fails to comply with its obligations, it risks exclusion from participation in Federal health care programs (for a material breach) and monetary penalties (for other breaches).

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