

Crime Does Pay ,Äi Big: GlaxoSmithKline Fined \$3 Billion; Stock Rises

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International pharmaceutical giant GlaxoSmithKline, LLC (GSK) recently [pleaded guilty](#) to alleged criminal activities and agreed to resolve civil issues including "unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices."¹ The alleged crimes committed by GSK include the following:

Paxil

- Unlawfully promoted Paxil for treating depression in patients under age 18, even though the FDA has never approved it for pediatric use.
- Participated in preparing, publishing and distributing a misleading medical journal article which reported 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.
- Did not make available data from two other studies in which Paxil also failed to demonstrate efficacy in treating depression in patients under age 18. (Paxil now includes a warning regarding the potential for suicidal behavior if taken by those under 18.)
- 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.

Wellbutrin

- Promoted Wellbutrin for weight loss, the treatment of sexual dysfunction, substance addictions and attention deficit hyperactivity disorder, among other off-label uses, even though it was only approved for [major depressive disorder](#).
- Paid millions of dollars to doctors to speak at and attend meetings, sometimes at lavish resorts, at which the off-label uses of Wellbutrin were routinely promoted.
- Used sales representatives, sham advisory boards, and supposedly independent continuing medical education (CME) programs to promote Wellbutrin for these unapproved uses.

Avandia

- Failed to include certain safety data about Avandia, a diabetes drug, in reports to the FDA that are meant to allow the FDA to determine if a drug continues to be safe for its approved indications and to spot drug safety trends.
- 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.

Civil Settlement Agreement

According to terms of the civil settlement agreement, GSK was found guilty of promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses, and paying kickbacks to physicians to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex; making false and misleading statements concerning the safety of Avandia; reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program.

The punishment: Pay \$3 billion to resolve its criminal and civil liability; execute a five-year corporate integrity agreement with the Department of Health and Human Services.

The above is taken directly from the press release issued by the U.S. Department of Justice.¹ And while this all sounds like a big bust for the feds, this is how GSK [reported the event](#):² "Under the terms of the settlement, GSK will plead guilty to misdemeanor violations"; "Fundamental changes to US compliance, marketing and selling procedures [were] implemented in recent years"; and "GSK will make payments totalling \$3 [billion] which are covered by existing provisions and will be funded through *existing cash resources*." [Emphasis added]

So, at the end of the day, after getting caught in a well-orchestrated scheme of fraud, kickbacks and rewards that influenced many MDs and potentially endangered the lives of millions of patients, many of those children, GSK pleads guilty to a few misdemeanors, pays some fines from cash reserves and agrees to marketing changes, most of which were already in place. In fact, "GSK stock rose after news of the settlement, climbing 1.6% to a share price of \$46.30."³

Perhaps the saddest part of all is that GSK can go right on selling the very drugs in question. It didn't lose its license to sell these drugs and is not banned from making more money in the Medicare and Medicaid programs.

Make no mistake: This was a marketing campaign that is probably similar to campaigns used to market most drugs. In this case, GSK got caught and had to give back some of its profits; but the power of Big Pharma is still growing and still impacting the health of most consumers.

References

1. "GlaxoSmithKline to Plead Guilty and Pay \$3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data." Department of Justice, Office of Public Affairs, July 2, 2012.
2. "GlaxoSmithKline Concludes Previously Announced Agreement in Principle to Resolve Multiple Investigations With US Government and Numerous States." GSK press release, July 2, 2012.
3. "GlaxoSmithKline Agrees to Pay \$3 Billion in Largest U.S. Healthcare Fraud Settlement." Modernhealthcare.com, posted July 2, 2012.

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