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Government Announces Largest Health Care Fraud Settlement in U.S. History; GlaxoSmithKline, LLC, Enters Corporate Integrity Agreement With Novel Provisions

Yesterday, the U.S. Department of Justice announced that GlaxoSmithKline, LLC ("GSK"), would pay $3 billion in criminal and civil penalties to resolve multiple investigations into the company's sales, marketing and pricing practices for nine of its drugs. Specifically, GSK agreed to plead guilty to criminal charges and pay $1 billion in criminal fines and forfeitures for:

- Marketing the antidepressant drug Paxil for unapproved, pediatric uses in violation of the misbranding provisions of the Federal Food, Drug, and Cosmetic Act ("FD&C Act").
- Off-label marketing of Wellbutrin, another drug approved for treating depression, by promoting the drug for the treatment of obesity, attention deficit hyperactivity disorder and sexual dysfunction, in violation of the FD&C Act's misbranding provisions.
- Failing to disclose safety data from studies of Avandia, the diabetes drug that now contains a black box warning regarding congestive heart failure and myocardial infarction, to the Food and Drug Administration ("FDA"), in violation of Sections 301(e) and 505(k) of the FD&C Act.

In the plea agreement, "GSK expressly and unequivocally admits that it committed the crimes charged [relating to off-label marketing of Paxil and Wellbutrin and failure to disclose Avandia safety data], and is in fact guilty of those offenses." A copy of the plea agreement in *United States v. GlaxoSmithKline LLC* is available here.

Although critics of the pharmaceutical industry have urged the criminal prosecution of executives or the barring of them from participating in federal health care programs, and although the government has expressed its desire to do so, no executive has been charged to date.

In addition, GSK agreed to pay an additional $2 billion to resolve civil allegations that caused false claims to be submitted to federal health care programs as a result of GSK's illegal promotional practices and payments to physicians. Whistleblowers (and the government) accused GSK of:

- Promoting Paxil, Wellbutrin, asthma drug Advair, anti-epileptic drug Lamictal and anti-nausea drug Zofran for off-label 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 about the safety of Avandia.
- Reporting false best prices and underpaying rebates owed under the Medicaid Drug Rebate Program.

The allegations included claims that GSK promoted Advair for first-line therapy for mild asthma patients, even though it was not FDA-approved or medically appropriate for such patients, and for treatment of chronic obstructive pulmonary disease with misleading claims about relevant treatment guidelines. The government also alleged that GSK promoted Lamictal, which was approved to treat epilepsy, for the treatment of neuropathic pain and pain management, and Zofran, which was only approved for postoperative nausea, for the treatment of morning sickness in pregnant women. It also alleged that GSK

paid kickbacks to doctors to induce them to prescribe GSK drugs. Although GSK agreed to settle the allegations, the company issued a statement making clear that the "civil settlement reached with the Government does not constitute an admission of any liability or wrongdoing in the selling and marketing of Lamictal, Zofran, Imitrex, Lotronex, Flovent, Valtrex, Avandia or Advair products, nor in its nominal pricing practices."

As part of the settlement, GSK agreed to a five-year corporate integrity agreement ("CIA") with the Office of the Inspector General ("OIG") at the U.S. Department of Health and Human Services ("HHS"). The CIA includes novel provisions that require GSK to change the way it does business, including:

- Changing the way its sales force is compensated, to remove compensation based on sales goals for territories.
- Changing its executive compensation program to permit the company to "clawback" or recoup annual bonuses and long-term incentives from executives if they, or their subordinates, engage in significant misconduct.

Specifically, under the CIA, GSK agreed that it

> will not provide financial reward (through compensation, including incentive compensation or otherwise) or discipline (through tangible employment action) [to] its prescribing-customer-facing field sales professionals (pharmaceutical sales representatives) or their direct managers based upon the volume of sales of GSK products within a given employee's own territory or the manager's district.

Instead, sales representatives will be evaluated based on their "business acumen, customer engagement, and scientific knowledge about GSK's products." In addition, GSK agreed to establish "a financial recoupment program that puts at risk of forfeiture and recoupment an amount equivalent to up to 3 years of annual performance pay (i.e., annual bonus, plus long-term incentives) for an executive who is discovered to have been involved in any significant misconduct." This clawback program applies to both current and former GSK employees. A copy of the GSK CIA is available here.

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Hunton & Williams LLP attorneys have helped guide pharmaceutical and medical device companies through investigations, settlements and post-settlement compliance activities. We have advised pharmaceutical and medical device clients on a wide array of enforcement and regulatory proceedings, including the Anti-Kickback Statute, the Prescription Drug Marketing Act, the False Claims Act, current good manufacturing practice ("cGMP") and quality system regulation requirements. We also have advised drug and device clients in Foreign Corrupt Practices Act ("FCPA") matters.

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