

**GOVERNMENT OF THE DISTRICT OF COLUMBIA**  
**Office of the Inspector General**

Inspector General  
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**GLAXOSMITHKLINE TO PAY \$3 BILLION TO SETTLE DRUG  
MARKETING AND PRICING CLAIMS**

Inspector General Charles J. Willoughby announced today that the District of Columbia, the states, and the federal government have reached an agreement in principle for the largest healthcare fraud settlement in U.S. history. Under the terms of the settlement, GlaxoSmithKline (GSK) has agreed to pay \$3 billion to resolve allegations that GSK engaged in various illegal schemes related to the marketing and pricing of drugs it manufactures. As part of the settlement, GSK will pay to the states and the federal government a total of \$2 billion in damages and civil penalties to compensate various federal healthcare programs, including Medicaid, for harm allegedly suffered as a result of the illegal conduct. As part of this settlement, D.C. will receive \$2,217,815 in recoveries from GSK. In addition, GSK has agreed to plead guilty to federal criminal charges relating to drug labeling and Federal Drug Administration (FDA) reporting and has agreed to pay a \$1 billion criminal fine in connection with these allegations.

The state and federal governments alleged that GSK engaged in a pattern of unlawfully marketing certain drugs for uses for which the drugs were not approved by the FDA, making false representations regarding the safety and efficacy of certain drugs, offering kickbacks to medical professionals, and underpaying rebates owed to government programs for various drugs paid for by Medicaid and other federally-funded healthcare programs. Specifically, the government alleged that GSK engaged in the following activities:

- Marketing Paxil, an anti-depressant, for off-label uses, such as use by children and adolescents;
- Marketing Wellbutrin, an anti-depressant, for off-label uses, such as weight loss and treatment of sexual dysfunction, and at higher-than-approved dosages;

- Marketing Advair, a drug used to treat asthma, for off-label uses, including first-line use for asthma;
- Marketing Lamictal, an anti-seizure drug, for off-label uses, including bipolar depression, neuropathic pain, and various other psychiatric conditions;
- Marketing Zofran, an anti-nausea drug, for off-label uses, including pregnancy-related nausea;
- Making false representations regarding the safety and efficacy of Paxil, Wellbutrin, Advair, Lamictal, Zofran, and Avandia, a drug used to treat diabetes;
- Offering kickbacks, including entertainment, cash, travel, and meals, to healthcare professionals to induce them to promote and prescribe Paxil, Wellbutrin, Advair, Lamictan, Zofran, the migraine drug Imitrex, Lotronex, used to treat irritable bowel syndrome, Flovent, an anti-asthma drug, and Valtrex, used to treat shingles and herpes; and
- Submitting incorrect pricing data for various drugs, thereby underpaying rebates owed to Medicaid and other federal healthcare programs.

As part of the settlement, GSK has also agreed to plead guilty to criminal charges that it violated the federal Food, Drug, and Cosmetic Act in connection with certain activities. The government alleges that GSK introduced Wellbutrin and Paxil into interstate commerce when the drugs were misbranded, meaning they contained labels that were not in accordance with their FDA approvals, and that GSK failed to report certain clinical data regarding Avandia to the FDA.

The settlement is based on four *qui tam* actions brought by private individuals pursuant to state and federal false claims acts and filed in or transferred to the United States District Court for the District of Massachusetts, as well as investigations conducted by the U.S. Attorney's Office for the District of Massachusetts and the Civil Frauds Division of the U.S. Department of Justice.

A National Association of Medicaid Fraud Control Units team participated in the investigation and analysis of the claims and conducted the settlement negotiations with GSK on behalf of the settling states. Team members included representatives from Massachusetts, California, Colorado, New York, and Ohio.

Inspector General Willoughby thanked the Department of Health Care Finance for providing claims data for analysis, and Medicaid Fraud Control Unit attorney Elaine Block and auditors Yolanda Mobuary and E-Rika Sellers for their work on this matter.