



## AG ANNOUNCES ALABAMA TO RECEIVE ALMOST SIX MILLION DOLLARS FROM GLAXOSMITHKLINE TO SETTLE DRUG MARKETING AND PRICING CLAIMS

(MONTGOMERY)--Attorney General Luther Strange announced today that Alabama and various other 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, Alabama will receive a total of \$5,909,500 in recoveries from GSK. In addition, GSK has agreed to plead guilty to federal criminal charges relating to drug labeling and FDA reporting and has agreed to pay a \$1 billion criminal fine in connection with those 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 Food and Drug Administration (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 the depression drug Paxil for off-label uses, such as use by children and adolescents;
- Marketing the depression drug Wellbutrin for off-label uses, such as for weight loss and treatment of sexual dysfunction, and at higher-than-approved dosages;

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- Marketing the asthma drug Advair for off-label uses, including first-line use for asthma;
- Marketing the seizure medication Lamictal for off-label uses, including bipolar depression, neuropathic pain, and various other psychiatric conditions;
- Marketing the nausea drug Zofran for off-label uses, including pregnancy-related nausea;
- Making false representations regarding the safety and efficacy of Paxil, Wellbutrin, Advair, Lamictal, Zofran, and the diabetes drug Avandia;
- 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, the irritable bowel syndrome drug Lotronex, the asthma drug Flovent, and the shingles and herpes drug Valtrex; 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 (“FDCA”) in connection with certain activities. The government alleges that GSK introduced Wellbutrin and Paxil into interstate commerce when the drugs were misbranded, meaning containing 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.