Press Releases

July 2, 2012

MADIGAN: GLAXOSMITHKLINE TO PAY $3 BILLION TO SETTLE DRUG MARKETING AND PRICING CLAIMS

Illinois Receives Nearly $25 Million from Largest-Ever Healthcare Fraud Settlement

Chicago — Attorney General Lisa Madigan joined her state counterparts and the federal government today to announce the largest healthcare fraud settlement in U.S. history with GlaxoSmithKline for $3 billion. The settlement, which includes nearly $25 million for Illinois, resolves allegations that the company engaged in illegal schemes in marketing and pricing its drugs to sell to manufacturers.

Madigan, the states and the federal government alleged that GSK unlawfully marketed certain drugs or "off-label uses," or uses not approved by the Food and Drug Administration, and made false representations regarding the safety and efficacy of certain drugs. GSK also allegedly offered kickbacks to medical professionals and underpaid rebates owed to government programs for various drugs paid for by Medicaid and other federally funded healthcare programs.

"Promoting drugs for unapproved, off-label uses is a potentially deadly practice that can threaten patients' lives when these drugs are promoted before they've been determined to be safe for a specific use. It also results in unwarranted costs to the state and taxpayers," Madigan said.

Under the settlement, GSK will 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. GSK also will pay 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. Illinois' share is nearly $25 million.

Specifically, the states and federal government alleged that GSK:

- Marketed the depression drug Paxil for off-label use, including use by children and adolescents;
- Marketed the depression drug Wellbutrin for off-label uses, such as for weight loss and treatment of sexual dysfunction, and at higher-than-approved dosages;
- Marketed the asthma drug Advair for off-label uses, including first-line use for asthma;
- Marketed the seizure medication Lamictal for off-label uses, including bipolar depression, neuropathic pain, and various other psychiatric conditions;
- Marketed the nausea drug Zofran for off-label uses, including pregnancy-related nausea;
- Made false representations regarding the safety and efficacy of Paxil, Wellbutrin, Advair, Lamictal, Zofran, and the diabetes drug Avandia;
- Offered 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
- Submitted incorrect pricing data for various drugs, thereby underpaying rebates owed to Medicaid and other federal healthcare programs.

GSK has also agreed to plead guilty to criminal charges that it violated the federal Food, Drug, and Cosmetic Act. The government alleges that GSK introduced Wellbutrin and Paxil into interstate commerce when the drugs were misbranded, or 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 U.S. 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.

Madigan's office previously entered into a $40.75 million civil consumer protection settlement with GlaxoSmithKline and 37 other state attorneys general in June 2011 over allegations the company violated drug manufacturing standards. The states alleged that from 2001 to 2004 drug batches were manufactured improperly and distributed to vulnerable patients nationwide and involved instances where certain batches were not sterilized or, in other cases, medication contained different dosages than indicated on the bottle, among other alleged violations.

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