Press Releases

**June 4, 2014**

# MADIGAN: $105 MILLION SETTLEMENT WITH GLAXOSMITHKLINE

***Attorneys General Alleged GSK Violated State Consumer Protection Laws by Illegally Marketing Advair, Paxil & Wellbutrin***

**Chicago** — Attorney General Lisa Madigan today announced a $105 million settlement with GlaxoSmithKline LLC (GSK). The settlement resolves allegations by Madigan and 44 other state attorneys general that GSK unlawfully promoted its asthma drug Advair and antidepressants Paxil and Wellbutrin.

Madigan and the attorneys general alleged GSK violated state consumer protection laws by misrepresenting the proper use for and qualities of Advair, Paxil and Wellbutrin and by marketing the drugs for "off-label uses," or uses that were not approved by the U.S. Food and Drug Administration (FDA). Illinois will receive $5.1 million under the settlement.

The attorneys general alleged GSK promoted Advair for off-label use to mild asthma sufferers. Mild asthmatics were steered to the drug for initial treatment, which was not a use approved by the FDA, even when substantially cheaper alternative medications were a better treatment option for these patients.

GSK also illegally marketed its antidepressant drug, Paxil, as safe and effective for children and teens, which the FDA had not approved, in spite of clinical trials that raised concerns the drug was associated with an increased risk of suicide.

The attorneys general alleged GSK also illegally marketed a second antidepressant drug, Wellbutrin, to children without FDA approval. GSK also unlawfully marketed Wellbutrin as an "off-label" drug for weight loss and to treat attention deficit disorder, addiction, anxiety and bi-polar disorder.

"GlaxoSmithKline put its business interests ahead of what was best for vulnerable patients," Madigan said. "This settlement will put a stop to the illegal marketing practices the company used to boost its sales."

Under the settlement, GlaxoSmithKline also must reform its marketing and promotional practices. Specifically, GSK is prohibited from:

- Making any claims about GSK products that are false, misleading, or deceptive;
- Making promotional claims, not approved or permitted by the FDA that a GSK product is better, more effective, safer, or has less serious side effects than has been demonstrated by substantial evidence or substantial clinical experience;
- Presenting favorable information or conclusions from a study that is inadequate in design, scope, or conduct to furnish significant support for such information or conclusions when presenting information about a clinical study regarding GSK products in any promotional materials;
- Provide samples of GSK products to those health care professionals who are not expected to prescribe the sampled GSK products for an approved use, but who would be expected to prescribe the sampled product for an off-label use; or
- Disseminate information describing any off-label use of a GSK product, unless such information and materials are consistent with applicable FDA regulations and FDA Guidance for Industry.

The settlement will require GSK to continue its so-called "Patient First Program" for five years. The Patient First Program reduces the level of financial incentives by the company to drug sales representatives in order to reduce deceptive marketing tactics. The settlement also requires scientifically trained personnel to develop and approve responses to health care provider questions to ensure their responses are unbiased and do not promote specific drugs.

Joining Madigan in today's settlement were attorneys general from the following states: Alabama, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Indiana, Iowa, Kansas, Kentucky, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, Wisconsin and Wyoming.

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