State of California ≈ Department of Justice
OFFICE of the ATTORNEY GENERAL
KAMALA D. HARRIS

Attorney General Kamala D. Harris Secures $105 Million Multistate Settlement with GlaxoSmithKline

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SAN FRANCISCO – Attorney General Kamala D. Harris today announced a $105 million multistate settlement with GlaxoSmithKline, LLC (GSK) to resolve allegations that the company unlawfully promoted its asthma drug, Advair, and antidepressant drugs, Paxil and Wellbutrin. California's portion of the settlement is the largest of any state, at $7,087,897.

For the first time in a settlement with a large pharmaceutical manufacturer, GSK is prohibited from providing incentive payments to its salespeople, which serve to encourage off-label promotion of drugs, and from using paid doctors to promote its products.

"Patient care is undermined when pharmaceutical companies promote uses for drugs that have not been approved by the FDA or pay medical professionals to promote certain drugs," Attorney General Harris said. "This settlement requires GSK to pay a significant penalty and imposes strong new rules designed to prevent future misrepresentations of GSK products."

The Complaint and Stipulated Judgment, submitted today to the San Diego County Superior Court, alleges that GSK violated state consumer protection laws by misrepresenting the uses and qualities of certain drugs. Specifically, GSK shall not:

- Make, or cause to be made, any written or oral claim that is false, misleading, or deceptive about any GSK product;
- Make promotional claims, not approved or permitted by the FDA that a GSK product is better, more effective, safer, or has less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience;
- Present 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 Guidances for Industry.

The Stipulated Judgment also requires GSK to continue its Patient First Program at least through March 2019. The Patient First Program reduces financial incentives for sales representatives to engage in deceptive marketing. In addition, the Judgment requires scientifically trained personnel to be ultimately responsible for developing and approving responses to health care provider questions and for these responses to be unbiased and non-promotional.

Forty-three additional states and the District of Columbia participating in the settlement include: Alabama, Arkansas, Colorado, Connecticut, Delaware, the District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, 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.

Copies of the documents filed with the court are attached to the electronic version of this release at: http://oag.ca.gov/news

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Attachment	Size
GSK Complaint.pdf	712.56 KB
GSK Stipulation For Entry of Final Judgment.pdf	2.59 MB