GOVERNMENT OF THE DISTRICT OF COLUMBIA
Office of the Inspector General

Inspector General
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GLAXOSMITHKLINE TO PAY $750 MILLION DOLLARS TO SETTLE ALLEGATIONS OF SELLING ADULTERATED DRUGS

Inspector General Charles J. Willoughby announced on November 26, 2010, that the District of Columbia and the states joined the federal government to reach an agreement in principle with the pharmaceutical manufacturer GlaxoSmithKline (GSK) to settle allegations that the company introduced adulterated drugs into interstate commerce. As a result, GSK will pay the states and the federal government $600 million in civil damages and penalties for Medicaid and other federally-funded health care programs. Additionally, a GSK subsidiary, SB Pharmaco of Puerto Rico, where the drugs were manufactured, has agreed to plead guilty to a felony violation of the Federal Food, Drug, and Cosmetic Act, and has agreed to pay $150 million in criminal fines and forfeitures.

The federal and state civil settlement, totaling $600 million dollars, resolves allegations of poor manufacturing practices in the GSK facility located in Cidra, Puerto Rico. The investigation grew out of a false claims action filed in 2004 in U.S. District Court in Massachusetts. The whistleblower's complaint alleged that GSK knowingly manufactured, distributed, and sold four products – Paxil CR, Avandamet, Kytril, and Bactroban – whose strength, purity, and/or quality fell below the standards required by the FDA:

Paxil CR: A controlled-release antidepressant that included split tablets, causing recipients to receive either product with no active ingredient and/or product with only the active ingredient layer and no controlled release mechanism;

Avandamet: A diabetes medication with tablets containing higher or lower amounts of the active ingredient than specified;

Kytril: An anti-nausea drug labeled as sterile but with some vials containing impurities; and

Bactroban: Antibiotic ointments and creams that, in some packages, were contaminated with microorganisms.

This settlement agreement reimburses the federal government and the participating states for the amounts paid by the Medicaid program as a result of GSK's conduct. Additionally, GSK has agreed to the terms of a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services Office of the Inspector General, which will require scrutiny of GSK's future manufacturing practices.

A team from the National Association of Medicaid Fraud Control Units represented the interests of the states during negotiations with GSK. Team members included representatives from New York, Massachusetts, and Ohio.