GlaxoSmithKline Pays $750 Million For Adulterated Drugs

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BOSTON (AP) — British pharmaceutical company GlaxoSmithKline PLC will pay $750 million to settle allegations that it knowingly manufactured and sold adulterated drugs, including the popular antidepressant Paxil, federal prosecutors in Massachusetts said.

U.S. Attorney Carmen Ortiz announced Tuesday that the London-based company will pay $150 million in criminal fines and $600 million in civil penalties related to faulty manufacturing processes at its plant in Cidra, Puerto Rico. The company allowed several drugs to be adulterated between 2001 and 2005, including Paxil CR, a skin-infection ointment called Bactroban, and an anti-nausea drug called Kytril, and a diabetes drug called Avandamet, Ortiz said.

GlaxoSmithKline said in a statement that it regrets operating the plant in a manner that violated good manufacturing practices. The company said the plant closed in 2009 due to declining demand for the medicines made there. Executives disclosed a $750 million charge to the company's second-quarter 2010 earnings on July 15 in connection with the agreement.

Ortiz said that no patients appeared to have been harmed by the quality problems at the plant, which included failing to ensure that Bactroban and Kytril were free of contamination from microorganisms and causing Paxil controlled release tablets to split, causing the potential distribution of tablets that did not have any therapeutic effect.

The investigation began after Cheryl Eckard, the company's global quality assurance manager, went to the Puerto Rico plant in August 2002 to lead a team of scientists and quality experts to correct manufacturing violations cited by the FDA.

Eckard discovered numerous violations, including a contaminated water system and an air system that allowed for cross-contamination between different products being made there. She reported the problems to her superiors and the company's compliance department, her lawyers said.

Eckard eventually went to the Food and Drug Administration to report the problems and later filed a whistleblower lawsuit.

Eckard, who worked at the company's offices in North Carolina, said she was fired in 2003 after repeatedly reporting the problems to the company.

"This is not something I ever wanted to do, but because of patient safety issues, it was necessary," she told reporters after the settlement was announced Tuesday.

As a whistleblower under the federal False Claims Act, Eckard will receive $96 million of the settlement paid by the company. The $600 million civil penalty will be paid to the federal government and the states to cover false claims submitted to the Medicaid program and other health care programs.

The agreement between SB Pharmco Puerto Rico Inc. — an indirect subsidiary of GlaxoSmithKline — is the fourth-largest amount ever paid by a pharmaceutical company to the government to resolve civil and criminal allegations, said Tony West, assistant attorney general for the civil division at the U.S. Department of Justice.

"At the end of the day, consumers have a right to rely on the representations companies make about the products they sell," said West, who joined Ortiz at a news conference in Boston to announce the settlement.

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