JUSTICE NEWS

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GlaxoSmithKline to Plead Guilty & Pay $750 Million to Resolve Criminal and Civil Liability Regarding Manufacturing Deficiencies at Puerto Rico Plant

BOSTON – SB Pharmco Puerto Rico Inc., a subsidiary of GlaxoSmithKline, PLC (GSK), has agreed to plead guilty to charges relating to the manufacture and distribution of certain adulterated drugs made at GSK's now-closed Cidra, Puerto Rico, manufacturing facility, the Justice Department announced today. The resolution includes a criminal fine and forfeiture totaling $150 million and a civil settlement under the False Claims Act and related state claims for $600 million.

The drugs, manufactured at the plant between 2001and 2005, are Kytril, Bactroban, Paxil CR and Avandamet. Kytril is a sterile anti-nausea medication. Bactroban is a topical anti-infection ointment commonly used to treat skin infections. Paxil CR is the controlled release formulation of the popular anti-depressant drug, Paxil, and Avandamet is a combination Type II diabetes drug.

The Food, Drug and Cosmetic Act (FDCA) prohibits the introduction or delivery for introduction into interstate commerce of any drug that is adulterated. Under the FDCA, a drug is deemed adulterated if the methods used in, or the facilities or controls used for, its manufacturing, processing, packing or holding did not conform to or were not operated or administered in conformity with current good manufacturing practice to assure that such drug met the requirements as to safety and had the identity and strength, and met the quality and purity characteristics, which it purported or was represented to possess.

The criminal information filed today alleges that SB Pharmco's manufacturing operations failed to ensure that Kytril and Bactroban finished products were free of contamination from microorganisms. The criminal information further alleges that SB Pharmco's manufacturing process caused Paxil CR two-layer tablets to split. The splitting, which the company itself called a "critical defect," caused the potential distribution of tablets that did not have any therapeutic effect and tablets that did not contain any controlled release mechanism.

The criminal information also alleges that Avandamet tablets manufactured by SB Pharmco did not always have the Food and Drug Administration (FDA)-approved mix of active ingredients, and, as a result, potentially contained too much or too little of the ingredient with the therapeutic effect. Finally, the criminal information alleges that SB Pharmco's Cidra facility suffered from longstanding problems of product mix-ups, which caused tablets of one drug type and strength to be commingled with tablets of another drug type and/or strength in the same bottle.

SB Pharmco has agreed to plead guilty to a criminal felony for releasing into interstate commerce adulterated Kytril, Bactroban, Paxil CR and Avandamet, in violation of the FDCA. Under the plea agreement, the company will pay a criminal fine of $150 million, which includes forfeiting assets of $10 million. The guilty plea and sentence is not final until accepted by the U.S. District Court in Boston.

Under the civil settlement, GSK has agreed to pay an additional $600 million to the federal government and the states to resolve claims that it caused false claims to be submitted to government health care programs for certain quantities of adulterated Kytril, Bactroban, Paxil CR and Avandamet. The United States contends that GSK sold certain batches, lots or portions of lots of drugs, the strength of which differed materially from, or the purity or quality of which fell materially below, the strength, purity or quality specified in the drugs' FDA applications or related documents. GSK thereby knowingly caused false and/or fraudulent claims to be submitted to, or caused purchases by, Medicaid and the other federal health care programs.

The federal share of the civil settlement amount is $436,440,000, and GSK will pay up to $163,560,000 to states that participate in the agreement.

"Adulterated drugs undermine the integrity of the FDA's approval process, can introduce substandard or ineffective drugs on to the market and, in the worst cases, can potentially put patients' health at risk," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "We will continue to work with our law enforcement partners to hold pharmaceutical companies accountable for this type of conduct and protect taxpayers from fraud, waste, and abuse."

"The industry has an obligation to ensure that all rules, regulations and laws are complied with," said U.S. Attorney Carmen Ortiz. "To do less erodes public confidence and compromises patient safety. As this investigation demonstrates, we will not tolerate corporate attempts to profit at the expense of the ill and needy in our society - or those who cut corners that result in potentially dangerous consequences to consumers."

"In fiscal year 2010, the Department of Health and Human Services, Office of the Inspector General (HHS-OIG) realized nearly $2.3 billion in settlements and judgments against the pharmaceutical industry," said Daniel R. Levinson, Inspector General of the Department of Health and Human Services. "If all pharmaceutical manufacturers complied with the law, there would be no need for such massive settlements and judgments. But until they stop stealing from taxpayers and threatening the health and lives of Americans – as is alleged here today – HHS-OIG will continue to vigorously pursue these corporations and their executives."

"FDA's manufacturing standards are designed to ensure the safety and quality of drugs distributed to American consumers," said Mark Dragonetti, Special Agent in Charge, FDA New York Field Office. "FDA expects pharmaceutical companies to abide by these manufacturing standards and correct deficiencies in an expedited manner. FDA and its law enforcement partners will continue to aggressively pursue those companies that place the public health at risk by distributing products that do not comply with all FDA requirements."

"This settlement demonstrates that the government will not stand for sub-standard drug product. As a result of this extensive investigation, millions of dollars will be returned to the Department of Veterans Affairs' Pharmaceutical Supply Fund for the direct benefit of our Nation's veterans," said Jeffrey G. Hughes, Special Agent in Charge, Office of Inspector General for the Department of Veterans Affairs.

"Federal employees deserve health care providers and suppliers, including drug manufacturers, that meet the highest standards of ethical and professional behavior," said Patrick E. McFarland, Inspector General of the U.S. Office of Personnel Management. "Today's settlement reminds the pharmaceutical industry that they must observe those standards and reflects the commitment of Federal law enforcement organizations to pursue improper and illegal conduct that places health care consumers at risk."

The civil settlement resolves one lawsuit filed in federal court in the District of Massachusetts under the *qui tam*, or whistleblower, provisions of the False Claims Act, which allow private citizens to bring civil actions on behalf of the United States and share in any recovery. As part of today's resolution, the whistleblower - Cheryl Eckard - will receive approximately $96 million from the federal share of the settlement amount.

The criminal case is being prosecuted by the U.S. Attorney's Office for the District of Massachusetts and the Department of Justice's Office of Consumer Litigation. The civil settlement was negotiated by the U.S. Attorney's Office for the District of Massachusetts and the Civil Division's Commercial Litigation Branch. The HHS Office of Counsel to the Inspector General, the Center for Medicare and Medicaid Services, FDA's Office of Chief Counsel, and the National Association of Medicaid Control Units provided assistance.

The case was investigated by agents from the FBI, the Department of Veterans Affairs, Office of the Inspector General, HHS-IG, the FDA's Office of Criminal Investigations, the Defense Criminal Investigative Service and the Office of the Inspector General for the Office of Personnel Management.

This settlement is part of the government's emphasis on combating health care fraud. One of the most powerful tools in that effort is the False Claims Act, which the Justice Department has used to recover approximately $4.2 billion since January 2009 in cases involving fraud against federal health care programs. The Justice Department's total recoveries in False Claims Act cases since January 2009 have topped $5.4 billion.

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Civil Division

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