# Department of Justice

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**District of Massachusetts**

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## GLAXOSMITHKLINE WILL PLEAD GUILTY AND PAY $750 MILLION TO RESOLVE MANUFACTURING DEFICIENCIES AT PUERTO RICO PLANT

Boston, Mass. - The Justice Department announced today that SB Pharmco Puerto Rico, Inc., a subsidiary of GlaxoSmithKline, PLC ("GSK"), has agreed to plead guilty to charges relating to the manufacturing and distribution of certain adulterated drugs made at GSK's now-closed Cidra, Puerto Rico, manufacturing facility. 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 2001 and 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 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. It is further alleged 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.

According to the information, Avandamet tablets manufactured by SB Pharmco did not always have the 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, it is alleged in the criminal information 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.

Under the plea agreement, the company will pay a criminal fine of $150 million including forfeiting assets of $10 million. A date for the plea hearing has not been set.

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 government contends that GSK knowingly caused false and/or fraudulent claims to be submitted to, or caused purchases by, the Medicaid Program and the other federal health care programs, by selling drugs that did not meet the quality specified in the drugs' NDAs.

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

U.S. Attorney Carmen Ortiz said, "The industry has an obligation to ensure that all rules, regulations and laws are complied with. 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."

"This resolution demonstrates the Department of Justice's ongoing dedication to taking action against pharmaceutical fraud in all its forms," said Tony West, Assistant Attorney General for the Civil Division of the Department of Justice. "The knowing, unlawful distribution of drugs whose strength, purity, and quality are not reliable undermines the integrity of our health care system and we will continue to pursue these types of violations."

"In fiscal year 2010, 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 -- 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, 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."

FBI SAC Richard DesLauriers said, "The completion of this investigation reflects law enforcement's efforts to make companies like GlaxoSmithKline accountable for knowingly manufacturing and releasing defective products to millions of adults and children suffering from diabetes, depression, and skin infection. To avoid lost profits, GlaxoSmithKline intentionally disregarded the potential harmful effects of these defective drugs on consumers. The FBI will continue to work collaboratively with our law enforcement partners to identify individuals and companies who seek to line their pockets at the expense of the health care system and safety of each of us."

"The Defense Criminal Investigative Service (DCIS) and the DoD's Office of Inspector General are committed to ensuring that TRICARE, the Defense Department's health care program, continues to provide safe and superior medical care to America's military members and their families. A vital part of that effort is to ensure that drugs purchased by the DoD are manufactured in accordance with the appropriate rules and regulations. The successful resolution of this case demonstrates the importance of joint investigations to address and combat pharmaceutical fraud," said Leigh-Alistair Barzey Resident Agent-in-Charge of the U.S. Department of Defense, Defense Criminal Investigative Service, Boston Resident Agency.

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.

This settlement is part of the government's emphasis on combating health care fraud and another step for the HEAT initiative, which was announced by Attorney General Holder and Secretary Sebelius in May 2009. The partnership between the two departments has focused efforts to reduce and prevent Medicare and Medicaid fraud through enhanced cooperation. One of the most powerful tools in that effort is the False Claims Act, which the Department of Justice has used to recover almost $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 are over $5.4 billion.

United States Attorney Carmen M. Ortiz; Tony West, Assistant Attorney General of the Justice Department's Civil Division; Richard DesLauriers, Special Agent in Charge of the Federal Bureau of Investigation- Boston Field Office; Jeffrey Hughes, Special Agent in Charge of the U.S. Department of Veterans Affairs, Office of the Inspector General, Office of Investigations- Northeast Field Office; Susan J. Waddell, Special Agent in Charge of Health and Human Services, Office of the Inspector General; Mark Dragonetti, Special Agent in Charge of the Food and Drug Administration, Office of Criminal Investigations; Leigh-Alistair Barzey, Resident Agent In Charge of the Defense Criminal Investigative Service, Boston Resident

Agency, and Drew Grimm, Special Agent in Charge of the Office of Personnel Management, Office of the Inspector General, Eastern Operations, announced the settlement today.

The criminal and civil cases were investigated and prosecuted by Assistant United States Attorneys Shannon T. Kelley and Susan G. Winkler of the United States Attorney's Office for the District of Massachusetts and Trial Attorney Mark L. Josephs of the Justice Department's Office of Consumer Litigation. The civil settlement negotiation was handled by the United States Attorney's Office for the District of Massachusetts and Trial Attorney Jamie A. Yavelberg of the Commercial Litigation Branch of the Justice Department's Civil Division. 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 in the investigation and resolution.

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