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## GLAXOSMITHKLINE PAYS \$750 MILLION FOR FRAUD ON MEDICAID: GETNICK & GETNICK LLP ANNOUNCES FIRST WHISTLEBLOWER RECOVERY FOR PHARMACEUTICAL MANUFACTURING VIOLATIONS

**BOSTON (October 26, 2010)** – GlaxoSmithKline (GSK) has agreed to pay the government \$750 million to settle civil and criminal charges that it manufactured and sold adulterated drug products to Medicaid and other government health plans, the Department of Justice announced today. The settlement was the result of a whistleblower lawsuit filed in 2004 by the law firm of Getnick & Getnick LLP on behalf of Cheryl Eckard, a former Quality Assurance Manager with GSK.

This is a groundbreaking case, the first time the whistleblower law has been successfully used to hold drug makers accountable for violations of government manufacturing standards. The civil settlement of \$600 million resolves charges that GSK released to the market Bactroban ointment, a topical antibiotic used to treat skin infections in babies, that contained microorganisms and Kytril injection, an anti-nausea drug used by cancer patients, that was not sterile. The settlement also covers the release of Paxil CR tablets that lacked the active ingredient and Avandamet tablets that were superpotent and subpotent. Paxil CR is an anti-depressant and Avandamet is a derivative of the diabetes drug Avandia. GSK also paid a criminal fine of \$150 million.

GSK reached the settlement with the U.S. Attorney's Office in Boston after more than six years of investigation and negotiations, which began when Ms. Eckard reported GSK's fraud to the FDA and filed a *qui tam* whistleblower lawsuit. This law allows a private citizen with knowledge of fraud on the government to sue on the government's behalf and receive a share of the proceeds. Ms. Eckard was fired by GSK in 2003 after repeatedly complaining to management about conditions at its former top-producing plant in Cidra, Puerto Rico.

"The success of this whistleblower lawsuit will change the way that drug companies run their factories," said Neil Getnick, managing partner of the Getnick firm. "Now every employee who works with manufacturing issues -- from quality assurance executives like Cheryl Eckard to

machine operators -- has a viable option if they have evidence that management is putting profits ahead of patient safety by letting bad products out the door."

"Drug manufacturing is vulnerable to abuse because consumers can't see the defects," said Getnick partner Lesley Ann Skillen. "Once the pill is swallowed, it's gone and there may be no way of telling whether someone got sick because the product was bad. As a result of this settlement and guilty plea, drug makers will now have more reason to live up to their motto that patient safety is their first priority."

In August 2002, Ms. Eckard, then a Global Quality Assurance Manager with GSK, was sent to the Cidra factory to lead a team of 100 scientists and quality experts brought from around the globe to fix manufacturing violations cited by the FDA. Cidra was then GSK's No. 1 factory in the world, making over 20 products worth \$5.5 billion annually, including blockbuster drugs Avandia, Paxil and Coreg.

What she discovered went far beyond the manufacturing violations previously uncovered by the FDA. Her whistleblower lawsuit, filed by the Getnick firm in February 2004, included details about mixed-up products, super and subpotent diabetes drugs, an area of the factory used to make injectible drugs that was not sterile, air handling systems that misdirected the flow of product powders, a water system contaminated with microorganisms, and a host of other manufacturing and quality testing problems that led her to conclude that GSK could not assure that its product was free from contamination and made according to the drug formula registered with the FDA.

From August 2002 to her firing in May 2003, Ms. Eckard urged GSK managers to take swift and decisive action at Cidra, including shutting down the plant. She made a full report to the GSK Compliance Department, which treated her complaints as unsubstantiated. She then reported the fraud to the FDA in San Juan.

The FDA executed search warrants in October 2003 and in February 2005 seized all stocks of Avandamet and Paxil CR in the largest seizure in FDA history, estimated by the FDA to be worth \$2 billion. The FDA also placed the Cidra plant under a Consent Decree, requiring that all products released to the market be approved by an independent monitor. The Cidra plant closed in 2009.

"Cheryl Eckard is a role model for whistleblowers," said Skillen. "Cheryl and our firm worked with the government and established a true public-private partnership. This result is a great credit to the vision and talent of the government's team in the Boston U.S. Attorneys Office, the Department of Justice, the VA, FDA, FBI, HHS, DCIS, OPM and other federal agencies, and the state Medicaid Fraud Control Units."

"The 'take-away' for corporate America should be that dedicated employees who try to do the right thing can't be silenced and made to go away," said Getnick. "The whistleblower laws -- which now cover tax, securities and commodities fraud, as well as health care and other frauds on federal and state government programs -- make sure that they have a voice and a remedy."

Ms. Eckard's lawsuit was filed under the False Claims Act, a Lincoln-era law that allows private citizens with knowledge of fraud on the government to sue and share in the proceeds of the recovery. Amendments passed in 1986 and in 2009 and 2010 have made the False Claims Act the government's chief weapon in the war on fraud against taxpayers.

Lead counsel for Ms. Eckard at Getnick & Getnick LLP were Neil Getnick and Lesley Ann Skillen, assisted by partners Judge Margaret Finerty and Richard Dircks, counsel Michael Getnick of Getnick Livingston Atkinson & Priori LLP and Boston counsel Scott Tucker of Tucker, Heifetz & Saltzman LLP. The federal government's team was led by Assistant U.S. Attorneys Shannon Kelley, Susan Winkler and Sara Bloom of the Boston U.S. Attorney's Office, Department of Justice Trial Attorney Mark Josephs, VA OIG Special Agent Donna Neves, and FBI Special Agent Rita Iacone. The state governments' team was led by Jay Spears, Robert Patten and John Guthrie for the National Association of Medicaid Fraud Control Units.

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Getnick & Getnick LLP is a Manhattan-based law firm, focusing on business integrity and antifraud litigation, including:

- \* Major qui tam whistleblower cases. The firm's lawsuit against Bayer Corporation for Medicaid drug pricing fraud, in which they represented a Bayer marketing executive, resulted in a \$257 million recovery in 2003. The firm's lawsuit against Laboratory Corporation of America, in which they represented a North Carolina doctor, led to a \$182 million recovery in 1996.
  - \* Representing individuals and companies victimized by business crime.
- \* Corporate integrity monitoring and compliance counseling. Public and privately held companies retain the Getnick firm to undertake internal investigations and monitor their operations. The firm was one of four integrity monitors selected by the City of New York for the World Trade Center site cleanup, monitoring the activities and financial requisitions of contractors and subcontractors.