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DOJ Escalates Its War on Health Care Fraud:

GlaxoSmithKline Agrees to Pay Record-setting $3 Billion to Settle U.S. Investigations

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British pharmaceutical company GlaxoSmithKline (GSK) announced on November 3, 2011, that it had reached an agreement in principle with the United States government to resolve multiple federal investigations regarding the company's alleged promotion of drugs for unapproved uses and other matters. As part of the settlement, GSK agreed to pay civil and criminal fines totaling $3 billion dollars. The $3 billion settlement is the largest in health care fraud history, surpassing the $2.3 billion paid by Pfizer in 2009 to settle allegations of off-label promotion of a number of its drugs.

Although GSK expects that the settlement will not be finalized until next year, it will address civil and criminal liabilities related to a number of major investigations, including:

- The investigation begun in 2004 by the U.S. Attorney's Office for the District of Colorado and later taken over by the District of Massachusetts into GSK's sales and marketing practices for several top-selling drugs, including Wellbutrin, Paxil, and Advair. The investigation led to the indictment of GSK's in-house counsel, Lauren Stevens, for obstruction of justice and making false statements in connection with letters she signed responding to Food and Drug Administration inquiries about the company's marketing of Wellbutrin. The case against Stevens went to trial earlier this year and was dismissed when the judge ruled that, based on the evidence presented at trial by the prosecution, there was no way a reasonable jury could convict Stevens.
- Department of Justice's (DOJ) investigation of GSK's use of the nominal price exception under the Medicaid Rebate Program. The investigation involved multiple pricing arrangements and possible bundled sales deals dating back to 1994.
- DOJ's investigation of the marketing and development of the diabetes drug Avandia. Avandia, which has been linked to heart attack risks, was withdrawn from the European market last year, and the Food and Drug Administration has severely restricted sales in the United States.

The record-breaking settlement was announced one day after Assistant Attorney General Tony West spoke at the 12th Annual Pharmaceutical Regulatory and Compliance Congress, where he announced that "[f]or every dollar Congress has provided for health care enforcement over the past three years, [the Department of Justice has] recovered nearly seven." West affirmed that since the formation of the Health Care Fraud Prevention and Enforcement Action Team (HEAT) in May 2009, DOJ has opened more health care fraud investigations, charged more criminal health care fraud defendants, and obtained more money on behalf of taxpayers—more than $8 billion in settlements, judgments, penalties, and fines—than ever before. West made clear that "some of [DOJ's] most significant enforcement work, both civilly and criminally, involves health care fraud in the pharmaceutical industry."

Significantly, West closed his remarks by affirming that DOJ will demand accountability with "creative negotiating resolutions," such as prosecuting individuals under the *Park* doctrine, which allows responsible corporate officers to be held strictly liable for criminal violations of the Food, Drug, and Cosmetic Act.

West's statements echo similar remarks in the past three years from officials that the U.S. government engaged in an aggressive, coordinated, and sustained effort to investigate and prosecute pharmaceutical, medical device, and biotech companies suspected of health care fraud. The $3 billion settlement is consistent with West's statement that DOJ "will always seek to disprove the ill-advised notion that health care fraud enforcement is simply the cost of doing business by insisting on judgments, convictions, settlements, penalties and fines that eliminate any benefit that may be obtained from engaging in unlawful conduct in the first place."

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