

# GlaxoSmithKline to pay \$3 billion for health fraud

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In this Jan. 20, 2010 file photo, Andrew Witty, CEO of GlaxoSmithKline, speaks in New York. GlaxoSmithKline LLC will pay \$3 billion and plead guilty to promoting two popular drugs for unapproved uses and to failing to disclose important safety information on a third in the largest health care fraud settlement in U.S. history, the Justice Department said Monday. (AP Photo/Mark Lennihan, File)

(AP) — GlaxoSmithKline LLC will pay \$3 billion and plead guilty to promoting two popular drugs for unapproved uses and to failing to disclose important safety information on a third in the largest health care fraud settlement in U.S. history, the Justice Department said Monday.

Accompanying the criminal case was a civil settlement in which the government said the company's improper marketing included providing doctors with expensive resort vacations, European hunting trips, high-

paid speaking tours and even tickets to a Madonna concert.

The \$3 billion combined criminal-civil fine will be the largest penalty ever paid by a drug company, Deputy Attorney General James M. Cole said. The corporation also agreed to be monitored by government officials for five years to attempt to ensure the company's compliance, Cole said.

"Let me be clear, we will not tolerate health care fraud," Cole told a news conference at the Justice Department. He would not say whether any company executives were under investigation. The company's guilty plea and sentence have to be approved by a federal court in Massachusetts.

"For far too long, we have heard that the pharmaceutical industry views these settlements merely as the cost of doing business," Acting Assistant Attorney General Stuart F. Delery, head of Justice's civil division, said at the news conference. "That is why this administration is committed to using every available tool to defeat health care fraud."

Delery added, "Today's resolution seeks not only to punish wrongdoing and recover taxpayer dollars, but to ensure GSK's future compliance with the law." He noted that a similar recent settlement with Abbott Laboratories also included continuing compliance monitoring.

GlaxoSmithKline CEO Sir Andrew Witty expressed regret and said they have learned "from the mistakes that were made."

"Today brings to resolution difficult, long-standing matters for GSK," he said in a statement. "Whilst these originate in a different era for the company, they cannot and will not be ignored."

Crimes and civil violations like those in the GlaxoSmithKline case have

been widespread in the pharmaceutical industry and have produced a series of case with hefty fines. One reason some have said the industry regards the fines as simply a cost of doing business is because aggressively promoting drugs to doctors for uses not officially approved — including inducing other doctors to praise the drugs to colleagues at meetings — has quickly turned numerous drugs from mediocre sellers into blockbusters, with more than \$1 billion in annual sales.

In the last few years, the Justice Department has become much more aggressive in pursuing such fraud, often in whistleblower cases taken on by a handful of U.S. attorneys focused on such fraud. Among the most active are the U.S. attorneys in Boston, Philadelphia and San Francisco — all in regions with numerous pharmaceutical and biotech company operations.

The prior record-setting case involved Pfizer Inc., the world's biggest drugmaker. Pfizer paid the government \$2.3 billion in criminal and civil fines for improperly marketing 13 different drugs, including Viagra and cholesterol fighter Lipitor. Pfizer was accused of encouraging doctors to prescribe its drugs with free golf, massages, and junkets to posh resorts.

It is illegal to promote uses for a drug that have not been approved by the Food and Drug Administration — a practice known as off-label marketing.

Prosecutors said GlaxoSmithKline illegally promoted the drug Paxil for treating depression in children from April 1998 to August 2003, even though the FDA never approved it for anyone under age 18. The corporation also promoted the drug Wellbutrin from January 1999 to December 2003 for weight loss, the treatment of sexual dysfunction, substance addictions and attention deficit hyperactivity disorder, although it was only approved for treatment of major depressive disorder.

Justice Department officials also said that between 2001 and 2007 GlaxoSmithKline failed to report to the FDA on safety data from certain post-marketing studies and from two studies of the cardiovascular safety of the diabetes drug Avandia. Since 2007, the FDA has added warnings to the Avandia label to alert doctors about potential increased risk of congestive heart failure and heart attack.

The drug corporation also agreed to resolve civil liability for promoting the drugs Paxil, Wellbutrin, Advair, Lamictal and Zofran for off-label, non-covered uses. In the civil settlement, the government said Advair was promoted as a first-line therapy for mild asthma though not approved for that and for chronic obstructive pulmonary disease with misleading claims. It said the anti-epileptic medicine Lamictal was promoted for off-label psychiatric uses, neuropathic pain and pain management. And it said certain forms of Zofran, approved only for post-operative nausea, were promoted to treatment of morning sickness in pregnant women.

The company also resolved accusations that it paid kickbacks to doctors to prescribe those drugs as well as the drugs Imitrex, Lotronex, Flovent and Valtrex.

"GSK's sales force bribed physicians to prescribe GSK products using every imaginable form of high priced entertainment, from Hawaiian vacations to paying doctors millions of dollars to go on speaking tours to a European pheasant hunt to tickets to Madonna concerts, and this is just to name a few," said Carmin M. Ortiz, U.S. attorney in Massachusetts.

Of the penalties, \$1 billion covers criminal fines and forfeitures and \$2 billion is for civil settlements with the federal government and the state governments of Massachusetts and Colorado.

In a statement, GlaxoSmithKline said it disagreed with some statements

the Justice Department made in court papers. For example, the company said its settlement with the government does "not constitute an admission of any liability or wrongdoing in the selling and marketing of Lamictal, Zofran, Imitrex, Lotronex, Flovent, Valtrex, Avandia or Advair products. The government also made allegations about Paxil, Wellbutrin that the company did not admit."

"The civil settlement agreement contains many allegations that are either inaccurate or incomplete, that selectively tell only parts of the story, and that draw unwarranted conclusions from disputed facts," the company said.

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