

## More Big Pharma Companies Cough Up Big Dollars in DOJ Settlements

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The parade of major drug companies coughing up nine-digit or ten-digit dollar amounts in settlements with the U.S. government is continuing.

GlaxoSmithKline recently broke a record by agreeing to pay the federal government \$3 billion to settle an illegal pharmaceutical marketing case. This surpasses the previous record of \$2.3 billion paid by Pfizer in 2009 over the marketing of its Bextra painkiller and other drugs. The same year, Eli Lilly & Co. paid \$1.4 billion in a settlement concerning sales of its Zyprexa anti-psychotic medicine. In late November, Merck & Co. agreed to pay \$950 million and plead guilty to a criminal misdemeanor charge to resolve allegations that it illegally promoted its former painkiller Vioxx and deceived the government about the drug's safety.

As these settlement amounts skyrocket, the industry is left wondering just how high they can go and how much the government will demand.

The huge Glaxo settlement covers civil and criminal liabilities following an eight-year-old probe into the company's marketing of several top-selling drugs. Most prominently, the settlement resolves charges that Glaxo illegally marketed the diabetes drug Avandia by paying doctors to promote it and manipulating medical research to downplay associated heart risks. It also follows the investigation of Glaxo's off-label marketing of anti-depression drug Wellbutrin, and the company's alleged misrepresentation of the potential suicide risk associated with another anti-depression medication, Paxil.

As a spin-off from the Wellbutrin probe, Lauren Stevens, a former vice president and associate general counsel of GlaxoSmithKline, faced criminal charges of obstruction of justice and making false statements to the Food and Drug Administration earlier this year. However, in a highly publicized and damaging loss for the Justice Department, a federal judge in Maryland acquitted her on all charges.

In June, Glaxo's U.S. subsidiary agreed to pay more than \$40 million to settle complaints about manufacturing processes at a plant in Puerto Rico, which has been closed. The company also paid a \$750 million fine in 2010 related to the Puerto Rico plant. Despite the huge cost of these settlements, some see them simply as the cost of doing business for these major pharmaceutical companies.

Still, we have to ask why the Department of Justice seems to be targeting this industry. Is it because they can pull in large profits in good years, when their blockbuster drugs remain under patent control? Of course, quite often the major pharma companies find their pipeline of inventions fairly narrow and their major inventions long since in the hands of the generic-drug companies.

As the companies' biggest client, the government has the power to strong arm them into settlement. The current cases prove, yet again, that the Department of Justice will continue to prioritize the issue of illegal pharmaceutical marketing and pursue larger and larger settlements against companies in this industry. They are certainly forewarned.

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