GlaxoSmithKline Pays $150 Million To Settle Drug Pricing Fraud Case

WASHINGTON, D.C. - GlaxoSmithKline has paid over $150 million to resolve allegations that the company violated the False Claims Act through fraudulent drug pricing and marketing of two anti-emetic drugs, Zofran and Kytril, used primarily in conjunction with oncology and radiation treatment, the Justice Department announced today.

The United States alleged in settlement documents that GlaxoSmithKline—one of the world's largest pharmaceutical manufacturers—engaged in a scheme to set and maintain fraudulent and inflated prices for Zofran and Kytril knowing that federal healthcare programs established reimbursement rates based on those prices. The difference between the reimbursement rate of the federal health care programs and the actual price paid by healthcare providers for a drug is commonly known as the "spread." The larger the spread on a drug, the larger the profit or return on investment for the provider. GlaxoSmithKline allegedly used the spread to market, promote, and sell the drugs to existing and potential customers. Because reimbursement from federal programs was based on the fraudulent, inflated prices, the United States contended that GlaxoSmithKline caused false and fraudulent claims to be submitted to federal healthcare programs.

"This agreement marks another in a series of cases in which a pharmaceutical manufacturer has settled claims that its fraudulent drug pricing cost federal healthcare programs and taxpayers millions of dollars," said Assistant Attorney General Peter D. Keisler of the Justice Department's Civil Division. "The Justice Department will continue to pursue these types of fraud schemes vigorously to make clear that we will not tolerate fraudulent pricing practices designed to reap profits for drug companies and doctors at the expense of healthcare programs for the poor and the elderly."

The United States also alleged that, with respect to Kytril, the drug company engaged in a "double dipping" billing scheme by encouraging customers to pool leftover vials of Kytril to create an extra dose, which then would be administered to a patient and re-billed to Medicare and other federal healthcare programs.

"Fraudulent pricing of prescription drugs can cost American taxpayers millions of dollars and undermine the financial integrity of the healthcare system," said U.S. Attorney Michael J. Sullivan of the District of Massachusetts. "To safeguard our nation's healthcare programs we will continue to aggressively investigate and prosecute healthcare fraud violations whether by pharmaceutical companies or individual practitioners."

"As our nation struggles to contain healthcare costs, we must ensure that drug manufacturers do not take advantage of the poor, the elderly or the sick by illegally inflating the price of prescription drugs. That a manufacturer would fraudulently inflate the cost of a drug used primarily to reduce the side effects of cancer treatments is unconscionable," said U.S. Attorney R. Alexander Acosta of the Southern District of Florida.

The investigation commenced after the filing of a civil False Claims Act suit by a small, home-infusion company, Ven-A-Care of the Florida Keys, Inc., and its principals. The civil False Claims Act allows for private persons to file whistleblower suits to provide the government information about wrongdoing. Where persons submit or cause others to submit false or fraudulent claims to the United States, the government is entitled to recover treble damages and $5,500 to $11,000 for each false or fraudulent claim. In cases in which the government is successful in resolving or litigating its claims, the whistleblower may receive a share of the recovery by receiving from 15-25% of the amount recovered. As part of this settlement, the Ven-A-Care whistleblowers will receive a share of approximately $26 million.

As part of a condition for doing business in the future with providers who do business with the Medicare and Medicaid programs, GlaxoSmithKline has agreed to enter into an addendum to its existing Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services that, among other things, will require the company to report accurate average sales prices and average manufacturer's prices for its drugs covered by Medicare and other federal healthcare programs.

"Any pharmaceutical company that intentionally inflates the cost of prescription drugs with elaborate pricing schemes..."
robs states and beneficiaries nationwide of millions of Medicare and Medicaid dollars. We will not tolerate any company abusing programs intended to benefit our most vulnerable citizens,” said Daniel R. Levinson, HHS Inspector General.

"CMS has a strong commitment to protect the integrity of the federal healthcare programs, ensuring that the financial burdens are not shifted to the programs, beneficiaries or taxpayers. This agreement reinforces that commitment," said Mark B. McClellan, M.D., Ph.D., Administrator for the Centers of Medicare and Medicaid Services.

Of the $150 million settlement, the federal recovery is approximately $140 million and the states' recovery for their share of Medicaid is $10 million.

The investigation was conducted by the Civil Division of the Department of Justice, the United States Attorney's Offices for the Districts of Massachusetts and the Southern District of Florida, the Office of Inspector General for the Department of Health and Human Services, the Office of Program Integrity of TRICARE Management Activity, and the National Association of Medicaid Fraud Control Units.

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