Department of Justice

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U.S. and 16 States Join Suits Against Pharmaceutical Giant, Wyeth

Drug Company Allegedly Failed to Pay Hundreds of Millions in Rebates to Medicaid Program

WASHINGTON – The United States and 16 states have joined in two whistleblower suits filed in the District of Massachusetts against the drug manufacturer, Wyeth, alleging that the company knowingly failed to give the government the same discounts it provided to private purchasers of its drugs, as required by laws governing the Medicaid program. As a result, Wyeth allegedly avoided paying hundreds of millions in rebates due to state Medicaid programs for its drugs, Protonix Oral and Protonix IV. These drugs belong to a class of drugs known as proton pump inhibitors (PPI), which are used to suppress stomach acid.

Under the Medicaid Drug Rebate Program, drug manufacturers of brand name drugs (i.e. non-generic drugs) are required to report to the government the prices they charge their customers, including the "best price" offered for their drugs. They also are required to pay rebates to the state Medicaid programs that are calculated on any discounted prices that are offered. Congress created the Medicaid Drug Rebate Program in order to ensure that Medicaid, one of the largest purchasers of drugs in the United States and the nation's provider of health insurance to the poor and the disabled, received the benefit of the same discounts offered to large commercial customers in the marketplace.

Between 2000 and 2006, Wyeth offered steep discounts to thousands of hospitals nationwide for Protonix Oral and Protonix IV under a pricing arrangement known as the "Protonix Performance Agreement." This pricing arrangement required that the hospitals purchase both drugs together under a so-called "bundled" arrangement and it offered them a steep discount for doing so. Wyeth did this in part to gain access to the far more lucrative retail outpatient market, intending that patients who used the intravenous version of Protonix in the hospital would later purchase Protonix Oral once they were discharged from the hospital. Under the Protonix Performance Agreement, hospitals that placed both products on their formularies and attained certain market share requirements were entitled to up to a 94% discount off the list price of Protonix Oral and up to 80% off the list price of Protonix IV. Although Wyeth was required under the Medicaid Drug Rebate Program to determine the effective prices paid by hospitals under this arrangement, and to pass along the benefit of the lowest prices to the state Medicaid programs, Wyeth allegedly failed to do so and therefore avoided paying hundreds of millions of dollars to Medicaid in quarterly rebates.

"Our complaint charges that Wyeth created the Protonix bundle so they could increase their market share at the expense of the Medicaid program -- a program to provide the least advantaged Americans with necessary medical care and services," said Tony West, Assistant Attorney General for the Civil Division. "By offering massive discounts to hospitals, but then hiding that information from the Medicaid program, we believe Wyeth caused Medicaid programs throughout the country to pay much more for these drugs than they should have."

The two separate civil False Claims Act suits – called *qui tam* actions – were filed against Wyeth and are pending in the District of Massachusetts. In addition to the United States, California, Delaware, the District of Columbia, Florida, Illinois, Indiana, Louisiana, Massachusetts, New York, Michigan, Nevada, New Hampshire, Tennessee, Texas, Virginia and Wisconsin also have intervened in the whistleblower suits against Wyeth.

"The best price reporting requirement is designed to assure that the nation's healthcare programs for the poor – the Medicaid programs - are treated equally with drug companies' best commercial customers," said Michael K. Loucks, Acting U.S. Attorney for the District of Massachusetts. "We seek through today's suit to put the Medicaid programs on par with Wyeth's best customers, as it had agreed."

The investigation was conducted by the Civil Division of the U.S. Department of Justice, the U.S. Attorney's Office for the District of Massachusetts, and the Offices of Inspector General of the Department of Health and Human Services.

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